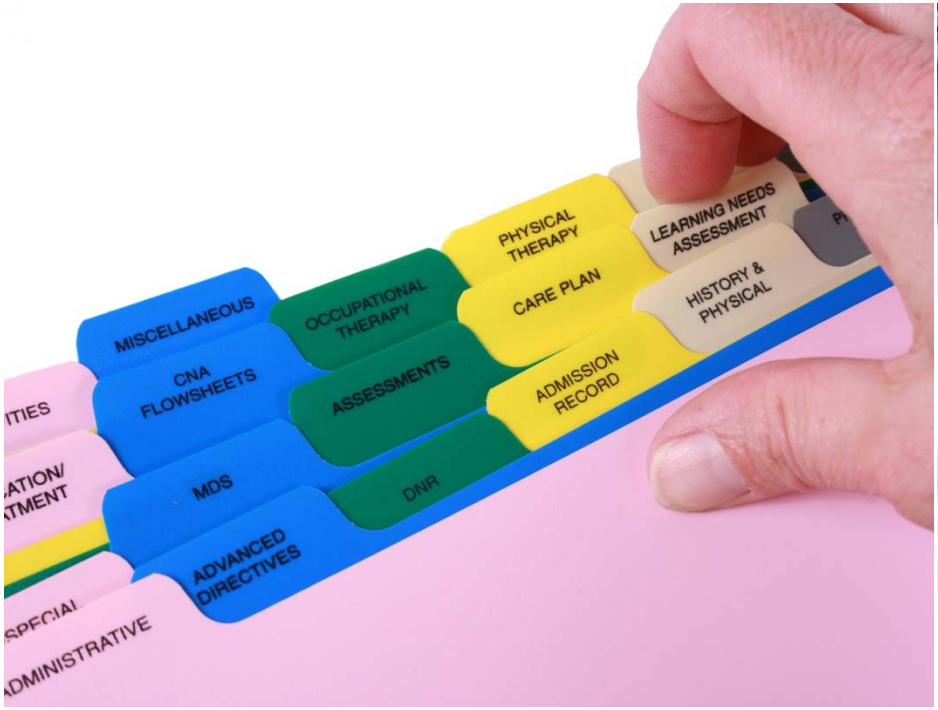
KCE REPORT 203S3

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

A NATIONAL GUIDELINE FOR THE TREATMENT OF PRESSURE ULCERS

APPENDIX VOLUME III



KCE REPORT 203S3
GOOD CLINICAL PRACTICE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
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A NATIONAL GUIDELINE FOR THE TREATMENT OF PRESSURE ULCERS

APPENDIX VOLUME III (APPENDIX 5)

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COLOPHON

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Acknowledgements:	We thank Liz Avital (NCGC, UK), Katie Jones (NCGC, UK) and Julie Neilson (NCGC, UK) for the collaboration in the preparation of the evidence reports.
External Validators :	Nicky Cullum (University of Manchester, United Kingdom); Bart Geurden (CEBAM); Sylvie Meaume (Hôpital Rothschild, France)
Other reported interests:	Dominique Putzeys and Dimitri Beeckman declared to have received funding for research related to the prevention and/or treatment of pressure ulcers. Diégo Backaert, Hilde Beele, Anne Hermand, Adinda Toppets, Geert Vanwalleghem, Dimitri Beeckman declared to have received a fee to lecture or reimbursement for training, travelling or participation to conferences related to the prevention and/or treatment of pressure ulcers
Layout :	Sophie Vaes

Publication date 04 July 2013

Domain:	Good Clinical Practice (GCP)
MeSH :	Pressure ulcer ; Practice Guidelines
NLM Classification :	WR 598
Language :	English
Format :	Adobe® PDF™ (A4)
Legal depot :	D/2012/10.273/33

How to refer to this document ?

Beeckman D, Matheï C, Van Lancker A, Vanwalleghem G, Van Houdt S, Gryson L, Heyman H, Thyse C, Toppets A, Stordeur S, Van Den Heede K. A national guideline for the treatment of pressure ulcers – Appendix volume III. Good Clinical Practice (GCP) Brussels: Belgian Health Care Knowledge Centre (KCE). 2013. KCE Reports 203S2. D/2013/10.273/33.

This document is available on the website of the Belgian Health Care Knowledge Centre

APPENDIX REPORT

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
ACA	Available case analysis
AHCPR	Agency for Heath Care Policy and Research
EQ5D	Euroqol instrument
HUI	Health Utilities Index
ICU	Intensive care unit
ITT	Intention-to-treat analysis
MD	Mean difference
MID	Minimal important difference
MRSA	Meticilline-resistent staphylococcus aureus
NPUAP	National Pressure Ulcer Advisory Panel
OR	Odds ratio
PICO	Research question: Population Intervention Comparison Outcome
PU	Pressure ulcer
PUSH	Pressure ulcer scaling for healing
RCT	Randomized controlled trial
RD	Risk difference
RR	Relative risk
SD	Standard deviation
WHOQOLBREF	WHO Quality of life - BREF

5. DRESSINGS

5.1. Review question

Table 1 – Protocol review question

Protocol	Dressings
Review question	What are the most clinically effective dressings for the treatment of pressure ulcers?
Population	Individuals of all ages, with at least one pressure ulcer of any category/stage
Intervention	Dressings (absorbing, impregnated, alginate, hydrocolloid, hydrofibre®, foam, collagen, hyaluronic acid, film, hydrogels)
Comparison	• No dressing • Comparison between dressings • Other type of therapy for pressure ulcer treatment
Outcomes	**Critical outcome for decision-making** • Time to complete healing (time to event data) • Rate of healing (continuous data) • Rate of reduction in size and volume of pressure ulcer (absolute and relative) (continuous data) • Reduction in size and volume of pressure ulcer (absolute and relative) (continuous data) • Proportion of patients completely healed within trial period (dichotomous) **Important outcomes** • Wound related pain • Health-related quality of life o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHOQOL-BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)

	• Acceptability of treatment (e.g. compliance, tolerance) • Time in hospital (continuous data) • Side effects (infection, health skin damage, healthy tissue damage, maceration, treatment related pain, skin irritation, allergic reaction, itching, odour, bleeding, rash, toxicity)
Study design	• High quality systematic reviews of RCT's or RCT's only. • Cochrane reviews will be included if they match the inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome • Non-English, non-French, non-Dutch language papers
Search strategy	**The electronic databases to be searched are:** • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years • Search strategy, see 5.2
Review strategy	**How will individual PICO characteristics be combined across studies)** • Population – any population will be combined except those specified in the strata. Must have active pressure ulcers at time of enrolment. • Intervention – any type of dressings will be combined for meta-analysis. • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – same outcomes will be combined for meta-analysis. • Blinding – Blinded and unblinded studies will be meta-analysed together. • Unit of analysis – patients, individual pressure ulcers • Minimum follow up = no minimum. • Minimum total size = no minimum • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	**The following groups will be considered separately if data are present:** • ICU patients, spinal cord patients, palliative patients, paediatric patients and adults (if not in other subgroup);

Subgroups:

The following groups will be considered separately as subgroups if data are present:

- Different categories of pressure ulcers (from category 2 upwards where outcomes are reported separately)
- Different locations of pressure ulcers: sacral, heel and others

Other terms

Notes

5.2. Search Strategy

5.2.1. Search Filters

Table 2 – Search filters Medline (OVID)

Date	**20-09-2012**	
Database	**Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)** 1946 to Present	
Search Strategy	1. exp Pressure Ulcer/	9146
	2. decubit*.ti,ab	3840
	3. (pressure adj (sore* or ulcer* or damage)).ti,ab	6044
	4. (bedsore* or bed-sore*).ti,ab	480
	5. ((friction or shear) adj2 (sore* or ulcer* or damage or wound* or inju* or lesion*)).ti,ab	242
	6. OR/1 – 5	
	7. Exp bandages/	13144
	8. bandage$.tw	18109
	9. dressing$.tw	3237
	10. hydrocolloid$.tw	12341
	11. exp colloids/	1122
	12. colloid$.tw	85663
	13. gauze$.tw	26395
	14. film$.tw	2561
	15. foam$.tw	67099
	16. layer$.tw	13729
	17. bind$.tw	198654
	18. wrap$.tw	851083

19.	tulle$.tw	8539
20.	occlusive.tw	105
21.	alginate$.tw	20184
22.	absorbing.tw	7611
23.	impregnat$.tw	6679
24.	capillar$.tw	11306
25.	hydrofib#$.tw	96406
26.	exp collagen/	83
27.	collagen$.tw	93102
28.	hyaluronic acid.tw	141865
29.	hydrogel.tw	9161
30.	hydropolymer$.tw	8393
31.	charcoal.tw	36
32.	silver.tw	8010
33.	honey.tw	30755
34.	sugar.tw	4364
35.	knitted viscose.tw	51920
36.	saline soak.tw	3
37.	cellulose, oxidized/	6
38.	cellulose$.tw	557
39.	growth factor$.tw	32835
40.	exp growth substances/	234380
41.	growth substance$.tw	57923
42.	compress$.tw	183
43.	skin, artificial/	84663
44.	skin substitute$.tw	1690
45.	exp polysaccharide/	678
46.	polysaccharide$.tw	27567
47.	matrix.tw	34807
48.	non adheren$.tw or non-adheren$.tw	199061
49.	OR/6 – 48	3569
50.	randomized controlled trial.pt.	2452323
51.	controlled clinical trial.pt.	336827
52.	randomi#ed.tw.	85183
53.	placebo.ab.	287309
54.	randomly.tw.	134609
55.	trial.ti	172345
56.	Clinical Trials as topic.sh.	103602

	57. OR/50 – 56	162509
	58. AND/6, 49, 56	795600
	59. Limit language: 'English, Dutch, Flemish, French'	319
		297

Table 3 – Search filters Embase

Date	**20-9-2012**	
Database	Embase	
Search Strategy (attention, for PubMed, check « Details »)	1. 'decubitus'/exp	15936
	2. Decubit*:ab,ti	5475
	3. (pressure NEAR/1 (sore* or ulcer* or damage)):ab,ti	4881
	4. (bed NEAR/2 sore*):ab,ti or bedsore*:ab,ti	742
	5. ((friction or shear) NEAR/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ab,ti	311
	6. OR/1 – 5	
	7. 'bandages and dressings'/exp	17523
	8. 'colloid'/exp	30472
	9. 'Bandage*':ti,ab	53696
	10. 'Dressing*':ti,ab	4446
	11. 'Hydrocolloid*':ti,ab	16636
	12. 'Colloid*':ti,ab	1434
	13. 'Gauze*':ti,ab	38057
	14. 'Film*':ti,ab	3473
	15. 'Foam*':ti,ab	96083
	16. 'Layer*':ti,ab	19342
	17. 'Bind*':ti,ab	261241
	18. 'Wrap*':ti,ab	967013
	19. 'Tulle*':ti,ab	10639
	20. 'occlusive':ti,ab	165
	21. 'alginate*':ti,ab	26699
	22. 'absorbing':ti,ab	10861
	23. 'impregnate*':ti,ab	8965
	24. 'capillary*':ti,ab	9930
	25. 'hydrofibre*':ti,ab	103086
	26. 'hydrofiber*':ti,ab	36
	27. 'collagen'/exp	85
	28. Collagen*':ti,ab	455697

29.	'hyaluronic acid'/exp	173749
30.	‘hyaluronic acid’:ti,ab	26246
31.	‘hydrogel’:ti,ab	11699
32.	‘hydropolymer*’:ti,ab	11032
33.	‘charcoal’:ti,ab	41
34.	‘silver’:ti,ab	10923
35.	‘honey’:ti,ab	40492
36.	‘sugar’:ti,ab	6109
37.	(knitted near/1 viscose):ti,ab	66778
38.	(saline NEAR/1 soak):ti,ab	6
39.	‘cellulose*’:ti,ab	5
40.	'growth factor'/exp	42771
41.	(growth NEAR/1 factor*):ti,ab	462006
42.	‘growth substances’/exp	271393
43.	(growth NEAR/1 substance*):ti,ab	7220
44.	‘compress*’:ti,ab	243
45.	'artificial skin'/exp	114930
46.	(skin NEAR/1 substitute*):ti,ab	1383
47.	'polysaccharide'/exp	918
48.	‘Polysaccharide*’:ti,ab	235830
49.	‘matrix’:ti,ab	42008
50.	‘non adheren*’:ti,ab or ‘non-adheren*’:ti,ab	247750
51.	OR/7 – 50	5652
52.	‘clinical trial’/exp	2920760
53.	‘clinical trial (topic)’/exp	1043680
54.	random*:ti,ab	45223
55.	factorial*:ti,ab	756348
56.	(crossover* or cross over*):ti,ab	19922
57.	((doubl* or singl*) adj blind*):ti,ab	120762
58.	(assign* or allocat* or volunteer* or placebo*):ti,ab	13
59.	‘crossover procedure’/exp	585391
60.	‘single blind procedure’/exp	35197
61.	‘double blind procedure’/exp	15827
62.	OR/52 – 61	110602
63.	AND/6, 51, 62	1894154
64.	Limit language: ’English, Dutch, French’	588
		528

Table 4 – Search filters CINAHL (EBSCO-Interface)

Date	**20-9-2012**	
Database	CINAHL (EBSCO-interface)	
Search Strategy (attention, for PubMed, check « Details »)	1. MH “Pressure Ulcer”	7749
	2. Bedsore* or bed-sore*	157
	3. Pressure n1 sore* or pressure n1 ulcer* or pressure n1 damage*	8547
	4. Decubit*	
	5. ((friction or shear) and (sore* or ulcer* or damage or wound* or injur* or lesion*))	487
	6. OR/1 – 5	806
	7. MH "Bandages and Dressings+"	
	8. “bandage$”	9407
	9. “dressing$”	7784
	10. “hydrocolloid$”	387
	11. MH “colloids+”	3559
	12. “colloid$”	525
	13. “gauze$”	6227
	14. “film$”	306
	15. “foam$”	612
	16. “layer$”	2162
	17. “bind$”	1277
	18. “wrap$”	2127
	19. “tulle$”	825
	20. “occlusive”	510
	21. “alginate$”	26
	22. “absorbing”	2419
	23. “impregnat$”	279
	24. “capillar$”	202
	25. MH “hydrofiber dressing”	460
	26. “hydrofiber”	1
	27. “hydrofibre”	26
	28. MH “collagen”	50
	29. “collagen$”	24
	30. “hyaluronic acid”	2730
	31. MH “hydrogel”	5063
	32. “hydrogel”	890
	33. “hydropolymer$”	368

34.	“charcoal”	566
35.	MH “ionic silver dressing”	30
36.	“silver”	487
37.	“honey”	70
38.	“knitted viscose”	2056
39.	“saline soak”	739
40.	MH “cellulose”	2
41.	“cellulose$”	1
42.	“growth factor$”	187
43.	MH “growth substances+”	360
44.	“growth substance$”	6742
45.	“compress$”	14368
46.	MH “skin, artificial”	455
47.	“skin substitute$”	138
48.	MH “polysaccharide+”	528
49.	“polysaccharide$”	67
50.	“matrix”	8683
51.	“non adheren$” or “non-adheren$”	464
52.	OR/7 – 51	5743
53.	MH "Clinical Trials+"	605
54.	“trial$”	61064
55.	“randomi#ed”	107538
56.	“randomly”	138201
57.	“randomized controlled trial”	66692
58.	PT “randomized controlled trial”	25374
59.	PT “clinical trial”	9144
60.	OR/53 – 59	10990
61.	AND/6, 52, 60	51404
62.	Limit language=’English, Dutch, French’	1694441
		259
		207

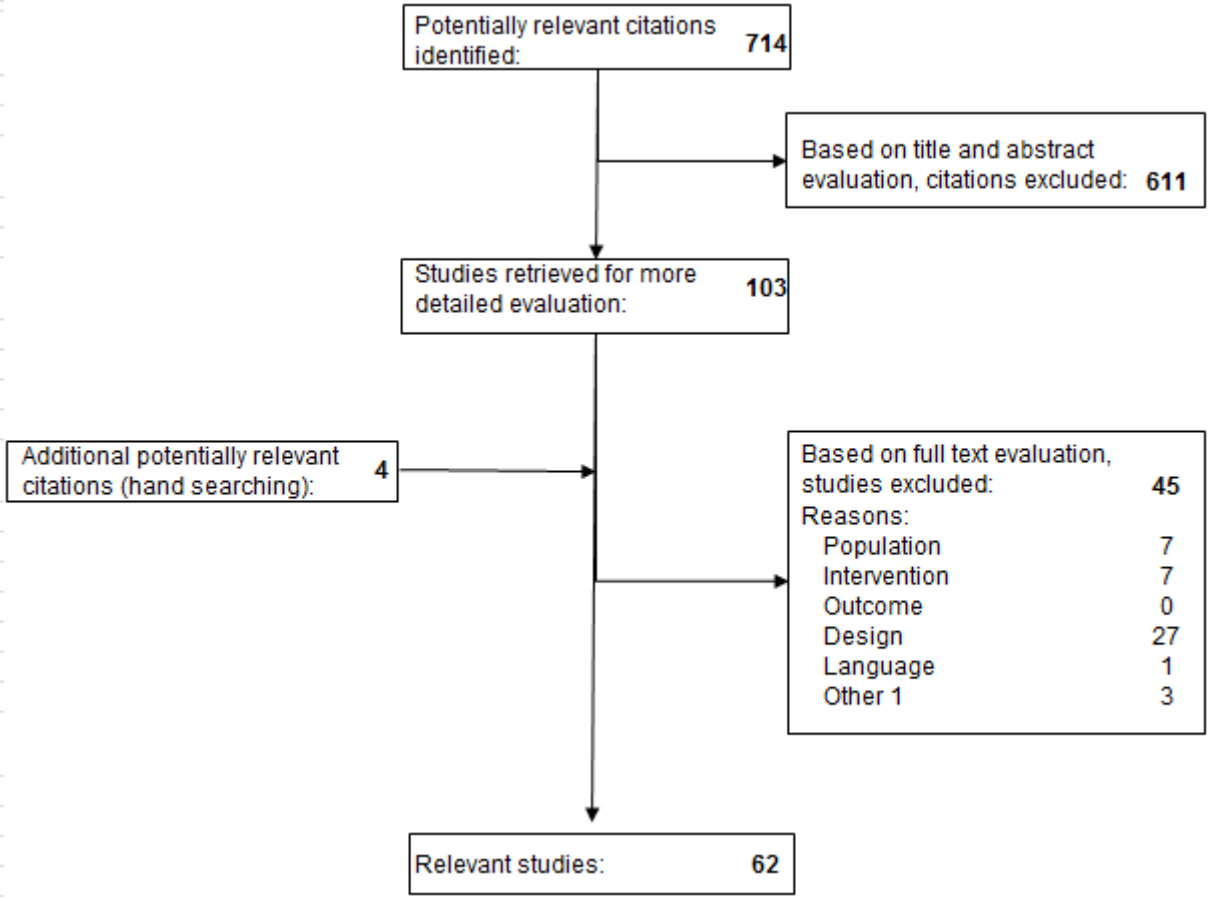
Table 5 – Search filters Cochrane Library

Date		
Database	The Library of the Cochrane Collaboration	
Search Strategy (attention, for PubMed, check « Details »):ti,ab,kw	1. "Pressure ulcer"[MeSH]	489
	2. Decubit*:ti,ab,kw	353
	3. (pressure near/2 (sore* or ulcer* or damage*)):ti,ab,kw	867
	4. (bedsore* or bed-sore*):ti,ab,kw	34
	5. ((friction or shear) near/2 (sore* or ulcer* or damage or wound* or injur* or lesion*)):ti,ab,kw	3
	6. OR/1 – 5	
	7. "bandages"[MeSH]	1150
	8. (bandage*):ti,ab,kw	1964
	9. (dressing*):ti,ab,kw	1919
	10. (hydrocolloid*):ti,ab,kw	2443
	11. "Colloids"[MeSH]	336
	12. (colloid*):ti,ab,kw	5185
	13. (gauze*):ti,ab,kw	1285
	14. (film*):ti,ab,kw	459
	15. (foam*):ti,ab,kw	1945
	16. (layer*):ti,ab,kw	906
	17. (bind*):ti,ab,kw	1998
	18. (wrap*):ti,ab,kw	6313
	19. (tulle*):ti,ab,kw	288
	20. (occlusive):ti,ab,kw	24
	21. (alginate*):ti,ab,kw	2411
	22. (absorbing):ti,ab,kw	370
	23. (impregnat*):ti,ab,kw	2598
	24. (capillar*):ti,ab,kw	543
	25. (hydrofib#*):ti,ab,kw	2333
	26. "collagen"[MeSH]	0
	27. (collagen*):ti,ab,kw	1632
	28. (hyaluronic acid):ti,ab,kw	3383
	29. (hydrogel):ti,ab,kw	915
	30. (hydropolymer*):ti,ab,kw	666
	31. (charcoal):ti,ab,kw	11
	32. (silver):ti,ab,kw	342

33.	(honey):ti,ab,kw	886
34.	(sugar):ti,ab,kw	176
35.	(knitted viscose):ti,ab,kw	1713
36.	(saline soak):ti,ab,kw	7
37.	“cellulose, oxidized”[MeSH]	82
38.	(cellulose*):ti,ab,kw	38
39.	(growth factor*):ti,ab,kw	855
40.	“growth substances”[MeSH]	6617
41.	(growth substance*):ti,ab,kw	2351
42.	(compress*):ti,ab,kw	347
43.	“skin, artificial”[MeSH]	3596
44.	(skin substitute*):ti,ab,kw	106
45.	“polysaccharide”[MeSH]	120
46.	(polysaccharide*):ti,ab,kw	11211
47.	(matrix):ti,ab,kw	1387
48.	(non adheren*):ti,ab,kw or (non-adheren*):ti,ab,kw	2398
49.	OR/7 – 48	782
50.	“Clinical Trial” [publication type]	55978
51.	“Randomized Controlled Trial” [publication type]	44
52.	“Randomized Controlled Trial” [MeSH]	51551
53.	“clinical trial” as topic	34
54.	(trial):ti,ab,kw	313815
55.	(randomi#ed):ti,ab,kw	335236
56.	(randomly):ti,ab,kw	1
57.	(group):ti,ab,kw	86115
58.	OR/50 – 57	274506
59.	AND/6, 49, 58	519131
		261

5.2.2. *Flow Chart*

Figure 1 – Flow chart search strategy



5.2.3. List of excluded studies

Reference	Reason of exclusion
Abbott 1968	Case report
Baker 1981	No RCT
Banks 1997	PU not reported separately
Barr 1993	No RCT
Barr 1995	No RCT
Barrois 2007	No RCT
Beele 2010	PU not reported separately
Bolton	No primary study
Brem 2000	No RCT
Carr 1990	No RCT
Cheneworth 1994	No RCT
Diehm 2005	No RCT
Engdahl 1980	Not retrievable
Fowler 1991	No RCT
Fowler 1981	No RCT
Fu 2002	PU not reported separately
Gerding 1992	Topical agent
Gorse 1987	No RCT
Hurd 2009	No RCT
Jones 1997	Case reports
Kallianinen 2000	No RCT
Kucan 1981	Topical agent
Leonard 2009	No RCT
Lingner 1984	No RCT
Lobe 1980	No RCT
Cheung 1996	Abstract proceeding, no full text
McMullen 1991	No RCT
Meaume 1996	French publication of Sayag
Mian 1992	No RCT
Moberg 1983	Topical agent
Motta 1991	No RCT
Motta 2004	PU not reported separately
Pierce 1994	See Mustoe
Price 2000	No dressing
Shamimi 2008	Topical agent
Sibbald 2011	No PU
Smietanka 1981	No RCT
Subbanna 2007	Topical agent
Takahash 2006	No RCT
Tytgat 1988	PU not reported separately
Van Leen 1994	No RCT
Walker 2008	PU not reported separately
Wollina 1997	No RCT

Reference	Reason of exclusion
Yura 1984	Japanese
Zur Nieden	Oral treatment

5.3. Clinical evidence

Sixty-one randomized controlled trials were included in this review.[1-61]

Various types of dressings are used to treat pressure ulcers. In this review different types of dressings are compared to each other or to placebo. Following categories were made:

- Basic dressings
  - Gauze dressings;
  - Paraffin gauze dressings;
  - Simple dressing pads.
- Active dressings
  - Hydrocolloid dressings;
  - Foam dressings;
  - Polyurethane film;
  - Hydrogel;
  - Alginate dressings;
  - Hydrofibre® dressings;
  - Collagen dressing;
  - Hyaluronic dressing;
  - Copolymer dressing;
  - Polyhexadine dressing;
  - Charcoal dressings;
  - Silver dressings;
  - Dextranomer;
  - Sugar;
  - Honey;
  - Skin replacement;
  - Platelet gel.

5.3.1. Summary table of included studies

Table 6 – Summary table of included studies

Study	Intervention/comparator	Population	Outcome	Study length
Alm 1989[1]	Hydrocolloid dressing Wet saline gauze dressing	Long-term care patients with PUs	Reduction in ulcer area Side effects	Six weeks of treatment and additional 3 and 6 weeks of follow-up
Amione 2005[2]	Foam dressing (Allevyn®) Foam dressing (Biatain®)	Patients with a grade II or III PU (EPUAP classification)	Proportion of patients completely healed Reduction in ulcer area Side effects	Seven dressings with a maximum of six weeks of treatment
Bale 1997[62]	Hydrocolloid dressing	Patients with a stage II or III	Proportion of patients	30 days of treatment or until

Study	Intervention/comparator	Population	Outcome	Study length
	Foam dressing	PU (Stirling classification)	completely healed	complete healing
Bale 1998[4]	Hydrogel (Sterigel®) Hydrogel (Intrasite®)	Patients with necrotic PUs	Wound pain Side effects	Four weeks of treatment or until complete debridement
Banks 1994a[5]	Hydrocolloid dressing Polyurethane film	Inpatients with a grade II or III PU.	Proportion of patients completely healed Proportion of patients improved Time to healing Side effects	Six weeks of treatment or until complete healing
Banks 1994b[6]	Hydrocolloid dressing Polyurethane film	Community patients with a grade II or III PU.	Proportion of patients completely healed Proportion of patients improved Side effects	Six weeks of treatment or until complete healing
Belmin 2002[7]	Hydrocolloid dressing Alginate dressing	Inpatients aged 65 years and older with a grade III or IV PU (Yarkony's classification)	Proportion of patients with ≥ 40% healing Reduction in ulcer area Side effects	Eight weeks of treatment
Bito 2012[8]	Wrap therapy (polyurethane dressing) Standard care	Inpatients aged 50 years and older with a stage II or III PU (NPUAP classification)	Time to healing Difference in PUSH score Side effects	Twelve weeks of treatment or until complete healing
Brod 1990[9]	Hydrocolloid dressing	Elderly patients with a grade II	Proportion of patients	Six weeks of treatment

Study	Intervention/comparator	Population	Outcome	Study length
	Poly-hema	or III PU	completely healed Time to healing Rate of healing Side effects	
Brown-Etris 2008[10]	Hydrocolloid dressing Polyurethane film	Patients with a stage II or shallow III PU	Proportion of patients completely healed Reduction in ulcer area Rate of healing Side effects	56 days of treatment or until complete healing
Burgos 2000[63]	Hydrocolloid dressing Collagenase ointment	Inpatients with a stage III PU	Proportion of patients completely healed Reduction in ulcer area Side effects	12 weeks of treatment or until complete healing
Chang 1998[12]	Hydrocolloid dressing Wet saline gauze dressing	Inpatients with a stage II or III PU	Reduction in ulcer area Side effects	Eight weeks of treatment or until complete healing
Chuansuwanich 2011[13]	Silver dressing Silver sulfadiazine cream	In- and outpatients with a stage III or IV PU (NPUAP classification)	Rate of healing Reduction in PUSH score Side effects	Eight weeks of treatment
Colin 1996[14]	Hydrogel Dextranomer	Patients with a grade I, II, III or IV PU (according to AHCRQ and International Association of Exteromstomal	Reduction in ulcer area Side effects	21 days of treatment or until complete healing

Study	Intervention/comparator	Population	Outcome	Study length
		Therapy)		
Colwell 1993[15]	Hydrocolloid dressing Moist gauze dressing	Inpatients with a stage II and/or III PU	Proportion of patients completely healed Reduction in ulcer area	Minimum eight days of treatment (range: 6-56 days)
Darkovich 1990[16]	Hydrocolloid dressing Hydrogel	Patients with a stage I or II PU (Enis and Sarmienti classification)	Proportion of ulcers completely healed Proportion of ulcers improved Proportion of ulcers not changed Proportion of ulcers worsened Reduction in ulcer area Rate of healing	60 days of treatment or until complete healing, discharge or no change based on clinical judgement
Day 1995[17]	Hydrocolloid dressing: triangular shape versus oval shape	Inpatients with a stage II or III sacral PU (NPUAP classification)	Proportion of patients completely healed Proportion of patients improved Proportion of patients not changed Proportion of patients worsened Reduction in ulcer length Side effects	Six dressings or until complete healing

Study	Intervention/comparator	Population	Outcome	Study length
Felzani 2011[18]	Hyaluronic acid Sodium hyaluronate	Inpatients with a stage I, II or III PU (NPUAP classification)	Reduction in ulcer area Time to 50% healing	15 days of treatment
Graumlich 2003[19]	Hydrocolloid dressing Collagen dressing	Patients with a stage II or III PU (NPUAP classification)	Proportion of patients completely healed Time to healing Reduction in ulcer area Side effects	Eight weeks of treatment with a median follow-up of 35 days
Günes 2007[20]	Honey dressing Ethoxydiaminoacridine and nitrofurazone dressing	Inpatients with a stage II or III PU (AHCRQ classification)	Proportion of ulcers completely healed Reduction in ulcer area Reduction in PUSH score Side effects	Five weeks or until complete healing
Hollisaz 2004[21]	Hydrocolloid dressing Gauze dressing Phenytoin cream	Patients with a spinal cord injury and a stage I or II PU (Shea classification)	Proportion of ulcers completely healed Proportion of ulcers improved Proportion of ulcers worsened Proportion of patients completely healed	Eight weeks of treatment
Hondé 2004[22]	Hydrocolloid dressing Amino acid copolymer dressing	Inpatients aged 65 years or older with a grade II, III or IV PU (NPUAP classification)	Proportion of patients completely healed Time to healing	Eight weeks of treatment or until complete healing

Study	Intervention/comparator	Population	Outcome	Study length
			Side effects	
Kaya 2005[23]	Hydrogel Povidone-iodine gauze dressing	Inpatients with a spinal cord injury and grade I, II or III PUs (NPUAP classification)	Rate of healing	Not reported
Kerihuel 2010[24]	Hydrocolloid dressing Charcoal dressing	Inpatients with a stage IIc or IV (Yarkoni classification)	Proportion of patients worsened Reduction in ulcer area Wound pain Side effects	Four weeks of treatment
Kim 1996[25]	Hydrocolloid dressing Povidone gauze dressing	Patients with a stage I or II PU (NPUAP classification)	Proportion of patients completely healed Rate of healing Side effects	Mean duration was 18.9 (8.2) days in group 1 and 24.3 (11.2) days in group 2
Kordestani 2008[26]	Hydrocolloid dressing Gauze dressing	Inpatients with a PU (NPUAP classification) – no stage reported	Proportion of ulcers completely healed Side effects	21 days of treatment and three months of follow-up
Kraft 1993[27]	Foam dressing Saline moistened gauze dressing	Male veterans with a stage II or III PU (Enterstomal Therapy definition)	Proportion of patients completely healed	24 days of treatment
Ljungberg 2009[28]	Saline gauze dressing Dextranomer	Male patients with a spinal cord injury and exudative PUs (Eltorai classification)	Proportion of ulcers improved Side effects	14 days of treatment
Matzen 1999[29]	Hydrocolloid dressing	Patients with a stage III or IV PU (Lowthian classification)	Proportion of patients completely healed	12 weeks of treatment or until complete healing

Study	Intervention/comparator	Population	Outcome	Study length
	Saline gauze dressing		Reduction in ulcer volume Side effects	
Meaume 2003[31]	Foam dressing (Mepilex®) Foam dressing (Tielle®)	Patients aged 65 years or older with a stage II PU (NPUAP classification)	Proportion of patients completely healed Proportion of patients improved Proportion of patients worsened Side effects	Eight weeks of treatment or until complete healing
Meaume 2005[30]	Alginate dressing Silver alginate dressing	Patients aged 65 years or older with a stage III or IV PU (NPUAP classification)	Proportion of patients worsened Reduction in ulcer area Rate of healing Side effects	Four weeks of treatment
Motta 1999[32]	Hydrocolloid dressing Hydrogel	Home care patients with a stage II or III PU	Proportion of patients completely healed Rate of healing Reduction in ulcer area Side effects	Eight weeks of treatment
Mulder 1993[33]	Hydrocolloid dressing Hydrogel	In- and outpatients with a stage II or III PU	Reduction in ulcer area Side effects	Eight weeks of treatment or until complete healing
Müller 2001[34]	Hydrocolloid dressing	Female inpatients with a	Proportion of patients	Maximum 16 weeks

Study	Intervention/comparator	Population	Outcome	Study length
	Collagenase ointment	grade IV heel PU	completely healed Time to healing	
Münter 2006[35]	Silver foam dressing Different types of dressings	Patients with a grade II or III PU (EPUAP classification)	Reduction in ulcer area	Four weeks of treatment
Nasar 1982[36]	Dextranomer Chlorinated lime solution	Elderly patients with a deep PU	Time to healing (defined as granulation and < 25% of original ulcer area) Pain	Until healing
Neill 1989[37]	Hydrocolloid dressing Saline gauze dressing	Patients with a grade II or III PU (Shea classification)	Proportion of ulcers completely healed Proportion of patients worsened Reduction in ulcer area Side effects	Eight weeks of treatment
Nisi 2005[38]	Protease modulating matrix Vaseline soaked gauze dressing	Inpatients with a stage II, III or IV PU (NPUAP classification)	Proportion of patients completely healed Time to healing Side effects	Treatment time not reported. Six months of follow-up.
Oleske 1986[39]	Polyurethane film Saline gauze dressing	Inpatients with a stage I or II PU (Enis and Sarmiento classification)	Proportion of ulcers completely healed Proportion of ulcers worsened Reduction in ulcer area	10 days of treatment

Study	Intervention/comparator	Population	Outcome	Study length
Parish 1979[40]	Dextranomer Sugar and eggs white	Long-term care patients with a PU	Proportion of ulcers completely healed Proportion of patients completely healed Proportion of ulcers improved Proportion of patients improved Side effects	Four weeks of treatment. Some patients were treated longer.
Payne 2004[42]	Skin replacement Saline moistened gauze dressing	Patients with a grade III PU	Proportion of patients completely healed Reduction in ulcer area Reduction in ulcer volume Side effects	Maximum 24 weeks of treatment and up to 2 weeks of follow-up
Payne 2009[41]	Foam dressing Saline soaked gauze dressing	Patients with a stage II PU (NPUAP classification)	Proportion of patients completely healed Time to healing	Four weeks of treatment or until complete healing
Rhodes 1979[43]	Sugar Different types of topical agents	Geriatric patients with a PU – stage not reported	Proportion of ulcers completely healed Mean healing index	Not reported
Rhodes 2001[44]	Hydrocolloid dressing Phenytoin ointment Antibiotic ointment	Nursing home patients with a stage II PU (AHCPR classification)	Time to healing Side effects	Not reported

Study	Intervention/comparator	Population	Outcome	Study length
Routkovsky-Norval 1996[45]	Hydrocolloid dressing (Comfeel®) Hydrocolloid dressing (Comfeel®Plus)	Patients with a necrotic or granulating PU	Reduction in ulcer area Side effects	Eight weeks of treatment or until complete healing
Sayag 1996 [46]	Alginate dressing Dextranomer	Patients with a grade III or IV PU (Yarkony classification)	Proportion of patients healed > 75% Proportion of patients healed > 40% Proportion of patients stagnated or worsened Reduction in ulcer area Side effects	Maximum eight weeks
Scevola 2010[47]	Allogeneic platelet gel Different types of dressings	Patients with a spinal cord injury and a grade III or IV PU (NPUAP classification)	Proportion of ulcers completely healed Proportion of ulcers improved Reduction in ulcer area	Eight weeks of treatment and up to four weeks of follow-up
Seaman 2000[48]	Hydrocolloid dressing (SignaDress®) Hydrocolloid dressing (Comfeel®Plus)	Nursing home patients with a stage II, III or IV PU (AHCPR classification)	Proportion of patients completely healed Reduction in ulcer area Side effects	Five dressing changes or until complete healing
Sebern 1989[49]	Polyurethane film Gauze dressing	Home care patients with a grade II or III PU (Shea classification)	Proportion of ulcers completely healed Proportion of ulcers not changed	Five dressing changes or until complete healing

Study	Intervention/comparator	Population	Outcome	Study length
			Proportion of ulcers worsened Proportion of ulcers decreased in PU grade Proportion of ulcers increased in PU grade Reduction in ulcer area Side effects	
Seeley 1999[50]	Hydrocolloid dressing Foam dressing	Patients with a stage II or III PU (AHCPR classification)	Proportion of patients completely healed Reduction in ulcer area Side effects	Eight weeks of treatment
Sipponen 2008[51]	Hydrofibre® dressing Resin salve	Hospitalized patients with a grade II to IV PU (EPUAP classification)	Proportion of patients completely healed Proportion of ulcers completely healed Proportion of ulcers improved Proportion of ulcers worsened Mean percentage reduction in ulcer width Mean percentage reduction in ulcer depth Speed of healing (days)	Six months

Study	Intervention/comparator	Population	Outcome	Study length
			Side effects	
Small 2002[52]	Hydrogel Different types of dressings	Community patients with a stage II, III or IV PU (Stirling classification)	Proportion of patients completely healed Reduction in ulcer area Side effects	Six weeks of treatment or until complete healing, withdrawal or occurrence of adverse events
Sopata 2002[53]	Foam dressing Hydrogel	Palliative care patients with a grade II or III PU (Torrance classification)	Proportion of ulcers completely healed Proportion of ulcers improved Rate of healing	Eight weeks of treatment or until complete healing
Thomas 1997[56]	Hydrocolloid dressing Foam dressing	Community patients with a grade II or III PU (Stirling classification)	Proportion of patients completely healed Proportion of patients improved Proportion of patients not changed Proportion of patients worsened Reduction in ulcer area Side effects	Six weeks of treatment
Thomas 1998[55]	Hydrogel Saline soaked gauze dressing	Patients with a stage II, III or IV PU	Proportion of patients completely healed Proportion of patients worsened	Ten weeks of treatment or until complete healing

Study	Intervention/comparator	Population	Outcome	Study length
			Reduction in ulcer area Time to healing	
Thomas 2005[54]	Hydrocolloid dressing Radiant heat dressing	Patients with a stage III or IV PU	Proportion of patients completely healed	12 weeks of treatment
Trial 2010[57]	Alginate dressing Silver alginate dressing	Patients with a PU – stage not reported	Decrease in infection score	15 days of treatment
Wild 2012[58]	Polyhexanide containing cellulose dressing Polyhexadine swab	In- and outpatients with a grade II, III or IV PU and MRSA (NPUAP classification)	Proportion of patients MRSA eradicated Side effects	14 days of treatment
Winter 1990[59]	Hydrocolloid dressing Paraffin gauze dressing	Patients with a PU – stage not reported	Proportion of patients completely healed Proportion of patients improved Proportion of patients not changed	12 weeks of treatment
Xakellis 1992[60]	Hydrocolloid dressing Saline wet-to-moist gauze dressing	Long term care patients with a stage II or III (Shea classification)	Proportion of patients completely healed Time to healing	Six months of treatment
Yastrub 2004[61]	Foam dressing Antibiotic ointment	Long term care patient with a stage II PU (AHCPR classification)	Proportion of patients improved PUSH score	Four weeks of treatment

* *Study published in French*

5.3.2. Types of dressings: description

Table 7 – Description of types of dressings

Type of dressing	Description
Hydrocolloid	Contains an elastomeric, adhesive, and gelling forming agent, such as carboxymethylcellulose, pectin or gelatin. It is often combined with adhesives and tackifiers and applied to a polyurethane foam or film carrier to create an absorbent, self-adhesive, waterproof sheet. The dressing is capable of absorbing low to moderate levels of exudate and can be used to promote autolytic debridement of dry, sloughy, or necrotic wounds.
Gauze	Comes in woven and non-woven form and are usually made of from cotton, viscose, polyester, or other suitable fibres. It is absorptive and permeable to water, water vapor, and oxygen.
Foam	Cellulose or polyurethane dressing that may be impregnated or coated with other material and has some absorptive properties. May have adhesive or soft silicon borders or be non-bordered.
Polyurethane film	It is a clear, semi-permeable, and non-absorptive, polymer-based adhesive dressing.
Hydrofibre®	It has highly absorbent, with gelling properties derived from 100% sodium carboxymethylcellulose hydrocolloid polymers.
Collagen	Collagen is the most abundant protein in the human body and is a major component of the extracellular matrix. The dressing can be derived from bovine, porcine and avian sources.
Hydrogel	It consists of insoluble polymers which have a hydrophilic nature. When mixed with aqueous solutions, they will absorb large volumes of water.
Impregnated gauze	Gauze that is impregnated with some other product such as paraffin.
Poly-hema	A biocompatible, hydrophilic, inert gel that is permeable to tissue fluids and functions as a hydrogel by rotating around its central carbon.
Amino acid co-polymer	It is permeable to water vapour, it does not allow microbial proliferation after in vitro inoculation, it is impermeable to bacteria, and is stable and flexible. Increases epithelisation. It is a skin substitute.
Alginate	These are derived from seaweed, usually prepared as the calcium salt of alginic acid. When in contact with serum, wound exudate or solutions containing sodium ions, the insoluble calcium alginate is partially converted to the soluble sodium salt, and a hydrophilic gel is produced.
Charcoal	Activated carbon in dressing adsorbs bacteria away from wound and helps reduce wound odor. The dressing is highly absorbent.
Dextranomer	It is a sterile, insoluble powder in the form of circular beads when dry. It is a long chain polysaccharide constructed in a three dimensional network of cross-linked dextran molecules. Dextranomer is highly hygroscopic due to its high hydroxyl group content and 1 g of it absorbs 4 ml of water and swells till it

	is saturated. The speed of this absorption is greater than the secretion by the wound. The microorganisms and high molecular weight substances which get confined to the interspaces move at a faster rate due to capillary action.
Protease modulating matrix	It consists of freeze-dried collagen and oxidised regenerated cellulose, which binds en inactivates protease.
Silver dressing	The presence of silver ions results in antimicrobial properties.
Sugar	The use of sugar is based on its high osmolality, which draws fluid out of the wound. Reducing water in the wound inhibits the growth of bacteria. The use of sugar also aids in the debridement of necrotic tissue, while preserving viable tissue.
Honey	Honey's beneficial effects are thought to be a result of hydrogen peroxide production from activity of the glucose oxidase enzyme. The low pH of honey also may accelerate healing.
Platelet gel	Concentrated platelet, which forms granulation and more collagen fibers.
Hyaluronic acid	Hyaluronic acid is a natural substance that is widely distributed throughout our bodies. It is an important component of cartilage, synovial fluid (the lubricating fluid found between joints) and skin. Hyaluronic acid cannot be absorbed when applied topically, which is why sodium hyaluronate is around. Sodium hyaluronate is the salt of hyaluronic acid and it has a much lower molecular size. One key feature of sodium hyaluronate is its ability to hold more than 1000 times its weight in water.

5.3.3. Clinical evidence GRADE tables

Table 8 – Hydrocolloid dressing versus gauze dressing

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Gauze dressing	Relative (95% CI)	Absolute		
Proportion of patients completely healed – general population and patients with a spinal cord injury – stage I or above – NPUAP, Shea, Lowthian classification[m]												
Hollisaz 2004; Kim 1996; Matzen 1999;Xakellis 1992	randomised trials	very serious[a,b]	very serious[c]	no serious indirectness	serious[d]	none	62/89 (69.7%)	40/81 (49.4%)	RR 1.38 (0.81 to 2.35)	188 more per 1000 (from 94 more to 667 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								53.7%		204 more per 1000 (from 102 more to 725 more)		
Proportion of patients completely healed - general population – stage I or above - NPUAP, Shea, Lowthian classification[m]												
Kim 1996; Matzen 1999; Xakellis 1992	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[d]	none	42/61 (68.9%)	32/54 (59.3%)	RR 1.07 (0.77 to 1.48)	41 more per 1000 (from 136 fewer to 284 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								77.8%		54 more per 1000 (from 179 fewer to 373 more)		
Proportion of patients completely healed - patients with spinal cord injury – stage I or above – Shea classification												
Hollisaz 2004	randomised trials	Serious[b]	no serious inconsistency	no serious indirectness	no serious imprecision	none	20/28 (71.4%)	8/27 (29.6%)	RR 2.41 (1.29 to 4.51)	418 more per 1000 (from 86 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL OUTCOME
								29.6%		417 more per 1000 (from 86 more to 1000 more)		

Proportion of ulcers completely healed (all sites) - general population and patients with a spinal cord injury – all stages – NPUAP, Shea classification[n]												
Hollisaz 2004; Colwell 1993; Kordestani 2008; Neill 1989	randomised trials	very serious[a,b]	no serious inconsistency	no serious indirectness	no serious imprecision	none	61/137 (44.5%)	23/136 (16.9%)	RR 2.53 (1.7 to 3.78)	259 more per 1000 (from 118 more to 470 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								24.4%		373 more per 1000 (from 171 more to 678 more)		
Proportion of ulcers completely healed (all sites) - general population – all stages - NPUAP, Shea classification[n]												
Colwell 1993; Kordestani 2008; Neill 1989	randomised trials	very serious[a]	Serious[e]	no serious indirectness	very serious[g]	none	38/106 (35.8%)	15/106 (14.2%)	RR 2.46 (1.01 to 5.96)	207 more per 1000 (from 1 more to 702 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								22.2%		324 more per 1000 (from 2 more to 1000 more)		
Proportion of ulcers completely healed (all sites) - Patients with a spinal cord injury – stage I and II - Shea classification												
Hollisaz 2004	randomised trials	Serious[b]	no serious inconsistency	no serious indirectness	no serious imprecision	none	23/31 (74.2%)	8/30 (26.7%)	RR 2.78 (1.48 to 5.22)	475 more per 1000 (from 128 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL OUTCOME
								26.7%		475 more per 1000 (from 128 more to 1000 more)		
Proportion of ulcers completely healed (all sites) - patients with a spinal cord injury – stage I – Shea classification												
Hollisaz 2004	randomised trials	Serious[b]	no serious inconsistency	no serious indirectness	Serious[d]	none	11/13 (84.6%)	5/11 (45.5%)	RR 1.86 (0.94 to 3.7)	391 more per 1000 (from 27 fewer to 1000 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								45.5%		391 more per 1000 (from 27 fewer to 1000		

										more)		
Proportion of ulcers completely healed (all sites) – general population and patients with a spinal cord injury – stage II – Shea classification												
Hollisaz 2004; Neill 1989	randomised trials	very serious[a,b]	Serious[f]	no serious indirectness	serious[d]	none	23/43 (53.5%)	12/53 (22.6%)	RR 2.42 (0.97 to 6.00)	322 more per 1000 (from 7 more to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								21.1%		3000 more per 1000 (from 6 more to 1000 more)		
Proportion of ulcers completely healed (all sites) - patients with a spinal cord injury – stage II – Shea classification												
Hollisaz 2004	randomised trials	Serious[b]	no serious inconsistency	no serious indirectness	no serious imprecision	none	12/18 (66.7%)	3/19 (15.8%)	RR 4.22 (1.42 to 12.54)	508 more per 1000 (from 66 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL OUTCOME
								15.8%		509 more per 1000 (from 66 more to 1000 more)		
Proportion of ulcers completely healed (all sites) - general population – stage II– Shea classification												
Neill 1989	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[d]	none	11/25 (44%)	9/34 (26.5%)	RR 1.66 (0.81 to 3.39)	175 more per 1000 (from 50 fewer to 633 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								26.5%		175 more per 1000 (from 50 fewer to 633 more)		
Proportion of ulcers completely healed (all sites) - general population – stage III – Shea classification												
Neill 1989	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[g]	none	2/17 (11.8%)	1/11 (9.1%)	RR 1.29 (0.13 to 12.62)	26 more per 1000 (from 79 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								9.1%		26 more per		

										1000 (from 79 fewer to 1000 more)		
Proportion of ulcers completely healed (sacral) - patients with a spinal cord injury – stage I and II – Shea classification												
Hollisaz 2004	randomised trials	Serious[b]	no serious inconsistency	no serious indirectness	Serious[d]	none	0/7 (0%)	4/8 (50%)	OR 0.09 (0.01 to 0.84)	417 fewer per 1000 (from 43 fewer to 490 fewer)	⊕⊕OO LOW	CRITICAL OUTCOME
								50%		417 fewer per 1000 (from 43 fewer to 490 fewer)		
Proportion of ulcers improved - patients with a spinal cord injury - stage I and II – Shea classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	27/31 (87.1%)	29/60 (48.3%)	RR 1.8 (1.34 to 2.42)	387 more per 1000 (from 164 more to 686 more)	⊕⊕⊕O MODERATE	CRITICAL OUTCOME
								48.3%		386 more per 1000 (from 164 more to 686 more)		
Proportion of ulcers worsened– general population and patients with a spinal cord injury – stage I to III - Shea classification												
Hollisaz 2004; Neill 1989	randomised trials	very serious[a,b]	very serious[c]	no serious indirectness	very serious[g]	none	16/73 (21.9%)	24/75 (32%)	RR 0.53 (0.12 to 2.46)	150 fewer per 1000 (from 282 fewer to 467 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								31.7%		149 fewer per 1000 (from 279 fewer to 463 more)		
Proportion of ulcers worsened - patients with a spinal cord injury – stage I to III - Shea classification												
Hollisaz 2004	randomised	Serious[b]	no serious	no serious	Serious[d]	none	2/31	9/30	RR 0.22 (0.05 to	234 fewer per 1000 (from 27	⊕⊕OO	CRITICAL

	trials		inconsistency	indirectness			(6.5%)	(30%)	0.91)	fewer to 285 fewer)	LOW	OUTCOME
								30%		234 fewer per 1000 (from 27 fewer to 285 fewer)		
Proportion of ulcers worsened - general population – stage II and III - Shea classification												
Neill 1989	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[g]	none	14/42 (33.3%)	15/45 (33.3%)	RR 1 (0.55 to 1.81)	0 fewer per 1000 (from 150 fewer to 270 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								33.3%		0 fewer per 1000 (from 150 fewer to 270 more)		
Proportion of ulcers worsened - general population – stage II- Shea classification												
Neill 1989	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[g]	none	7/25 (28%)	11/34 (32.4%)	RR 0.87 (0.39 to 1.92)	42 fewer per 1000 (from 197 fewer to 298 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								32.4%		42 fewer per 1000 (from 198 fewer to 298 more)		
Proportion of ulcers worsened - general population – stage III - Shea classification												
Neill 1989	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[g]	none	7/17 (41.2%)	4/11 (36.4%)	RR 1.13 (0.43 to 2.98)	47 more per 1000 (from 207 fewer to 720 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								36.4%		47 more per 1000 (from 207 fewer to 721 more)		

Mean percentage reduction in ulcer area – general population – stage II and III – classification system not reported												
Chang 1998; Mulder 1993	randomised trials	very serious[a,h,0]	no serious inconsistency	no serious indirectness	serious[d]	none	18.65 (n=38)	46.73 (n=37)	-	MD 0.34 higher (14.71 lower to 15.38 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean cm² reduction in ulcer area – inpatients – stage II and III – classification system not reported												
Colwell 1993	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[j]	none	0.73 (n=48)	-0.67 (n=49)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer area– long-term care patients – all stages – classification system not reported												
Alm 1989	randomised trials	very serious[k]	no serious inconsistency	no serious indirectness	very serious[l]	none	100 (n=28)	85.7 (n=21)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer area– in-and out patients – stage II and III - classification system not reported												
Mulder 1993	randomised trials	very serious[h]	no serious inconsistency	no serious indirectness	very serious[j]	none	7.4 (n=21)	7.0 (n=20)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer area - general population – stage II – Shea classification												
Neill 1989	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[j]	none	91 (n=25)	48 (n=34)	p>0.05	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer area - general population – stage III – Shea classification												
Neill 1989	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[i]	none	0.3 (n=17)	30 (n=11)	p>0.05	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean percentage reduction in volume – general population – stage III and IV – Lowthian classification												
Matzen 1999	randomised trials	very serious[a,p]	no serious inconsistency	no serious indirectness	no serious imprecision	none	26 (SD 20)	64 (SD 16)	-	MD 38 higher (50.49 to 25.51 lower)	⊕⊕OO LOW	CRITICAL OUTCOME
Mean healing speed (mm²/day) – general population - stage I and II - NPUAP classification												
Kim 1996	randomised	very	no serious	no serious	serious[d]	none	9.1	7.9	-	MD 1.2 higher (1.8 lower to	⊕OOO	CRITICAL

	trials	serious[a]	inconsistency	indirectness			(SD 5.4)	(SD 4.7)		4.2 higher)	VERY LOW	OUTCOME
Median time to healing (days) – long-term care patients – stage II or III – Shea classification												
Xakellis 1992	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[i]	none	9 (n=18)	11 (n=21)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patient with an infection – inpatients – stage II or III – no classification reported												
Chang 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[g]	none	0/17 (0%)	1/17 (0%)	OR 0.14 (0.00 to 6.82)	50 fewer per 1000 (from 59 fewer to 240 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		not pooled		
Proportion of infected ulcers – inpatients – no stage reported – NPUAP classification												
Kordestani 2008	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/16 (0%)	0/12 (0%)	not pooled	RD 0 fewer (from 130 fewer to 130 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 fewer (from 130 fewer to 130 more)		
Proportion of patients with hypergranulation - general population - stage I and II - NPUAP classification												
Kim 1996	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[g]	none	3/26 (11.5%)	0/18 (0%)	OR 5.9 (0.56 to 62.29)	RD 120 more (from 30 fewer to 260 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		RD 120 more (from 30 fewer to 260 more)		
Proportion of patients with skin irritation – general population – grade II or III – Shea classification												
Neill 1989	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/50 (0%)	9/50 (18%)	OR 0.11 (0.03 to	156 fewer per 1000 (from 92 fewer to 173	⊕⊕OO LOW	IMPORTANT OUTCOME

									0.44)	fewer)		
								18%		156 fewer per 1000 (from 92 fewer to 173 fewer)		
Proportion of patient with pain at dressing removal - inpatients – stage II or III – classification system not reported												
Chang 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/17 (0%)	7/17 (41.2%)	OR 0.09 (0.02 to 0.45)	352 fewer per 1000 (from 172 fewer to 398 fewer)	⊕⊕OO LOW	IMPORTANT OUTCOME
								41.2%		353 fewer per 1000 (from 172 fewer to 398 fewer)		
Median pain score during treatment (scoring system not reported) - general population – stage III and IV – Lowthian classification												
Matzen 1999	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[i]	none	2.0 (range: 1-3) (n=17)	2.0 (range: 1-3) (n=15)	-	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME
Median odour score during treatment (scoring system not reported) - general population – stage III and IV – Lowthian classification												
Matzen 1999	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[i]	none	2.0 (range: 1-4) (n=17)	2.0 (range: 1-3) (n=15)	-	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME
Proportion of patient with discomfort - inpatients – stage II or III – classification system not reported												
Chang 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/17 (0%)	9/17 (52.9%)	OR 0.07 (0.02 to 0.32)	456 fewer per 1000 (from 265 fewer to 507 fewer)	⊕⊕OO LOW	IMPORTANT OUTCOME
								52.9%		456 fewer per 1000 (from 265 fewer to 507 fewer)		

Median comfort score during treatment (scoring system not reported) - general population – stage III and IV – Lowthian classification												
Matzen	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[i]	none	4.0 (range: 3-4) (n=17)	3.0 (range: 2-4) (n=15)	-	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME

a Kim (1996), Matzen (1999), Xakellis (1992), Colwell (1993), Kordestani (2008), Neill (1989), Chang (1998): no report or insufficient information on sequence generation, allocation concealment and no blinding. Matzen (1999): drop out 10% differential or higher than event rate for proportion completely healed. Colwell (1990): Drop out is more than 10% higher than event rate for proportion completely healed. Kordestani (2008): Drop out is more than 10% higher than event rate for proportion completely healed for proportion of infected ulcers
b Hollisaz (2004): only blinding of outcome assessor.
c Different populations and high heterogeneity (> 50%) and p-value < 0.1
d Confidence interval crossed one MID point
e Heterogeneity > 50%
f Different populations and high heterogeneity (> 50%) but p-value > 0.1
g Confidence interval crossed both MID points
h Mulder (1993): no report on allocation concealment or blinding
i No standard deviations; small sample size
j No standard deviation; unknown if sample size was sufficient
k Alm (1989): no report on sequence generation; allocation concealment by stratification according to Norton score; only blinding of outcome assessor
l No standard deviation; number of patients completed per group unclear
m Kim (1996): NPUAP classification; Matzen (1999): Lowthian classification; Xakellis (1992) and Hollisaz (2004): Shea classification
n Kordestani (2008): NPUAP classification; Colwell (1993): no classification reported; Neill (1989) and Hollisaz (2004): Shea classification
o Chang (1998): standard deviation was calculated based on the available raw data. Mulder (1993): no transformation of data
p Matzen (1999): no log-transformation of data

Table 9 – Hydrocolloid dressing versus foam dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Foam dressing	Relative (95% CI)	Absolute		
Proportion of patients completely healed – general population – stage II and III – Stirling and AHCPR classification[g]												
Bale 1997; Seeley 1999; Thomas 1997	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	29/77 (37.7%)	25/80 (31.3%)	RR 1.24 (0.81 to 1.9)	75 more per 1000 (from 59 fewer to 281 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								40%		96 more per 1000 (from 76 fewer to 360 more)		
Proportion of patients improved – community patients – stage II or III – Stirling classification												
Thomas 1997	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	no serious imprecision	none	39/48 (81.3%)	39/48 (81.3%)	RR 1 (0.83 to 1.21)	0 fewer per 1000 (from 138 fewer to 171 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								81.3%		0 fewer per 1000 (from 138 fewer to 171 more)		
Proportion of patients not changed - general population – stage II or III – Stirling classification												
Bale 1997; Thomas 1997	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	very serious[d]	none	5/79 (6.3%)	2/77 (2.6%)	RR 2.17 (0.50 to 9.33)	30 more per 1000 (from 13 fewer to 216 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								4.2%		49 more per 1000 (from 21 fewer to 350 more)		

Proportion of patients worsened - general population – stage II or III – Stirling classification												
Bale 1997; Thomas 1997	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	very serious[d]	none	9/79 (11.4%)	6/77 (7.8%)	RR 1.48 (0.56 to 3.94)	37 more per 1000 (from 34 fewer to 229 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								10.4%		50 more per 1000 (from 46 fewer to 306 more)		
Mean percentage reduction in ulcer area – general population – stage II and III - AHCPR classification												
Seeley 1999	randomised trials	very serious[c,h]	no serious inconsistency	no serious indirectness	serious[b]	none	52 (SD 6.06)	50 (SD 6.06)	-	MD 2.0 higher (1.81 lower to 5.81 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with hypergranulation - community patients – stage II or III – Stirling classification												
Thomas 1997	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/49 (0%)	0/50 (0%)	not pooled	RD 0 more (from 4 fewer to 4 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		Rd 0 more (from 4 fewer to 4 more)		
Proportion of patient with bleeding - community patients – stage II or III – Stirling classification												
Thomas 1997	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	very serious[d]	none	2/49 (4.1%)	0/50 (0%)	OR 7.7 (0.47 to 124.89)	RD 4 more (from 3 fewer to 11 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		RD 4 more		

										(from 3 fewer to 11 more)		
Proportion of patients with maceration - community patients – stage II or III – Stirling classification												
Thomas 1997	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	Serious[b]	none	4/49 (8.2%)	0/50 (0%)	OR 8.04 (1.1 to 58.85)	RD 8 more (from 0 fewer to 170 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		RD 8 more (from 0 fewer to 170 more)		
Proportion of patients with inflammation or maceration – general population – stage II and III - AHCPR classification												
Seeley 1999	randomised trials	very serious[e]	no serious inconsistency	no serious indirectness	Serious[b]	none	6/19 (31.6%)	12/20 (60%)	RR 0.53 (0.25 to 1.12)	282 fewer per 1000 (from 450 fewer to 72 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								60%		282 fewer per 1000 (from 450 fewer to 72 more)		
Mean pain score at end of treatment (scale 0 no pain - 3 severe pain) – general population – stage II and III - AHCPR classification												
Seeley 1999	randomised trials	very serious[e]	no serious inconsistency	no serious indirectness	Serious[b]	none	0.47 (SD 0.9)	0.15 (SD 0.8)	-	MD 0.32 higher (0.22 lower to 0.86 higher)	⊕OOO VERY LOW	IMPORTANT OUTCOME
Mean odour score at end of treatment (scale 0 no odour - 3 severe odour) – general population – stage II and III - AHCPR classification												
Seeley 1999	randomised trials	very serious[e]	no serious inconsistency	no serious indirectness	Serious[b]	none	0.47 (SD 0.8)	0.16 (SD 0.5)	-	MD 0.31 higher (0.11 lower to 0.73 higher)	⊕OOO VERY LOW	IMPORTANT OUTCOME

Proportion of patients with adverse events (unknown if dressing related) – general population – stage II and III – Stirling and AHCPR classification[g]												
Seeley 1999; Bale 1997	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Very serious[d]	none	5/51 (9.8%)	8/49 (16.3%)	RR 0.61 (0.22 to 1.71)	64 fewer per 1000 (from 127 fewer to 116 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								17.7%		69 fewer per 1000 (from 138 fewer to 126 more)		

a Bale (1997): no report on sequence generation, allocation concealment and blinding; Seeley (1999): allocation concealment by stratification according to initial ulcer size and no blinding; Thomas (1997): no report on sequence generation and no blinding
b Confidence interval crossed one MID point
c Thomas (1997): no report on sequence generation and no blinding
d Confidence interval crossed both MID points
e Seeley (1999): allocation concealment by stratification according to initial ulcer size and no blinding
f No standard deviation; small sample size
g Bale (1997) and Thomas (1997): Stirling classification; Seeley (1999): AHCPR classification
h Seeley (1999): no log-transformation of data

Table 10 – Hydrocolloid dressing versus polyurethane film

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Polyurethane film	Relative (95% CI)	Absolute		
Proportion of patients completely healed – general population – stage II and III – classification system not reported												
Banks 1994a; Banks 1994b; Brown-Etris 2008	randomised trials	very serious[a]	Serious[b]	no serious indirectness	Serious[c]	none	43/59 (72.9%)	43/63 (68.3%)	RR 1.07 (0.87 to 1.33)	48 more per 1000 (from 89 fewer to 225 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								66.7%		47 more per 1000 (from 87 fewer to 220 more)		

Proportion of patients improved – community patients - stage II and III – classification system not reported											
Banks 1994b	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	10/10 (100%) 100%	18/18 (100%) 100%	RR 1 (0.86 to 1.16)	0 fewer per 1000 (from 140 fewer to 160 more) 0 fewer per 1000 (from 140 fewer to 160 more)	⊕⊕OO LOW	CRITICAL OUTCOME
Mean percentage reduction in ulcer area - general population – stage II and III – classification system not reported											
Brown-Etris 2008	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	23.8 (n=37)	26.7 (n=35)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median time to healing (days) – inpatients patients - stage II and III – classification system not reported											
Banks 1994a	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[e]	none	12.69 (n=12)	13.36 (n=10)	p > 0.05	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Linear healing rate (cm/week) - general population – stage II and III – classification system not reported											
Brown-Etris 2008	randomised trials	very serious[a,h]	no serious inconsistency	no serious indirectness	Serious[c]	none	0.12 (n=37)	0.10 (n=35)	-	MD 0.02 higher (0.06 lower to 0.1 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean odour score (1 very poor - 5 very good) - general population – stage II and III – classification system not reported											
Brown-Etris 2008	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	4.8 (SD 0.39)	5 (SD 0.14)	-	MD 0.2 lower (0.33 to 0.07 lower)	⊕OOO VERY LOW	IMPORTANT OUTCOME
Mean comfort score (1 very poor - 5 very good) - general population – stage II and III – classification system not reported											
Brown-Etris 2008	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	4.4 (SD 0.66)	4.8 (SD 0.34)	-	MD 0.4 lower (0.64 to 0.16 lower)	⊕OOO VERY LOW	IMPORTANT OUTCOME

Proportion of patients with adverse events - general population – stage II and III – classification system not reported												
Brown-Etris 2008	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/37 (0%)	0/35 (0%)	not pooled	RD 0 more (from 5 fewer to 5 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 5 fewer to 5 more)		
Proportion of patients with pain at dressing removal - general population – stage II and III – classification system not reported												
Banks 1994a; Banks 1994b	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[f]	none	-	-	p < 0.005	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		not pooled		
Proportion of patients with discomfort at dressing removal - general population – stage II and III – classification system not reported												
Banks 1994a; Banks 1994b	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[g]	none	-	-	p > 0.05	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		not pooled		

a No report on sequence generation, allocation concealment and no blinding
b Heterogeneity > 50%; p-value of 0.1
c Confidence interval crossed one MID point
d No standard deviation; unknown if sample size was sufficient
e No standard deviation; small sample size
f Only p-values and a figure are reported. Both studies showed more pain in the hydrocolloid group compared to the polyurethane group.
g Only p-values and a figure are reported. Both studies showed more discomfort in the hydrocolloid group compared to the polyurethane group.
h Brown-Etris (2008): no log-transformation of data

Table 11 – Hydrocolloid dressing versus collagenase ointment

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No of patients: Hydrocolloid dressing	No of patients: Collagenase	Effect: Relative (95% CI)	Effect: Absolute	Quality	Importance
Proportion of patients completely healed – general population – stage II and above – no system classification reported												
Burgos 200; Müller 2001	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	10/30 (33.3%)	14/30 (46.7%)	RR 0.75 (0.45 to 1.26)	117 fewer per 1000 (from 257 fewer to 121 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								54.2%		135 fewer per 1000 (from 298 fewer to 141 more)		
Proportion of patients completely healed (all sites) – inpatients – stage II and III – classification system not reported												
Burgos 2000	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	3/19 (15.8%)	3/18 (16.7%)	RR 0.95 (0.22 to 4.1)	8 fewer per 1000 (from 130 fewer to 517 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								16.7%		8 fewer per 1000 (from 130 fewer to 518 more)		
Proportion of patients completely healed (heel ulcers) – general population – stage IV – classification system not reported												
Müller 2001	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	7/11 (63.6%)	11/12 (91.7%)	RR 0.69 (0.43 to 1.12)	284 fewer per 1000 (from 522 fewer to 110 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								91.7%		284 fewer per 1000 (from 523 fewer to 110 more)		
Mean percentage reduction in ulcer area – inpatients –stage III - classification system not reported												
Burgos 2000	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	73.7	83.3	-	MD 9.6 lower (69.17 lower to	⊕OOO VERY	CRITICAL OUTCOME

							(SD=92.4)	(SD=92.4)		49.97 higher)	LOW	
Mean cm² reduction in ulcer area – inpatients –stage III - classification system not reported												
Burgos 2000	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	Serious[c]	none	6.2 (SD 9.8)	9.1 (SD 12.7)	-	MD 2.9 lower (10.24 lower to 4.44 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean time to healing (weeks) – general population – stage IV – classification system not reported												
Müller 2001	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	14 (SD 4.6)	10 (SD 4.6)	-	MD 4 higher (0.24 to 7.76 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with adverse events[e] – inpatients – stage III - classification system not reported												
Burgos 2000	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	2/19 (10.5%)	1/18 (5.6%)	RR 1.89 (0.19 to 19.13)	49 more per 1000 (from 45 fewer to 1000 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								5.6%		50 more per 1000 (from 45 fewer to 1000 more)		

a Burgos (2000a): no allocation concealment and only blinding of assessor; Müller (2001): no report on sequence generation, allocation concealment and no blinding.
b Confidence interval crossed both MID points
c Confidence interval crossed one MID point
d Burgos (2000a): no allocation concealment and only blinding of assessor; no log-transformation of data
e Hydrocolloid group: one patient had erythema and exudate and one patient had exudate and intense odour. Collagenase group: one patient had dermatitis

Table 12 – Hydrocolloid dressing versus collagen dressing

							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Collagen	Relative (95% CI)	Absolute		
Proportion of patients completely healed – inpatients – stage II and III - NPUAP classification												
Graumlich 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	15/30 (50%)	18/35 (51.4%)	RR 0.97 (0.6 to 1.57)	15 fewer per 1000 (from 206 fewer to 293 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								51.4%		15 fewer per 1000 (from 206 fewer to 293 more)		
Mean percentage reduction in ulcer area – inpatients – stage II and III - NPUAP classification												
Graumlich 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	9 (SD=73.98)	33 (SD=73.98)	-	MD 24 lower (60.08 lower to 12.08 higher)	⊕⊕OO LOW	CRITICAL OUTCOME
Mean healing speed (mm²/day) – inpatients – stage II and III - NPUAP classification												
Graumlich 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	6 (SD 16)	6 (SD 19)	-	MD 0 higher (8.23 lower to 8.23 higher)	⊕⊕⊕O MODERATE	CRITICAL OUTCOME
Mean time to healing (weeks) – inpatients – stage II and III - NPUAP classification												
Graumlich 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	6 (SD 2.68)	6 (SD 2.68)	-	MD 1 higher (0.36 lower to 2.36 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

Proportion of patients with adverse events – inpatients – stage II and III - NPUAP classification												
Graumlich 2003	randomised trials	very serious[d]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/30 (0%)	0/35 (0%)	not pooled	RD 5 more (from 120 fewer to 220 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 5 more (from 120 fewer to 220 more)		

a Only blinding of outcome assessor
b Confidence interval crossed both MID points
c Confidence interval crossed one MID point
e Only blinding of outcome assessor; drop out is more than 10% higher than event rate

Table 13 – Hydrocolloid dressing versus hydrogel

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Hydrocolloid dressing**	**Hydrogel**	**Relative (95% CI)**	**Absolute**		
Proportion of patients completely healed – community patients – stage II and III – classification system not reported												
Motta 1999	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	2/5 (40%)	2/5 (40%)	RR 1 (0.22 to 4.56)	0 fewer per 1000 (from 312 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								40%		0 fewer per 1000 (from 312 fewer to 1000 more)		
Proportion of ulcers completely healed (all sites) – general population- stage I and II – Enis and Sarmienti classification												
Darkovich 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	12/67 (17.9%)	24/62 (38.7%)	RR 0.46 (0.25 to 0.84)	209 fewer per 1000 (from 62 fewer to 290 fewer)	⊕OOO VERY LOW	CRITICAL OUTCOME
								38.7%		209 fewer per 1000 (from 62 fewer to 290 fewer)		

Proportion of ulcers not changed – general population- stage I and II – Enis and Sarmienti classification												
Darkovich 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[2]	none	8/67 (11.9%)	5/62 (8.1%)	RR 1.48 (0.51 to 4.28)	39 more per 1000 (from 40 fewer to 265 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								8.1%		39 more per 1000 (from 40 fewer to 266 more)		
Proportion of ulcers worsened– general population- stage I and II – Enis and Sarmienti classification												
Darkovich 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	7/67 (10.4%)	1/62 (1.6%)	RR 6.48 (0.82 to 51.16)	88 more per 1000 (from 3 fewer to 809 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								1.6%		88 more per 1000 (from 3 fewer to 803 more)		
Mean percentage reduction in ulcer area– general population – stage I - Enis and Sarmienti classification												
Darkovich 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	44 (n=31)	72 (n=27)	p > 0.05	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean percentage reduction in ulcer area– general population – stage II - Enis and Sarmienti classification												
Darkovich 1990	randomised trials	very serious[a,i]	no serious inconsistency	no serious indirectness	very serious[c,e]	none	34 (SD 47.7)	64 (SD 47.7)	-	MD 30 lower (52.19 to 7.81 lower)	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer area– in –and outpatients – stage II and III – classification system not reported												
Mulder 1993	randomised trials	very serious[6]	no serious inconsistency	no serious indirectness	very serious[d]	none	7.4 (n=21)	5.6 (n=20)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean healing rate (cm/day) – community patients – stage II and III – classification system not reported												
Motta 1999	randomised trials	very serious[a,i]	no serious inconsistency	no serious indirectness	very serious[b]	none	0.35 (SD 0.43)	0.15 (SD 0.22)	-	MD 0.2 higher (0.22 lower to 0.62 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

Healing rate (%/day) – general population- stage I and II – Enis and Sarmienti classification												
Darkovich 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[g]	none	3.1 (n=?)	8.1 (n=?)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median odour score during treatment – community patients – stage II and III – classification system not reported												
Motta 1999	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[h]	none	2 (n=5)	2 (n=5)	-	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME
Median comfort score during treatment – community patients – stage II and III – classification system not reported												
Motta 1999	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[h]	none	3 (n=5)	4 (n=5)	-	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME

a No report on sequence generation, allocation concealment and no blinding
b Confidence interval crossed both MID points
c Confidence interval crossed one MID point
d No standard deviation; unknown if sample size was insufficient
e SD was calculated on a p-value <0.01 (less precise)
f Mulder (1993): no report on allocation concealment and no blinding
g No standard deviation; unknown how many ulcers were included in analysis
h No standard deviation; very small sample size
i No log-trnasofmration of data

Table 14 – Hydrocolloid dressing versus impregnated gauze

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Impregnated gauze	Relative (95% CI)	Absolute		
Proportion of patients completely healed – general population – stage and classification system not reported												
Winter 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	5/6 (83.3%)	3/5 (60%)	RR 1.39 (0.62 to 3.09)	234 more per 1000 (from 228 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								60%		234 more per 1000 (from 228 fewer to 1000 more)		
Proportion of patients improved – general population – stage and classification system not reported												
Winter 1990	randomised trials	very serious[a,c]	no serious inconsistency	no serious indirectness	very serious[b]	none	6/6 (100%)	5/5 (100%)	RR 1 (0.73 to 1.37)	0 fewer per 1000 (from 270 fewer to 370 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								100%		0 fewer per 1000 (from 270 fewer to 370 more)		

a No report on sequence generation, allocation concealment and no blinding
b Confidence interval crossed both MID points
c Drop out is more than 10% higher than event rate

Table 15 – Hydrocolloid dressing versus poly-hema dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Poly-hema dressing	Relative (95% CI)	Absolute		
Proportion of patients completely healed – elderly patients – stage II and III – classification system not reported												
Brod 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	10/16 (62.5%)	14/27 (51.9%)	RR 1.21 (0.71 to 2.04)	109 more per 1000 (from 150 fewer to 539 more)	⊕OOO VERY	CRITICAL OUTCOME

								51.9%		109 more per 1000 (from 151 fewer to 540 more)	LOW	
Median time to healing (days) – elderly patients – stage II and III – classification system not reported												
Brod 1990	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	42 (n=16)	32 (n=27)	p=0.56	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Absolute rate of healing (cm²/week) – elderly patients – stage II and III – classification system not reported												
Brod 1990	randomised trials	very serious[a,g]	no serious inconsistency	no serious indirectness	Serious[d]	none	0.10 (SD 0.085)	0.18 (SD 0.085)	-	MD 0.08 lower (0.13 to 0.03 lower)	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with adverse events[e] – elderly patients – stage II and III – classification system not reported												
Brod 1990	randomised trials	very serious[a,f]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/16 (6.3%)	0/27 (0%)	OR 14.69 (0.25 to 847.55)	RD 6 more (from 8 fewer to 210 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		RD 6 more (from 8 fewer to 210 more)		

a Allocation concealment stratified according to lesion stage and only blinding of outcome assessor
b Confidence interval crossed both MID points
c No standard deviation; small sample size
d Confidence interval crossed one MID point
e unknown if adverse events were dressing related
f Drop out is more than 10% higher than event rate
g No log-transformation of data

Table 16 – Hydrocolloid dressing versus co-polymer (amino acid) dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Copolymer (amino acid)	Relative (95% CI)	Absolute		
Proportion of patients completely healed – inpatients – stage II, III or IV – NPUAP classification												
Hondé 1994	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	23/88 (26.1%)	31/80 (38.8%)	RR 0.67 (0.43 to 1.05)	128 fewer per 1000 (from 221 fewer to 19 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								38.8%		128 fewer per 1000 (from 221 fewer to 19 more)		
Median time to healing (days) – inpatients – stage II, III or IV – NPUAP classification												
Hondé 1994	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	38 (range: 13-59) (n=88)	32 (range:11-63) (n=80)	p=0.044 (adjusted for wound depth)	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patient with an infection – inpatients – stage II, III or IV – NPUAP classification												
Hondé 1994	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[d]	none	6/88 (6.8%)	6/80 (7.5%)	RR 0.91 (0.31 to 2.7)	7 fewer per 1000 (from 52 fewer to 128 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								7.5%		7 fewer per 1000 (from 52 fewer to 128 more)		

a No report on allocation concealment and no blinding
b Confidence interval crossed one MID point
c No standard deviation
d Confidence interval crossed both MID points
e Drop out is more than 10% higher than event rate

Table 17 – Hydrocolloid dressing versus phenytoin cream

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Phenytoin cream	Relative (95% CI)	Absolute		
Proportion of patients completely healed – patients with a spinal cord injury – stage I and II – Shea classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	20/28 (71.4%)	8/27 (29.6%)	RR 2.41 (1.29 to 4.51)	418 more per 1000 (from 86 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL OUTCOME
								29.6%		417 more per 1000 (from 86 more to 1000 more)		
Proportion of ulcers completely healed (all sites) – patients with a spinal cord injury – stage I and II – Shea classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	23/31 (74.2%)	12/30 (40%)	RR 1.85 (1.14 to 3.01)	340 more per 1000 (from 56 more to 804 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								40%		340 more per 1000 (from 56 more to 804 more)		
Proportion of ulcers completely healed (all sites) – patients with a spinal cord injury – stage I– Shea classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	11/13 (84.6%)	2/9 (22.2%)	RR 3.81 (1.1 to 13.21)	624 more per 1000 (from 22 more to 1000 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								22.2%		624 more per 1000 (from 22 more to 1000 more)		

Proportion of ulcers completely healed (all sites) – patients with a spinal cord injury – stage II – Shea classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	12/18 (66.7%)	10/21 (47.6%)	RR 1.4 (0.8 to 2.44)	190 more per 1000 (from 95 fewer to 686 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								47.6%		190 more per 1000 (from 95 fewer to 685 more)		
Proportion of ulcers completely healed (sacral) – patients with a spinal cord injury – stage I and II – Shea classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	4/7 (57.1%)	2/5 (40%)	RR 1.43 (0.41 to 4.99)	172 more per 1000 (from 236 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								40%		172 more per 1000 (from 236 fewer to 1000 more)		
Proportion of ulcers improved – patients with a spinal cord injury – stage I and II – Shea classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	27/31 (87.1%)	16/30 (53.3%)	RR 1.63 (1.14 to 2.34)	336 more per 1000 (from 75 more to 715 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								53.3%		336 more per 1000 (from 75 more to 714 more)		
Proportion of ulcers worsened– patients with a spinal cord injury – stage I and II – Shea classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	2/31 (6.5%)	2/30 (6.7%)	RR 0.97 (0.15 to 6.44)	2 fewer per 1000 (from 57 fewer to 363 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								6.7%		2 fewer per 1000 (from 57 fewer to 364 more)		

1 Only blinding of outcome assessor
2 Confidence interval crossed one MID point
3 Confidence interval crossed both MID points

Table 18 – Hydrocolloid dressing versus alginate dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Alginate dressing	Relative (95% CI)	Absolute		
Proportion of patients partially (40%) healed – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	31/53 (58.5%)	43/57 (75.4%)	RR 0.78 (0.59 to 1.02)	166 fewer per 1000 (from 309 fewer to 15 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								75.4%		166 fewer per 1000 (from 309 fewer to 15 more)		
Mean percentage reduction in ulcer area – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	no serious imprecision	none	42.6 (SD 49.1)	69.1 (SD 33.9)	-	MD 26.5 lower (42.38 to 10.62 lower)	⊕⊕OO LOW	CRITICAL OUTCOME
Mean cm² reduction in ulcer area – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	no serious imprecision	none	5.2 (SD 7.2)	9.7 (SD 7.1)	-	MD 4.5 lower (7.17 to 1.83 lower)	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patient with an infection – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/53 (0%)	1/57 (1.8%)	OR 0.15 (0 to 7.34)	15 fewer per 1000 (from 18 fewer to 98 more)	⊕OOO VERY LOW	IMPROTANT OUTCOME
								1.8%		15 fewer per 1000 (from 18 fewer to 101 more)		

Proportion of patients with skin irritation – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/53 (0%)	2/57 (3.5%)	OR 0.14 (0.01 to 2.31)	30 fewer per 1000 (from 35 fewer to 46 more)	⊕OOO VERY LOW	IMPROTANT OUTCOME
								3.5%		30 fewer per 1000 (from 35 fewer to 46 more)		
Proportion of patients with hypergranulation – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	5/53 (9.4%)	1/57 (1.8%)	RR 5.38 (0.65 to 44.54)	77 more per 1000 (from 6 fewer to 764 more)	⊕OOO VERY LOW	IMPROTANT OUTCOME
								1.8%		79 more per 1000 (from 6 fewer to 784 more)		
Proportion of patients with maceration – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/53 (0%)	1/57 (1.8%)	OR 0.15 (0 to 7.34)	15 fewer per 1000 (from 18 fewer to 98 more)	⊕OOO VERY LOW	IMPROTANT OUTCOME
								1.8%		15 fewer per 1000 (from 18 fewer to 101 more)		
Proportion of patient with bleeding – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/53 (0%)	1/57 (1.8%)	OR 0.15 (0 to 7.34)	15 fewer per 1000 (from 18 fewer to 98 more)	⊕OOO VERY LOW	IMPROTANT OUTCOME
								1.8%		15 fewer per 1000 (from 18 fewer to 101 more)		
Incidence of pain at dressing removal – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	411/1314 (31.3%)	316/887 (35.6%)	RR 0.88 (0.78 to 0.99)	43 fewer per 1000 (from 4 fewer to 78 fewer)	⊕OOO VERY LOW	IMPROTANT OUTCOME
								35.6%		43 fewer per 1000		

										(from 4 fewer to 78 fewer)		
Incidence of strong odor at dressing removal – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	Serious[b]	none	173/1314 (13.2%)	178/887 (20.1%)	RR 0.66 (0.54 to 0.79)	68 fewer per 1000 (from 42 fewer to 92 fewer)	⊕OOO VERY LOW	IMPROTANT OUTCOME
								20.1%		68 fewer per 1000 (from 42 fewer to 92 fewer)		
Incidence of mild odor at dressing removal – older inpatients – stage III and IV – Yarkony classification												
Belmin 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	382/1314 (40.7%)	361/887 (40.7%)	RR 0.71 (0.64 to 0.80)	118 fewer per 1000 (from 81 fewer to 147 fewer)	⊕OOO VERY LOW	IMPROTANT OUTCOME
								40.7%		118 fewer per 1000 (from 81 fewer to 147 fewer)		

a Sequence generation was by block of four patients; allocation was balanced by centre; only blinding of outcome assessor
b Confidence interval crossed one MID point
c Confidence interval crossed both MID points
d Drop out is more than 10% higher than event rate
e No log-transformation of data

Table 19 – Hydrocolloid dressing versus charcoal dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Charcoal dressing	Relative (95% CI)	Absolute		
Proportion of patients worsened – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/30 (3.3%)	0/29 (0%)	OR 7.15 (0.14 to 360.38)	RD 3 more (from 6 fewer to 120 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								0%		RD 3 more (from 6 fewer to 120 more)		
Median percentage reduction in ulcer area– inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	18.5 (range:100 to -260.9) (n=31)	26.9 (range: 82 to -97.9) (n=29)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median cm² reduction in ulcer area – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	3.1 (range: 24.1 to -46.0) (n=31)	4.3 (range: 31.2 to -13.8) (n=29)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with maceration – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[b]	none	2/30 (6.7%)	0/29 (0%)	OR 7.4 (0.45 to 121.22)	RD 7 more (from 4 fewer to 170 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		RD 7 more (from 4 fewer to 170 more)		

Proportion of patient with an infection – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[d]	none	2/30 (6.7%)	1/29 (3.4%)	RR 1.93 (0.19 to 20.18)	32 more per 1000 (from 28 fewer to 661 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								3.5%		33 more per 1000 (from 28 fewer to 671 more)		
Proportion of patients with hypergranulation – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[d]	none	1/30 (3.3%)	0/29 (0%)	OR 7.15 (0.14 to 360.38)	RD 3 more (from 6 fewer to 120 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		RD 3 more (from 6 fewer to 120 more)		
Proportion of patients with skin irritation and eczema – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[4]	none	1/30 (3.3%)	0/29 (0%)	OR 7.15 (0.14 to 360.38)	RD 3 more (from 6 fewer to 120 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								0%		RD 3 more (from 6 fewer to 120 more)		
Proportion of patient with bleeding – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/30 (0%)	0/29 (0%)	not pooled	RD 0 more (from 6 fewer to 6 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 6 fewer to 6 more)		
Proportion of patients with pruritus – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[d]	none	0/30 (0%)	1/29 (3.4%)	OR 0.13 (0 to 6.59)	30 fewer per 1000 (from 34 fewer to 156 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								3.5%		30 fewer per 1000 (from 35		

										fewer to 158 more)		
Proportion of patients with wound pain – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/30 (0%)	0/29 (0%)	not pooled	RD 0 more (from 6 fewer to 6 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 6 fewer to 6 more)		
Proportion of patient with pain at dressing removal – inpatients – stage IIc and IV – Yarkoni classification												
Kerihuel 2010	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	19/30 (63.3%)	19/29 (65.5%)	RR 0.97 (0.66 to 1.41)	20 fewer per 1000 (from 223 fewer to 269 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								65.5%		20 fewer per 1000 (from 223 fewer to 269 more)		

a No report on sequence generation and only blinding of outcome assessor
b Confidence interval crossed both MID points
c No standard deviation; unknown if sample size was sufficient.
d Confidence interval crossed both MID points
e Drop out is more than 10% higher than event rate

Table 20 – Hydrocolloid dressing versus phenytoin ointment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Phenytoin ointment	Relative (95% CI)	Absolute		
Mean time to healing (days) – nursing home patients – stage II – AHCPR classification												
Rhodes 2001	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	51.8 (SD 19.6)	35.3 (SD 14.3)	-	MD 16.5 higher (3.62 to 29.38 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

Proportion of patients with adverse events – nursing home patients – stage II – AHCPR classification												
Rhodes 2001	randomised trials	very serious[a,c]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/13 (0%)	0/15 (0%)	not pooled	RD 0 more (from 130 fewer to 130 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 130 fewer to 130 more)		

a No report on sequence generation, allocation concealment and no blinding
b Confidence interval crossed one MID point
c Drop out is more than 10% higher than event rate

Table 21 – Hydrocolloid dressing versus antibiotic ointment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing	Antibiotic ointment	Relative (95% CI)	Absolute		
Mean time to healing (days) – nursing home patients – stage II – AHCPR classification												
Rhodes 2001	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	51.8 (SD 19.6)	53.8 (SD 8.5)	-	MD 2 lower (13.78 lower to 9.78 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with adverse events – nursing home patients – stage II – AHCPR classification												
Rhodes 2001	randomised trials	very serious[a,c]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/13 (0%)	0/11 (0%)	not pooled	RD 0 more (from 150 fewer to 150 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 150 fewer to 150 more)		

a No report on sequence generation, allocation concealment and no blinding
b Confidence interval crossed both MID points
c Drop out is more than 10% higher than event rate

Table 22 – Hydrocolloid dressing: triangular shape versus oval shape

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloid dressing: triangular shape	Hydrocolloid dressing: oval shape	Relative (95% CI)	Absolute		
Proportion of patients completely healed – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	17/47 (36.2%)	11/49 (22.4%)	RR 1.61 (0.85 to 3.07)	137 more per 1000 (from 34 fewer to 465 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								22.5%		137 more per 1000 (from 34 fewer to 466 more)		
Proportion of patients improved – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	41/47 (87.2%)	31/49 (63.3%)	RR 1.38 (1.08 to 1.75)	240 more per 1000 (from 51 more to 474 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								63.3%		241 more per 1000 (from 51 more to 475 more)		
Proportion of patients not changed – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	4/47 (8.5%)	3/49 (6.1%)	RR 1.39 (0.33 to 5.88)	24 more per 1000 (from 41 fewer to 299 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								6.1%		24 more per 1000 (from 41 fewer to 298 more)		

Proportion of patients worsened – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/47 (4.3%)	15/49 (30.6%)	RR 0.14 (0.03 to 0.58)	263 fewer per 1000 (from 129 fewer to 297 fewer)	⊕⊕OO LOW	CRITICAL OUTCOME
								91.8%		789 fewer per 1000 (from 386 fewer to 890 fewer)		
Mean percentage reduction in ulcer length – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	32 (SD 34.15)	17 (SD 34.15)	-	MD 15 higher (1.33 to 28.67 higher)	⊕⊕OO LOW	CRITICAL OUTCOME
Mean percentage reduction in ulcer width – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	28 (n=47)	24 (n=49)	p > 0.05	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean pain at dressing change – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2.1 (SD 2.1)	4.3 (SD 1.75)	-	MD 2.2 lower (2.97 to 1.43 lower)	⊕⊕OO LOW	IMPORTANT OUTCOME
Proportion of patients with ulcer pain – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	8/47 (17%)	15/49 (30.6%)	RR 0.56 (0.26 to 1.19)	135 fewer per 1000 (from 227 fewer to 58 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								30.6%		135 fewer per 1000 (from 226 fewer to 58 more)		

Proportion of patients with adverse events[e] – inpatients – stage II and III – NPUAP classification												
Day 1995	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	0/47 (0%)	4/49 (8.2%)	OR 0.13 (0.02 to 0.97)	70 fewer per 1000 (from 2 fewer to 80 fewer)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								8.2%		71 fewer per 1000 (from 2 fewer to 80 fewer)		

a Randomized schedule and no report on allocation concealment and no blinding; no log-transformation of data
b Confidence interval crossed one MID point
c Confidence interval crossed both MID points
d No standard deviation; unknown if sample size was sufficient
e Oval group: increase in necrotic tissue, wound size and depth, inflammation of surrounding skin, severe pain upon dressing removal, and bleeding

Table 23 – Hydrocolloid dressing: Comfeel® versus Comfeel®Plus

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloids: Comfeel	Hydrocolloids: ComfeelPlus	Relative (95% CI)	Absolute		
Percentage reduction in ulcer area - general population – necrotic PU – no classification reported												
Routkovsky-Norval 1996 [d]	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	44 (n=31)	49 (n=30)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with dressing intolerance - general population – necrotic PU – no classification reported												
Routkovsky-Norval 1996 [d]	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	2/31 (6.5%)	3/30 (10%)	RR 0.65 (0.12 to 3.59)	35 fewer per 1000 (from 88 fewer to 259 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								10%		35 fewer per 1000 (from 88 fewer to 259 more)		
Proportion of patients reporting the dressing as good to excellent for comfort at dressing change - general population – necrotic PU – no classification reported												
Routkovsky-Norval 1996 [d]	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	142/167 (85%)	150/166 (90.4%)	RR 0.94 (0.87 to 1.02)	54 fewer per 1000 (from 117 fewer to 18 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								90.4%		54 fewer per 1000 (from 118 fewer to 18 more)		

a No report on sequence generation, allocation concealment and no blinding
b No standard deviation; unknown if sample size was sufficient
c Confidence interval crossed both MID points
d Study published in French

Table 24 – Hydrocolloid dressing: SignaDress® versus Comfeel®Plus

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrocolloids: SingaDress	Hydrocolloids: ComfeelPlus	Relative (95% CI)	Absolute		
Proportion of patients completely healed – nursing home patients – stage II, III and IV – AHCPR classification												
Seaman 2000	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	Serious[b]	none	6/17 (35.3%)	1/18 (5.6%)	RR 6.35 (0.85 to 47.44)	297 more per 1000 (from 8 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								5.6%		300 more per 1000 (from 8 fewer to 1000 more)		
Percentage reduction in ulcer area – nursing home patients – stage II, III and IV – AHCPR classification												
Seaman 2000	randomised trials	Very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[c]	none	60 (n=17)	22 (n=18)	p=0.01	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Healing rate (%/week) – nursing home patients – stage II, III and IV – AHCPR classification												
Seaman 2000	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	33.8 (n=17)	7.0 (n=18)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with adverse events – nursing home patients – stage II, III and IV – AHCPR classification												
Seaman 2000	randomised trials	Very serious[a,d]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/17 (0%)	0/18 (0%)	not pooled	RD 0 (from 100 fewer to 100 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 (from 100 fewer to 100 more)		

a No report on blinding
b Confidence interval crossed one MID point
c No standard deviation; small sample size

d Drop out is more than 10% higher than event rate
e No log-transformation of data

Table 25 – Gauze dressing versus foam dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Gauze dressing	Foam dressing	Relative (95% CI)	Absolute		
Proportion of patients completely healed – general population – stage II and III – Enterostomal Therapy and NPUAP classification[d]												
Kraft 1993; Payne 2009	randomised trials	very serious[a,e]	no serious inconsistency	no serious indirectness	Serious[b]	none	9/30 (30%)	20/44 (45.5%)	RR 0.64 (0.34 to 1.22)	164 fewer per 1000 (from 300 fewer to 100 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								45.8%		165 fewer per 1000 (from 302 fewer to 101 more)		
Median time to 50% healing (days) – general population – stage II – NPUAP classification												
Payne 2009	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	28 (n=16)	28 (n=20)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME

a No report on sequence generation, allocation concealment and no blinding
b Confidence interval crossed one MID point
c No standard deviation; small sample size
d Kraft (2003): Enterostomal therapy classification; Payne (2009): NPUAP classification
e Kraft (1993): Drop out is more than 10% higher than event rate

Table 26 – Gauze dressing versus polyurethane film

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Gauze dressing	Polyurethane dressing	Relative (95% CI)	Absolute		
Proportion of ulcers completely healed (all sites) – general population – all stages – Enis and Sarmiento and Shea classification[f]												
Oleske 1986;	randomised trials	very serious[a,b]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/22 (0%)	15/31 (48.4%)	OR 0.08 (0.02 to	414 fewer per 1000 (from 259	⊕⊕OO	CRITICAL OUTCOME

Sebern 1989									0.31)	fewer to 465 fewer)	LOW	
								37.4%		328 fewer per 1000 (from 218 fewer to 362 fewer)		
Proportion of ulcers completely healed (all sites) – community patients – stage II – Shea classification												
Sebern 1989	randomised trials	very serious[b]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/12 (0%)	14/22 (63.6%)	OR 0.08 (0.02 to 0.32)	514 fewer per 1000 (from 277 fewer to 603 fewer)	⊕⊕OO LOW	CRITICAL OUTCOME
								63.6%		513 fewer per 1000 (from 277 fewer to 02 fewer)		
Proportion of ulcers worsened – general population – Enis and Sarmiento and Shea classification[f]												
Oleske 1986; Sebern 1989	randomised trials	very serious[a,b]	no serious inconsistency	no serious indirectness	no serious imprecision	none	9/22 (40.9%)	4/31 (12.9%)	RR 3.46 (1.26 to 9.49)	317 more per 1000 (from 34 more to 1000 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								12.4%		305 more per 1000 (from 32 more to 1000 more)		
Proportion of ulcers decreased in ulcer stage– community patients - stage II – Shea classification												
Sebern 1989	randomised trials	very serious[b]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/12 (0%)	16/22 (72.7%)	OR 0.06 (0.01 to 0.24)	589 fewer per 1000 (from 337 fewer to 701 fewer)	⊕⊕OO LOW	CRITICAL OUTCOME
								72.7%		589 fewer per 1000 (from 337 fewer to 701 fewer)		
Proportion of ulcers increased in ulcer stage – community patients –stage II – Shea classification												
Sebern	randomised	very	no serious	no serious	Serious[c]	none	5/12	1/22	RR 9.17	371 more per	⊕OOO	CRITICAL

1989	trials	serious[b]	inconsistency	indirectness			(41.7%)	(4.5%)	(1.21 to 69.69)	1000 (from 10 more to 1000 more)	VERY LOW	OUTCOME
								4.6%		376 more per 1000 (from 10 more to 1000 more)		
Mean percentage reduction in ulcer area – inpatients – stage I and II – Enis and Sarmiento classification												
Oleske 1986	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	2.5 (n=10)	42.9 (n=9)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer area– community patients – stage II – Shea classification												
Sebern 1989	randomised trials	very serious[b]	no serious inconsistency	no serious indirectness	very serious[e]	none	52 (n=22)	100 (n=22)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer area– community patients – stage III – Shea classification												
Sebern 1989	randomised trials	very serious[b]	no serious inconsistency	no serious indirectness	very serious[d]	none	44 (n=15)	67 (n=15)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with maceration – community patients – Shea classification												
Sebern 1989	randomised trials	very serious[b]	no serious inconsistency	no serious indirectness	Serious[c]	none	10/12 (83.3%)	17/22 (77.3%)	RR 1.08 (0.77 to 1.51)	62 more per 1000 (from 178 fewer to 394 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								77.3%		62 more per 1000 (from 178 fewer to 394 more)		

a Olekse (1986): no report on sequence generation, allocation concealment and no blinding; no log-transformation of data
b Sebern (1989): no report on allocation concealment and no blinding
c Confidence interval crossed one MID point
d No standard deviation; small sample size
e No standard deviation; unknown if sample size was sufficient
f Oleske (1986): Enis and Sarmiento classification; Sebern (1989): Shea classification

Table 27 – Gauze dressing versus hydrogel

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Gauze dressing	Hydrogel dressing	Relative (95% CI)	Absolute		
Proportion of patients completely healed – general population – stage II, III and IV – classification system not reported												
Thomas 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	9/14 (64.3%)	10/16 (62.5%)	RR 1.03 (0.6 to 1.77)	19 more per 1000 (from 250 fewer to 481 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								62.5%		19 more per 1000 (from 250 fewer to 481 more)		
Proportion of patients worsened – general population – stage II, III and IV – classification system not reported												
Thomas 1998	randomised trials	very serious[a,f]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/19 (5.3%)	1/22 (4.5%)	RR 1.16 (0.08 to 17.28)	7 more per 1000 (from 42 fewer to 740 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								4.6%		7 more per 1000 (from 42 fewer to 749 more)		
Mean percentage reduction in ulcer area – In- and outpatients – stage II and III – classification system not reported												
Mulder 1993	randomised trials	very serious[c]	no serious inconsistency	no serious indirectness	Serious[d]	none	5.1 (SD 14.8)	8 (SD 14.8)	-	MD 2.9 lower (12.07 lower to 6.27 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean healing rate (cm²/day) – patients with a spinal cord injury – stage I, II and III – NPUAP classification												
Kaya 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	0.12 (SD 0.16)	0.09 (SD 0.05)	-	MD 3 higher (5.58 lower to 11.58 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean time to healing (weeks) – general population – stage II, III and IV – classification system not reported												
Thomas 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	5.2 (SD 2.4)	5.3 (SD 2.3)	-	MD 0.1 lower (1.79 lower to 1.59 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

a No report on sequence generation, allocation concealment and no blinding; no log-transformation of data
b Confidence interval crossed both MID points
c Mulder (1993): no report on allocation concealment and no blinding
d Confidence interval crossed one MID point
e No standard deviation; small sample size
f Drop out is more than 10% higher than event rate

Table 28 – Gauze dressing versus dextranomer

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Gauze dressing	Dextranomer dressing	Relative (95% CI)	Absolute		
Proportion of ulcers improved – patients with a spinal cord injury – stage II, III and IV – Eltorai classification												
Ljungberg 2009	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/15 (13.3%)	11/15 (73.3%)	RR 0.18 (0.05 to 0.68)	601 fewer per 1000 (from 235 fewer to 697 fewer)	⊕⊕OO LOW	CRITICAL OUTCOME
								73.3%		601 fewer per 1000 (from 235 fewer to 696 fewer)		
Proportion of patients with adverse events - patients with a spinal cord injury – stage II, III and IV – Eltorai classification												
Ljungberg 2009	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/15 (0%)	0/15 (0%)	not pooled	RD 0 more (from 120 fewer to 120 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 120 fewer to 120 more)		

a Ljungberg (2009): no report on sequence generation, allocation concealment and no blinding
b Sebern (2009): no report on sequence generation, allocation concealment and no blinding
c Confidence interval crossed one MID point

Table 29 – Gauze dressing versus phenytoin cream

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Gauze dressing	Phenytoin cream	Relative (95% CI)	Absolute		
Proportion of patients completely healed – patients with a spinal cord injury – stage I and II – NPUAP classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	8/27 (29.6%)	11/28 (39.3%)	RR 0.75 (0.36 to 1.58)	98 fewer per 1000 (from 251 fewer to 228 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								39.3%		98 fewer per 1000 (from 252 fewer to 228 more)		
Proportion of ulcers completely healed (all sites) – patients with a spinal cord injury – stage I and II – NPUAP classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	8/30 (26.7%)	12/30 (40%)	RR 0.67 (0.32 to 1.39)	132 fewer per 1000 (from 272 fewer to 156 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								40%		132 fewer per 1000 (from 272 fewer to 156 more)		
Proportion of ulcers completely healed (all sites) – patients with a spinal cord injury – stage II – NPUAP classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	3/19 (15.8%)	10/21 (47.6%)	RR 0.33 (0.11 to 1.03)	319 fewer per 1000 (from 424 fewer to 14 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								47.6%		319 fewer per 1000 (from 424 fewer to 14 more)		
Proportion of ulcers completely healed (all sites) – patients with a spinal cord injury – stage I – NPUAP classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	5/11 (45.5%)	2/9 (22.2%)	RR 2.05 (0.51 to 8.16)	233 more per 1000 (from 109 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								22.2%		233 more per 1000 (from 109 fewer to 1000 more)		

Proportion of ulcers completely healed (sacral) – patients with a spinal cord injury – stage I and II – NPUAP classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	4/8 (50%)	2/5 (40%)	RR 1.25 (0.35 to 4.49)	100 more per 1000 (from 260 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								40%		100 more per 1000 (from 260 fewer to 1000 more)		
Proportion of ulcers improved – patients with a spinal cord injury – stage I and II – NPUAP classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	13/30 (43.3%)	16/30 (53.3%)	RR 0.81 (0.48 to 1.38)	101 fewer per 1000 (from 277 fewer to 203 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								53.3%		101 fewer per 1000 (from 277 fewer to 203 more)		
Proportion of ulcers worsened – patients with a spinal cord injury – stage I and II – NPUAP classification												
Hollisaz 2004	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	9/30 (30%)	2/30 (6.7%)	RR 4.5 (1.06 to 19.11)	233 more per 1000 (from 4 more to 1000 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								6.7%		235 more per 1000 (from 4 more to 1000 more)		

a Only blinding of outcome assessor
b Confidence interval crossed both MID points
c Confidence interval crossed one MID point

Table 30 – Foam dressing versus skin replacement

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Foam dressing	skin replacement	Relative (95% CI)	Absolute		
Proportion of patients completely healed – general population – stage III – classification system not reported												
Payne 2004	randomised trials	Very serious[a,f]	no serious inconsistency	no serious indirectness	very serious[b]	none	2/16 (12.5%)	2/18 (11.1%)	RR 1.12 (0.18 to 7.09)	13 more per 1000 (from 91 fewer to 677 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								11.1%		13 more per 1000 (from 91 fewer to 676 more)		
Median percentage reduction in ulcer area (closed ulcers) – general population – stage III – classification system not reported												
Payne 2004	randomised trials	S-very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[c]	none	33.5 (range:-77.5-100) (n=16)	49.5 (range: -81.7-100) (n=18)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer area (unclosed ulcers) – general population – stage III – classification system not reported												
Payne 2004	randomised trials	Very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[c]	none	17.4 (range: -434.5-100) (n=16)	38.8 (range:-201.7-100) (n=18)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean percentage reduction in ulcer volume – general population – stage III – classification system not reported												
Payne 2004	randomised trials	Very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[c]	none	4.1 (n=16)	18.7 (n=18)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Median percentage reduction in ulcer volume – general population – stage III – classification system not reported												
Payne 2004	randomised trials	Very serious[a,e]	no serious inconsistency	no serious indirectness	very serious[c]	none	17.4 (n=16)	41.2 (n=18)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME

Proportion of patients with infection – general population – stage III – classification system not reported												
Payne 2004	randomised trials	Very serious[a,f]	no serious inconsistency	no serious indirectness	very serious[b]	none	3/16 (18.8%)	3/18 (16.7%)	RR 1.13 (0.26 to 4.8)	22 more per 1000 (from 123 fewer to 633 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								16.7%		22 more per 1000 (from 124 fewer to 635 more)		
Proportion of patients with adverse events – general population – stage III – classification system not reported												
Payne 2004	randomised trials	Very serious[a,f]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/16 (0%)	0/18 (0%)	not pooled	RD 0 more (from 110 fewer to 110 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 110 fewer to 110 more)		

a Single blinding (no additional information)
b Confidence interval crossed both MID points
c No standard deviation; small sample size
d Drop out is more than 10% higher than event rate
e No log-transformation of data

Table 31 – Foam dressing versus antibiotic ointment

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Foam dressing	Antibiotic ointment	Relative (95% CI)	Absolute		
Proportion of patients completely healed – long-term care patients – stage II – AHCPR classification												
Yastrub 2004	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	18/21 (85.7%)	15/23 (65.2%)	RR 1.31 (0.93 to 1.86)	202 more per 1000 (from 46 fewer to 561 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								65.2%		202 more per 1000 (from 46 fewer to 561 more)		

Mean PUSH score at end of treatment – long-term care patients – stage II – AHCPR classification												
Yastrub 2004	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	3.24 (n=19)	1.61 (n=23)	p > 0.05	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME

a No report on sequence generation, allocation concealment and no blinding; no log-transformation of data
b Confidence interval crossed one MID point
c No standard deviation; small sample size

Table 32 – Foam dressing: Allevyn® versus Biatain®

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Allevyn	Biatain	Relative (95% CI)	Absolute		
Proportion of patients completely healed – general population – stage II and III – NPUAP classification												
Amione 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	11/14 (78.6%)	5/18 (27.8%)	RR 2.83 (1.28 to 6.25)	508 more per 1000 (from 78 more to 1000 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								27.8%		509 more per 1000 (from 78 more to 1000 more)		
Median percentage reduction in ulcer area – general population – stage II and III – NPUAP classification												
Amione 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	38.2 (range: -97.6-99.4) (n=14)	45.8 (range: -56.9-90.0) (n=18)	p > 0.05	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean pain score at dressing removal (1: none - 4 severe) – general population – stage II and III – NPUAP classification												
Amione 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	1.01 (range: 1.00-1.17) (n=14)	1.10 (range: -1.00-2.17) (n=18)	p > 0.05	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME

Mean comfort score at dressing removal (1: none - 4 severe) – general population – stage II and III – NPUAP classification												
Amione 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	1.84 (SD 0.26)	2.11 (SD 0.26)	-	MD 0.27 lower (0.45 to 0.09 lower)	⊕OOO VERY LOW	IMPORTANT OUTCOME
Proportion of patients with dressing related adverse events – general population – stage II and III – NPUAP classification												
Amione 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	1/14 (7.1%)	4/18 (22.2%)	RR 0.32 (0.04 to 2.57)	151 fewer per 1000 (from 213 fewer to 349 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								22.2%		151 fewer per 1000 (from 213 fewer to 349 more)		

a No report on sequence generation and no blinding and allocation according to baseline exudate level and treatment centre; no log-transformation of data
b No report on standard deviation; small sample size
c Confidence interval crossed one MID point
d Confidence interval crossed both MID points

Table 33 – Foam dressing: Mepilex® versus Tielle®

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mepilex	Tielle	Relative (95% CI)	Absolute		
Proportion of patients completely healed – elderly patients – stage II – NPUAP classification												
Meaume 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	8/18 (44.4%)	10/20 (50%)	RR 0.89 (0.45 to 1.75)	55 fewer per 1000 (from 275 fewer to 375 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								50%		55 fewer per 1000 (from 275 fewer to 375 more)		
Proportion of patients improved – elderly patients – stage II – NPUAP classification												
Meaume 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	15/18 (83.3%)	19/20 (95%)	RR 0.88 (0.7 to 1.1)	114 fewer per 1000 (from 285 fewer to 95 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								95%		114 fewer per 1000		

										(from 285 fewer to 95 more)		
Proportion of patients worsened – elderly patients – stage II – NPUAP classification												
Meaume 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	2/18 (11.1%)	1/20 (5%)	RR 2.22 (0.22 to 22.49)	61 more per 1000 (from 39 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								5%		61 more per 1000 (from 39 fewer to 1000 more)		
Proportion of patients with maceration – elderly patients – stage II – NPUAP classification												
Meaume 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	0/18 (0%)	3/20 (15%)	OR 0.13 (0.01 to 1.38)	128 fewer per 1000 (from 148 fewer to 46 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								15%		128 fewer per 1000 (from 148 fewer to 46 more)		
Proportion of patients reporting odour – elderly patients – stage II – NPUAP classification												
Meaume 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	0/18 (0%)	3/20 (15%)	OR 0.13 (0.01 to 1.38)	128 fewer per 1000 (from 148 fewer to 46 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								15%		128 fewer per 1000 (from 148 fewer to 46 more)		
Proportion of patients with adverse events[d] – elderly patients – stage II – NPUAP classification												
Meaume 2003	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	1/18 (5.6%)	3/20 (15%)	RR 0.37 (0.04 to 3.25)	95 fewer per 1000 (from 144 fewer to 338 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								15%		95 fewer per 1000 (from 144 fewer to 338 more)		

a No report on blinding
b Confidence interval crossed both MID points
c Confidence interval crossed one MID point
d Mepilex group: hyperganulation; Tielle group: hypergranulation, new ulcer, and redness and irritation

Table 34 – Hydrogel (aquagel) versus polyurethane foam (lyofoam) dressing

Quality assessment							No of ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrogel dressing	Foam dressing	Relative (95% CI)	Absolute		
Proportion of ulcers completely healed - palliative care patients – stage II and III – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	15/20 (75%)	15/18 (83.3%)	RR 0.9 (0.65 to 1.25)	83 fewer per 1000 (from 292 fewer to 208 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								83.3%		83 fewer per 1000 (from 292 fewer to 208 more)		
Proportion of ulcers completely healed - palliative care patients – stage II – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	6/6 (100%)	6/6 (100%)	RR 1 (0.75 to 1.34)	0 fewer per 1000 (from 250 fewer to 340 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								100%		0 fewer per 1000 (from 250 fewer to 340 more)		
Proportion of ulcers completely healed - palliative care patients – stage III – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	9/14 (64.3%)	9/12 (75%)	RR 0.86 (0.52 to 1.43)	105 fewer per 1000 (from 360 fewer to 322 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								75%		105 fewer per 1000 (from 360 fewer to 322 more)		
Proportion of ulcers improved - palliative care patients – stage II and III – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	19/20 (95%)	18/18 (100%)	RR 0.95 (0.83 to 1.1)	50 fewer per 1000 (from 170 fewer to 100 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								100%		50 fewer per 1000 (from 170 fewer to 100 more)		

Proportion of ulcers improved - palliative care patients – stage II – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	6/6 (100%)	6/6 (100%)	RR 1 (0.75 to 1.34)	0 fewer per 1000 (from 250 fewer to 340 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								100%		0 fewer per 1000 (from 250 fewer to 340 more)		
Proportion of ulcers improved - palliative care patients – stage III – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	13/14 (92.9%)	12/12 (100%)	RR 0.94 (0.77 to 1.14)	60 fewer per 1000 (from 230 fewer to 140 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								100%		60 fewer per 1000 (from 230 fewer to 140 more)		
Mean healing rate healed ulcers (cm²/day) - palliative care patients – stage II – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	0.67 (SD 0.37)	1.23 (SD 1.33)	-	MD 0.56 lower (1.66 lower to 0.54 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean healing rate healed ulcers (cm²/day) - palliative care patients – stage III – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	0.31 (SD 0.21)	0.44 (SD 0.27)	-	MD 0.13 lower (0.32 lower to 0.06 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean healing rate improved ulcers (cm²/day) - palliative care patients – stage III – Torrance classification												
Sopata 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	0.27 (SD 0.11)	0.7 (SD 0.63)	-	MD 0.43 lower (0.79 to 0.07 lower)	⊕OOO VERY LOW	CRITICAL OUTCOME

a No report on allocation concealment and no blinding; no log-transformation of data
b Confidence interval crossed one MID point
c Confidence interval crossed both MID points

Table 35 – Hydrogel versus dextranomer

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrogel dressing	Dextranomer	Relative (95% CI)	Absolute		
Median percentage reduction in ulcer area – general population – grade I, II, III and IV – AHCPR and International Association of Exteromstomal Therapy classification												
Colin 1996	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	35 (n=67)	7 (n=68)	p=0.03	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with pain at dressing application – general population - grade I, II, III and IV – AHCPR and International Association of Exteromstomal Therapy classification												
Colin 1996	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/67 (0%)	1/68 (1.5%)	OR 0.14 (0 to 6.92)	13 fewer per 1000 (from 15 fewer to 79 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								1.5%		13 fewer per 1000 (from 15 fewer to 80 more)		

a No report on sequence generation, allocation concealment and no blinding
b No standard deviation
c Confidence interval crossed both MID points

Table 36 – Hydrogel, foam dressing or transparant film versus different types of dressings

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrogel dressings	Different types of dressings	Relative (95% CI)	Absolute		
Proportion of patients completely healed – community patients – stage II, III and IV – Stirling classification												
Small 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	15/23 (65.2%)	9/18 (50%)	RR 1.3 (0.75 to 2.26)	150 more per 1000 (from 125 fewer to 630 more)	⊕OOO VERY	CRITICAL OUTCOME

								50%		150 more per 1000 (from 125 fewer to 630 more)	LOW	
Percentage healed per week – community patients – stage II, III and IV – Stirling classification												
Small 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	n=28	n=30	P=0.15 (log-rank test)		⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients reporting the application of the dressing as comfortable – community patients – stage II, III and IV – Stirling classification												
Small 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	14/14 (100%)	6/7 (85.7%)	RR 1.83 (0.88 to 3.79)	711 more per 1000 (from 103 fewer to 1000 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								85.7%		711 more per 1000 (from 103 fewer to 1000 more)		
Proportion of patient reporting discomfort at dressing removal – community patients – stage II, III and IV – Stirling classification												
Small 2002	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Very serious[c]	none	0/14 (0%)	1/7 (14.3%)	OR 0.05 (0.00 to 3.18)	135 fewer per 1000 (143 fewer to 204 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								14.3%		135 fewer per 1000 (143 fewer to 204 more)		
Proportion of patients with adverse events – community patients – stage II, III and IV – Stirling classification												
Small 2002	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/28 (0%)	0/30 (0%)	not pooled	RD 0 more (from 6 fewer to 6 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 6 fewer to 6 more)		

a Allocation according to PU stage and no report on blinding
b Confidence interval crossed one MID point
c Confidence interval crossed both MID points
d Drop out is more than 10% higher than event rate

Table 37 – Hydrogel: Sterigel® versus Intrasite®

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Sterigel	Intrasite	Relative (95% CI)	Absolute		
Mean percentage reduction in ulcer area – general population – necrotic Pus – classification not reported												
Bale 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[d]	none	-82.3	7.45	not pooled	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patient with intermittent ulcer pain at end of study[e] – general population – necrotic Pus – classification not reported												
Bale 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	13/24 (54.2%)	16/23 (69.6%)	RR 0.78 (0.49 to 1.23)	153 fewer per 1000 (from 355 fewer to 160 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								69.6%		153 fewer per 1000 (from 355 fewer to 160 more)		
Proportion of patient with continuous ulcer pain at end of study[f] – general population – necrotic Pus – classification not reported												
Bale 1998	randomised trials	very serious[a,g]	no serious inconsistency	no serious indirectness	very serious[c]	none	1/24 (4.2%)	2/23 (8.7%)	RR 0.48 (0.05 to 4.93)	45 fewer per 1000 (from 83 fewer to 342 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								8.7%		45 fewer per 1000 (from 83 fewer to 342 more)		
Proportion of patient with slight pain at dressing removal – general population – necrotic Pus – classification not reported												
Bale 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	5/22 (22.7%)	6/20 (30%)	RR 0.76 (0.27 to 2.1)	72 fewer per 1000 (from 219 fewer to 330 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								30%		72 fewer per 1000 (from 219 fewer to 330 more)		

Proportion of patient with severe pain at dressing removal – general population – necrotic Pus – classification not reported												
Bale 1998	randomised trials	very serious[a,g]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/22 (0%)	1/20 (5%)	OR 0.12 (0 to 6.2)	44 fewer per 1000 (from 50 fewer to 196 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								5%		44 fewer per 1000 (from 50 fewer to 196 more)		
Proportion of patient with discomfort – general population – necrotic Pus – classification not reported												
Bale 1998	randomised trials	very serious[a,g]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/22 (0%)	1/20 (5%)	OR 0.12 (0 to 6.2)	44 fewer per 1000 (from 50 fewer to 196 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								5%		44 fewer per 1000 (from 50 fewer to 196 more)		
Proportion of patient with maceration – general population – necrotic Pus – classification not reported												
Bale 1998	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	8/21 (38.1%)	9/17 (52.9%)	RR 0.72 (0.36 to 1.46)	148 fewer per 1000 (from 339 fewer to 244 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								52.9%		148 fewer per 1000 (from 339 fewer to 243 more)		

a No report on allocation concealment and only blinding of outcome assessor; no log-transformation of data
b Confidence interval crossed one MID point
c Confidence interval crossed both MID points
d Reduction was calculated based on reported baseline value and value at 14 days. No p-value or SD could be derived.
e At start of the study 17/24 and 18/23 reported intermittent pain.
f At start of the study 3/24 and 2/23 reported continuous pain
g Drop out is more than 10% higher than event rate.

Table 38 – Protease modulating matrix versus impregnated gauze dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Collagen dressing	Impregnated gauze dressing	Relative (95% CI)	Absolute		
Proportion of patients completely healed – Inpatients – stage II, III and IV – NPUAP classification												
Nisi 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	36/40 (90%)	28/40 (70%)	RR 1.29 (1.02 to 1.61)	203 more per 1000 (from 14 more to 427 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								70%		203 more per 1000 (from 14 more to 427 more)		
Time to complete healing (days) – Inpatients – stage II, III and IV – NPUAP classification												
Nisi 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	6-15 (n=40)	14-52 (n=40)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with adverse events – Inpatients – stage II, III and IV – NPUAP classification												
Nisi 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/40 (0%)	0/40 (0%)	not pooled	RD 0 more (from 5 fewer to 5 more)	⊕⊕OO LOW	IMPORTANT OUTCOME

a No report on sequence generation, allocation concealment and no blinding
b Confidence interval crossed one MID point
c Only range values were reported

Table 39 – Polyurethane film versus different types of dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Polyurethane film	Different types of dressings	Relative (95% CI)	Absolute		
Mean time to healing (days)– inpatients – stage II and III – NPUAP classification												
Bito 2012	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	59.8 (SD 29.4)	57.5 (SD 33.5)	-	MD 2.3 higher (13.31 lower to 17.91 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean time to healing (days)– inpatients – stage II – NPUAP classification												
Bito 2012	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	18.8 (SD 5.3)	16 (SD 9.4)	-	MD 2.8 higher (5.53 lower to 11.13 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean time to healing (days)– inpatients –stage III – NPUAP classification												
Bito 2012	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	63.2 (SD 27.8)	71.8 (SD 23)	-	MD 8.6 lower (22.48 lower to 5.28 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean difference in PUSH score – inpatients – stage II and III – NPUAP classification												
Bito 2012	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0.9 (SD 1.3)	1.1 (SD 2.1)	-	MD 0.2 lower (1.08 lower to 0.68 higher)	⊕⊕OO LOW	CRITICAL OUTCOME
Proportion of patient with systemic worsening – inpatients – stage II and III – NPUAP classification												
Bito 2012	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	4/35 (11.4%)	3/29 (10.3%)	RR 1.1 (0.27 to 4.54)	10 more per 1000 (from 76 fewer to 366 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								10.3%		10 more per 1000 (from 75 fewer to 365 more)		

Proportion of patients with localized adverse events – inpatients – stage II and III – NPUAP classification												
Bito 2012	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	6/35 (17.1%)	7/29 (24.1%)	RR 0.71 (0.27 to 1.88)	70 fewer per 1000 (from 176 fewer to 212 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								24.1%		70 fewer per 1000 (from 176 fewer to 212 more)		

a No report on sequence generation and only blinding of outcome assessor; no log-transformation of data
b Confidence interval crossed one MID point
c Confidence interval crossed both MID points
d Drop out is more than 10% higher than event rate

Table 40 – Alginate dressing versus silver alginate dressing

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alginate dressing	Silver alginate dressing	Relative (95% CI)	Absolute		
Proportion of patients worsened – elderly patients – stage III and IV – NPUA classification												
Meaume 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	4/15 (26.7%)	2/13 (15.4%)	RR 1.73 (0.38 to 7.98)	112 more per 1000 (from 95 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								15.4%		112 more per 1000 (from 95 fewer to 1000 more)		
Mean percentage reduction in ulcer area – elderly patients – stage III and IV – NPUA classification												
Meaume 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	13.9 (SD 50.3)	31.6 (SD 38.1)	-	MD 17.7 lower (50.52 lower to 15.12 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Absolute cm² decrease in ulcer area – elderly patients – stage III and IV – NPUA classification												
Meaume 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	0.8 (SD 10)	7.2 (SD 9)	-	MD 6.4 lower (13.44 lower to 0.64 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

Mean rate of healing (cm²/day) – elderly patients – stage III and IV – NPUA classification												
Meaume 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	0.03 (SD 0.36)	0.26 (SD 0.32)	-	MD 0.23 lower (0.48 lower to 0.02 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with infection – elderly patients – stage III and IV – NPUA classification												
Meaume 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	2/15 (13.3%)	1/13 (7.7%)	RR 1.73 (0.18 to 16.99)	56 more per 1000 (from 63 fewer to 1000 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								7.7%		56 more per 1000 (from 63 fewer to 1000 more)		
Percentage reduction in infection score – general population – stage and classification system not reported												
Trial 2010	randomised trials	very serious[d]	no serious inconsistency	no serious indirectness	very serious[e]	none	50 (n=13)	52 (n=11)	-	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME
Mean mASEPSIS index at end of treatment – elderly patients – stage III and IV – NPUA classification												
Meaume 2005	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[c]	none	115.3 (SD 80.2)	81.8 (SD 45.1)	-	MD 33.5 higher (13.92 lower to 80.92 higher)	⊕OOO VERY LOW	IMPORTANT OUTCOME
Proportion of patients with poor acceptability and/or tolerability – elderly patients – stage III and IV – NPUA classification												
Meaume 2005	randomised trials	very serious[a,f]	no serious inconsistency	no serious indirectness	very serious[b]	none	0/15 (0%)	1/13 (7.7%)	OR 0.12 (0 to 5.91)	67 fewer per 1000 (from 77 fewer to 253 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								7.7%		67 fewer per 1000 (from 77 fewer to 253 more)		

a Meaume (2005): allocation according to wound type and no report on blinding
b Confidence interval crossed both MID points
c Confidence interval crossed one MID point
d Trial (2010): no report on sequence generation and blinding
e No standard deviation; small sample size
f Drop out is more than 10% higher than event rate

Table 41 – Alginate dressing versus dextranomer

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Alginate dressing	Detraxomer	Relative (95% CI)	Absolute		
Proportion of patients with > 75% reduction in ulcer area – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	Serious[b]	none	15/47 (31.9%)	6/45 (13.3%)	RR 2.39 (1.02 to 5.62)	185 more per 1000 (from 3 more to 616 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								13.3%		185 more per 1000 (from 3 more to 614 more)		
Proportion of patients with > 40% reduction in ulcer area – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	35/47 (74.5%)	19/45 (42.2%)	RR 1.76 (1.21 to 2.58)	321 more per 1000 (from 89 more to 667 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								42.2%		321 more per 1000 (from 89 more to 667 more)		
Proportion of patients worsened or stagnated – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/47 (4.3%)	15/45 (33.3%)	RR 0.13 (0.03 to 0.53)	290 fewer per 1000 (from 157 fewer to 323 fewer)	⊕⊕OO LOW	CRITICAL OUTCOME
								33.3%		290 fewer per 1000 (from 157 fewer to 323 fewer)		
Mean rate of healing in patients improved > 40% (cm²/week) – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	3.55 (SD 2.18)	2.15 (SD 3.6)	-	MD 1.4 higher (0.18 to 2.62 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

Mean rate of healing (cm²/week) – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	2.39 (SD 3.54)	0.27 (SD 3.21)	-	MD 2.12 higher (0.74 to 3.5 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with infection – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	2/47 (4.3%)	2/45 (4.4%)	RR 0.96 (0.14 to 6.51)	2 fewer per 1000 (from 38 fewer to 245 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								4.4%		2 fewer per 1000 (from 38 fewer to 242 more)		
Proportion of patients with hypergranulation – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	1/47 (2.1%)	3/45 (6.7%)	RR 0.32 (0.03 to 2.96)	45 fewer per 1000 (from 65 fewer to 131 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								6.7%		46 fewer per 1000 (from 65 fewer to 131 more)		
Proportion of patients with skin irritation – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	1/47 (2.1%)	1/45 (2.2%)	RR 0.96 (0.06 to 14.85)	1 fewer per 1000 (from 21 fewer to 308 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								2.2%		1 fewer per 1000 (from 21 fewer to 305 more)		
Proportion of patients with bleeding – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	Serious[b]	none	0/47 (0%)	3/45 (6.7%)	OR 0.12 (0.01 to 1.22)	58 fewer per 1000 (from 66 fewer to 13 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								6.7%		58 fewer per 1000 (from 66 fewer to 14 more)		

Proportion of patients with pain – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/47 (0%)	5/45 (11.1%)	OR 0.12 (0.02 to 0.71)	96 fewer per 1000 (from 30 fewer to 109 fewer)	⊕⊕OO LOW	IMPORTANT OUTCOME
								11.1%		96 fewer per 1000 (from 30 fewer to 109 fewer)		
Proportion of patients with pruritus – general population – stage III and IV – Yarkony classification												
Sayag 1996	randomised trials	very serious[a,d]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/47 (0%)	1/45 (2.2%)	OR 0.13 (0 to 6.53)	19 fewer per 1000 (from 22 fewer to 107 more)	⊕OOO VERY LOW	IMPORTANT OUTCOME
								2.2%		19 fewer per 1000 (from 22 fewer to 106 more)		

a Sayag (1996): no report sequence generation and blinding; no log-transformation of data
b Confidence interval crossed one MID point
c Confidence interval crossed both MID points
d Drop out is more than 10% higher than event rate

Table 42 – Silver dressing versus different types of dressings

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Silver dressing	Different types of dressings	Relative (95% CI)	Absolute		
Mean percentage reduction in ulcer area – general population – stage II and III – NPUAP classification												
Münter 2006	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	58.5 (n=24)	33.3 (n=24)	-	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME

a No report on blinding
b No standard deviation; unknown if sample size was sufficient as sample size calculation was based on the inclusion of different types of wounds.

Table 43 – Silver dressing versus silver cream

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Silver dressing	Silver cream	Relative (95% CI)	Absolute		
Mean percentage reduction in ulcer area – in- and outpatients – stage IV – NPUAP classification												
Chuansuwanich 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	36.95 (SD 56.13)	25.06 (SD 56.13)	-	MD 11.89 higher (22.9 lower to 46.68 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Percentage reduction in PUSH score – in- and outpatients – stage IV – NPUAP classification												
Chuansuwanich 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	28.15 (n=20)	34.51 (n=20)	p=0.473	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Proportion of patients with adverse events – in- and outpatients – stage IV – NPUAP classification												
Chuansuwanich 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/20 (0%)	0/20 (0%)	not pooled	RD 0 more (from 9 fewer to 9 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 6 fewer to 6 more)		

a No report on allocation concealment and no blinding
b Confidence interval crossed both MID points
c No standard deviation; small sample size

Table 44 – Sugar versus dextranomer

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Sugar	Dextranomer	Relative (95% CI)	Absolute		
Proportion of patients completely healed – long-term care patients – stage and classification system not reported												
Parish 1979	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	0/5 (0%)	4/7 (57.1%)	OR 0.09 (0.01 to 0.97)	464 fewer per 1000 (from 7 fewer to 558 fewer)	⊕OOO VERY LOW	CRITICAL OUTCOME
								57.1%		464 fewer per 1000 (from 7 fewer to 558 fewer)		
Proportion of patients improved – long-term care patients – stage and classification system not reported												
Parish 1979	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/5 (0%)	7/7 (100%)	OR 0.02 (0 to 0.21)	RD 2 more (from 0 more to 210 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								100%		RD 2 more (from 0 more to 210 more)		
Proportion of ulcers completely healed – long-term care patients – stage and classification system not reported												
Parish 1979	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	0/9 (0%)	6/14 (42.9%)	OR 0.12 (0.02 to 0.77)	346 fewer per 1000 (from 62 fewer to 414 fewer)	⊕OOO VERY LOW	CRITICAL OUTCOME
								42.9%		346 fewer per 1000 (from 63 fewer to 414 fewer)		
Proportion of ulcers improved — long-term care patients – stage and classification system not reported												
Parish 1979	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/9 (0%)	12/14 (85.7%)	OR 0.04 (0.01 to 0.19)	664 fewer per 1000 (from 324 fewer to 801 fewer)	⊕⊕OO LOW	CRITICAL OUTCOME
								85.7%		664 fewer per 1000 (from 325 fewer to 800 fewer)		

a No sequence generation and allocation concealment and blinding failed; b Confidence interval crossed one MID point

Table 45 – Sugar versus different types of topical agents

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Sugar	Different types of topical agents	Relative (95% CI)	Absolute		
Proportion of patients completely healed – geriatric patients – stage and classification system not reported												
Rhodes 1979	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	16/17 (94.1%)	9/21 (42.9%)	RR 2.2 (1.32 to 3.65)	514 more per 1000 (from 137 more to 1000 more)	⊕⊕OO LOW	CRITICAL OUTCOME
								42.9%		515 more per 1000 (from 137 more to 1000 more)		
Mean healing index – geriatric patients – stage and classification system not reported												
Rhodes 1979	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	16.8 (SD 39.65)	-3.8 (SD 39.65)	-	MD 20.6 higher (4.75 lower to 45.95 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

a No report on allocation concealment and no blinding
b Confidence interval crossed one MID point

Table 46 – Honey versus ethoxydiaminoacridine and nitrofurazone

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Honey	Ethoxydiamino-acridine and nitrofurazone	Relative (95% CI)	Absolute		
Proportion of ulcers completely healed – inpatients – stage II and III – AHCPR classification												
Günes 2007	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	5/25 (33.3%)	0/25 (0%)	OR 8.83 (1.42 to 54.99)	-	⊕⊕OO LOW	CRITICAL OUTCOME
								0%		-		

Mean percentage reduction in ulcer area – inpatients – stage II and III – AHCPR classification												
Günes 2007	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	56 (SD 28.92)	13 (SD 28.92)	-	MD 43 higher (24.49 to 61.51 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean percentage decrease un PUSH score – inpatients – stage II and III – AHCPR classification												
Günes 2007	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	12.62 (SD 2.15)	6.55 (SD 2.14)	-	MD 6.07 higher (4.40 to 7.74 higher)	⊕⊕OO LOW	CRITICAL OUTCOME
Proportion of patients with adverse events – inpatients – stage II and III – AHCPR classification												
Günes 2007	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/15 (0%)	0/11 (0%)	not pooled	RD 0 more (from 140 fewer to 140 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								0%		RD 0 more (from 140 fewer to 140 more)		

a No report on sequence generation, allocation concealment and no blinding; no log-transformation of data; b b SD calculated on a p-value < 0.001 (less precise)

Table 47 – Platelet gel versus other treatment

Quality assessment							No of ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Platelet gel	Other treatment	Relative (95% CI)	Absolute		
Proportion of ulcers completely healed – patients with a spinal cord injury – stage III and IV – NPUAP classification												
Scevola 2010	randomised trials	very serious[a,c]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/8 (0%)	0/8 (0%)	not pooled	RD 0 more (from 210 fewer to 210 more)	⊕⊕OO LOW	CRITICAL OUTCOME

								0%		RD 0 more (from 210 fewer to 210 more)		
Proportion of ulcers improved – patients with a spinal cord injury – stage III and IV – NPUAP classification												
Scevola 2010	randomised trials	very serious[a,c]	no serious inconsistency	no serious indirectness	Serious[b]	none	8/8 (100%)	7/8 (87.5%)	RR 1.13 (0.81 to 1.58)	114 more per 1000 (from 166 fewer to 508 more)	⊕OOO VERY LOW	CRITICAL OUTCOME
								87.5%		114 more per 1000 (from 166 fewer to 508 more)		
Mean percentage reduction in ulcer volume – patients with a spinal cord injury – stage III and IV – NPUAP classification												
Scevola 2010	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	55 (SD 22.9)	17.2 (SD 98.1)	-	MD 37.8 higher (32.01 lower to 107.61 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

a No report on sequence generation, allocation concealment and no blinding
b Confidence interval crossed one MID point
c Drop out is more than 10% higher than event rate

Table 48 – Hyaluronic acid versus sodium hyaluronic

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hyaluronic acid	Sodium hyaluronate	Relative (95% CI)	Absolute		
Mean percentage reduction in ulcer area– inpatients – stage I – NPUAP classification												
Felzani 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	90 (SD 21.29)	70 (SD 21.29)	-	MD 20 higher (1.34 to 38.66 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME
Mean percentage reduction in ulcer area– inpatients – stage II – NPUAP classification												
Felzani 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	70 (SD 26.28)	40 (SD 26.28)	-	MD 30 higher (6.96 to 53.04 higher)	⊕OOO VERY LOW	CRITICAL OUTCOME

Mean percentage reduction in ulcer area– inpatients – stage III – NPUAP classification											
Felzani 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[d]	none	(n=7)	(n=7)	p<0.01	not pooled	⊕OOO VERY LOW	CRITICAL OUTCOME
Time to 50% reduction ulcer diameter (days)– inpatients – stage I – NPUAP classification											
Felzani 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	9 (SD 6.39)	15 (SD 6.39)	-	MD 6 lower (11.6 to 0.4 lower)	⊕OOO VERY LOW	CRITICAL OUTCOME
Time to 50% reduction ulcer diameter (days)– inpatients – stage II – NPUAP classification											
Felzani 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	9.5 (SD 5.85)	15 (SD 5.85)	-	MD 5.5 lower (10.63 to 0.37 lower)	⊕OOO VERY LOW	CRITICAL OUTCOME
Time to 50% reduction ulcer diameter (days)– inpatients – stage III – NPUAP classification											
Felzani 2011	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[b]	none	12.9 (SD 6.71)	19.2 (SD 6.71)	-	MD 6.3 lower (13.33 lower to 0.73 higher)		CRITICAL OUTCOME

a No report on sequence generation and allocation concealment and blinding of nurse, outcome assessor and statistician, blinding of patient not reported; no log-transformation of data
b Confidence interval crossed one MID point; SD calculated on a p-value < 0.05 (less precise)
c Confidence interval crossed one MID point; SD calculated on a p-value < 0.02 (less precise)
d Only p-value were reported

Table 49 – Polyhexadine dressing versus polyhexadine swab

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Polyhexadine dressing	p-Polyhexadine swab	Relative (95% CI)	Absolute		
Proportion of patients MRSA eradiacted – in- and outpatients with MRSA – stage II, III and IV – NPUAP classification												
Wild 2012	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	15/15 (100%)	10/15 (66.7%)	RR 1.48 (1.02 to 2.13)	320 more per 1000 (from 13 more to 753 more)	⊕⊕OO LOW	IMPORTANT OUTCOME
								66.7%		320 more per 1000 (from 13 more to 754 more)		
Percentage reduction in pain score – in- and outpatients with MRSA – stage II, III and IV – NPUAP classification												
Wild 2012	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	82.4 (n=15)	52.6 (n=15)	-	not pooled	⊕OOO VERY LOW	IMPORTANT OUTCOME

a Only blinding of outcome assessor ;
b Confidence interval crossed one MID point
c No standard deviation; small sample size

Table 50 – Hydrofibre® dressing versus resin salve

Quality assessment							No of patients/ulcers		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hydrofibre	Resin salve	Relative (95% CI)	Absolute		
Proportion of patients completely healed – hospitalised patients – stage II to IV – EPUAP classification												
Sipponen 2008	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	4/9 (44.4%)	12/13 (92.3%)	RR 0.48 (0.23 to 1.02)	480 fewer per 1000 (from 711 fewer to 18 more)	⊕⊕OO LOW	Critical outcome
								92.3%		480 fewer per 1000 (from 711 fewer to 18 more)		
Proportion of ulcers completely healed – hospitalised patients – stage II to IV – EPUAP classification												
Sipponen 2008	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	4/11 (36.4%)	17/18 (94.4%)	RR 0.39 (0.17 to 0.85)	576 fewer per 1000 (from 142 fewer to 784 fewer)	⊕⊕OO LOW	Critical outcome
								94.4%		576 fewer per 1000 (from 142 fewer to 784 fewer)		
Proportion of ulcers improved – hospitalised patients – stage II to IV – EPUAP classification												
Sipponen 2008	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	10/11 (90.9%)	18/18 (100%)	RR 0.9 (0.72 to 1.13)	100 fewer per 1000 (from 280 fewer to 130 more)	⊕⊕OO LOW	Critical outcome
								100%		100 fewer per 1000 (from 280 fewer to 130 more)		
Proportion of ulcers worsened – hospitalised patients – stage II to IV – EPUAP classification												
Sipponen 2008	randomised trials	Very serious[a,f]	no serious inconsistency	no serious indirectness	very serious[c]	none	1/11 (9.1%)	0/18 (0%)	OR 13.96 (0.25 to 792.93)	-	⊕OOO VERY LOW	Critical outcome
								0%		-		
Mean percentage reduction in ulcer width – hospitalised patients – stage II to IV – EPUAP classification												
Sipponen 2008	randomised trials	Very serious[a,g]	no serious inconsistency	no serious indirectness	very serious[d]	none	57.14 (n=11)	93.75 (n=18)	-	not pooled	⊕OOO VERY LOW	Critical outcome
Mean percentage reduction in ulcer depth – hospitalised patients – stage II to IV – EPUAP classification												
Sipponen 2008	randomised trials	Very serious[a,g]	no serious inconsistency	no serious indirectness	very serious[d]	none	-1.89 (n=11)	88.46 (n=18)	-	not pooled	⊕OOO VERY LOW	Critical outcome

Speed of healing (days) (log-rank-test) – hospitalised patients – stage II to IV – EPUAP classification												
Sipponen 2008	randomised trials	Serious[a]	no serious inconsistency	no serious indirectness	very serious[e]	none	(n=11)	N=18)	P=0.013 (favour resin salve)	not pooled	⊕OOO VERY LOW	Critical outcome
Proportion of patients with allergic skin reaction – hospitalised patients – stage II to IV – EPUAP classification												
Sipponen 2008	randomised trials	Very serious[a,f]	no serious inconsistency	no serious indirectness	very serious[c]	none	0/16 (0%)	1/21 (4.8%)	OR 0.17 (0 to 8.97)	39 fewer per 1000 (from 48 fewer to 262 more)	⊕OOO VERY LOW	Important outcome
								4.8%		40 fewer per 1000 (from 48 fewer to 263 more)		

a No blinding; no intention-to-treat analysis; b Confidence interval crossed one MID point; c Confidence interval crossed both MID points; d No standard deviation; small sample size
e No values, only p-value; small sample size; f Drop out is more than 10% higher than event rate; g No log-transformation

Table 51 – Dextranomer versus chlorinated lime solution

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Dextranomer**	**Chlorinated lime solution**	**Relative (95% CI)**	**Absolute**		
Time to healing (defined as granulating and < 25% of original ulcer area) (days) – elderly patients – stage not reported – classification system not reported												
Nasar 1982	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	Serious[b]	none	39.3 (SD 17.67)	61.8 (SD 13.86)	-	MD 22.5 lower (41.14 to 3.86 lower)	⊕OOO VERY LOW	Critical outcome
Proportion of patients with pain												
Nasar 1982	randomised trials	very serious[a]	no serious inconsistency	no serious indirectness	very serious[c]	none	1/?	3/?	not pooled	not pooled	⊕OOO VERY LOW	Important outcome
										not pooled		

a No report on allocation concealment, sequence generation, and no blinding; no ITT analysis
b Confidence interval crossed one MID point
c Unclear how many patients were included in each group

5.3.4. *Forest plots*

Figure 2 – Hydrocolloid dressing versus gauze dressing – proportion of patients completely healed

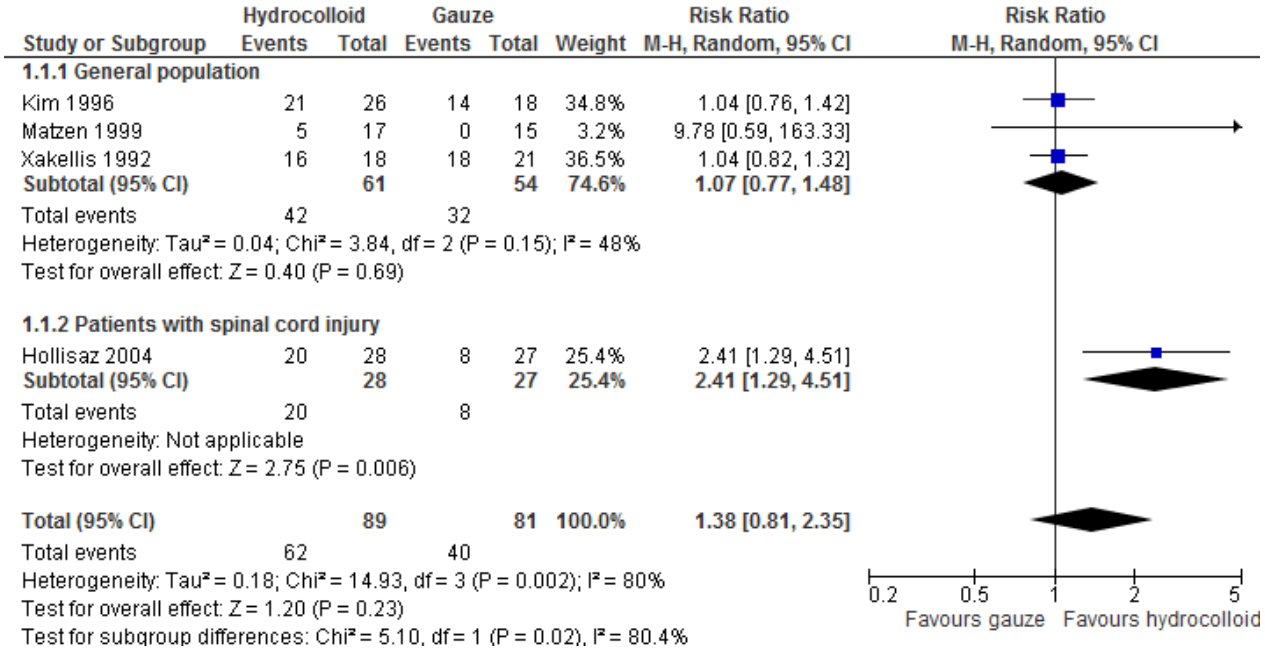
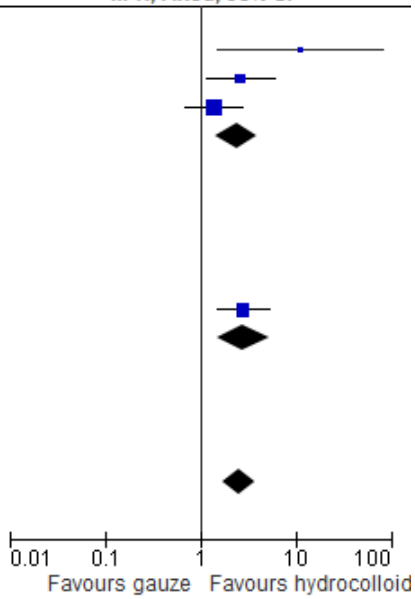
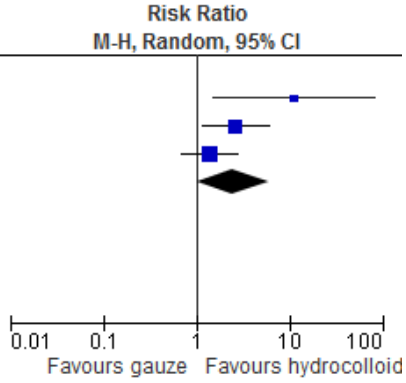


Figure 3 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers completely healed (all stages – all sites)

Study or Subgroup	Hydrocolloid Events	Total	Gauze Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.2.1 General population						
Colwell 1993	11	48	1	49	4.2%	11.23 [1.51, 83.64]
Kordestani 2008	14	16	4	12	19.6%	2.63 [1.15, 5.97]
Neill 1989	13	42	10	45	41.4%	1.39 [0.69, 2.83]
Subtotal (95% CI)		**106**		**106**	**65.2%**	**2.40 [1.44, 4.02]**
Total events	38		15			
Heterogeneity: Chi² = 4.58, df = 2 (P = 0.10); I² = 56%						
Test for overall effect: Z = 3.35 (P = 0.0008)						
1.2.2 Patients with a spinal cord injury						
Hollisaz 2004	23	31	8	30	34.8%	2.78 [1.48, 5.22]
Subtotal (95% CI)		**31**		**30**	**34.8%**	**2.78 [1.48, 5.22]**
Total events	23		8			
Heterogeneity: Not applicable						
Test for overall effect: Z = 3.19 (P = 0.001)						
Total (95% CI)		**137**		**136**	**100.0%**	**2.53 [1.70, 3.78]**
Total events	61		23			
Heterogeneity: Chi² = 4.94, df = 3 (P = 0.18); I² = 39%						
Test for overall effect: Z = 4.58 (P < 0.00001)						
Test for subgroup differences: Chi² = 0.13, df = 1 (P = 0.72), I² = 0%						



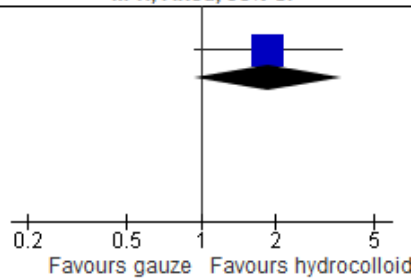
Study or Subgroup	Hydrocolloid Events	Total	Gauze Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.3.1 General population						
Colwell 1993	11	48	1	49	14.8%	11.23 [1.51, 83.64]
Kordestani 2008	14	16	4	12	40.6%	2.63 [1.15, 5.97]
Neill 1989	13	42	10	45	44.6%	1.39 [0.69, 2.83]
Subtotal (95% CI)		**106**		**106**	**100.0%**	**2.46 [1.01, 5.96]**
Total events	38		15			
Heterogeneity: Tau² = 0.33; Chi² = 4.58, df = 2 (P = 0.10); I² = 56%						
Test for overall effect: Z = 1.99 (P = 0.05)						



Test for subgroup differences: Not applicable

Figure 4 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers completely healed (stage I – all sites)

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Gauze Events	Gauze Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.3.1 Patients with a spinal cord injury						
Hollisaz 2004	11	13	5	11	100.0%	1.86 [0.94, 3.70]
Subtotal (95% CI)		**13**		**11**	**100.0%**	**1.86 [0.94, 3.70]**
Total events	11		5			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.77 (P = 0.08)						



Test for subgroup differences: Not applicable

Figure 5 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers completely healed (stage II – all sites)

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Gauze Events	Gauze Total	Weight	Risk Ratio M-H, Random, 95% CI
1.5.1 Patients with a spinal cord injury						
Hollisaz 2004	12	18	3	19	40.2%	4.22 [1.42, 12.54]
Subtotal (95% CI)		**18**		**19**	**40.2%**	**4.22 [1.42, 12.54]**
Total events	12		3			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.59 (P = 0.010)						
1.5.2 General population						
Neill 1989	11	25	9	34	59.8%	1.66 [0.81, 3.39]
Subtotal (95% CI)		**25**		**34**	**59.8%**	**1.66 [0.81, 3.39]**
Total events	11		9			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.40 (P = 0.16)						
Total (95% CI)		**43**		**53**	**100.0%**	**2.42 [0.97, 6.00]**
Total events	23		12			
Heterogeneity: Tau² = 0.23; Chi² = 2.03, df = 1 (P = 0.15); I² = 51%						
Test for overall effect: Z = 1.90 (P = 0.06)						
Test for subgroup differences: Chi² = 1.97, df = 1 (P = 0.16), I² = 49.2%						

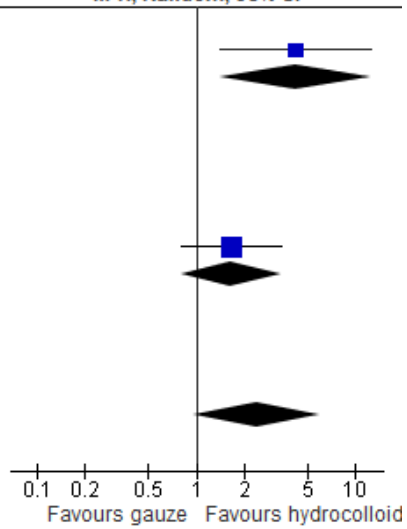
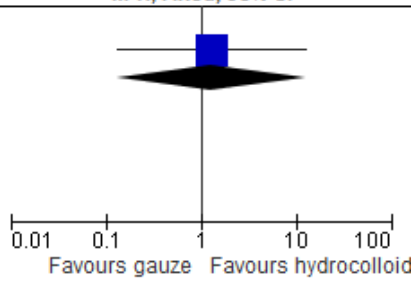


Figure 6 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers completely healed (stage III – all sites)

Study or Subgroup	Hydrocolloid Events	Total	Gauze Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.5.1 Gauze						
Neill 1989	2	17	1	11	100.0%	1.29 [0.13, 12.62]
Subtotal (95% CI)		**17**		**11**	**100.0%**	**1.29 [0.13, 12.62]**
Total events	2		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.22 (P = 0.82)

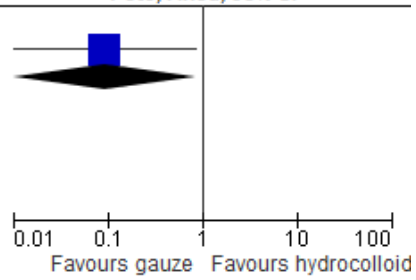


Test for subgroup differences: Not applicable

Figure 7 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers completely healed (all stages - sacral)

Study or Subgroup	Hydrocolloid Events	Total	Gauze Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.6.1 Gauze						
Hollisaz 2004	0	7	4	8	100.0%	0.09 [0.01, 0.84]
Subtotal (95% CI)		**7**		**8**	**100.0%**	**0.09 [0.01, 0.84]**
Total events	0		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.11 (P = 0.03)



Test for subgroup differences: Not applicable

Figure 8 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers improved

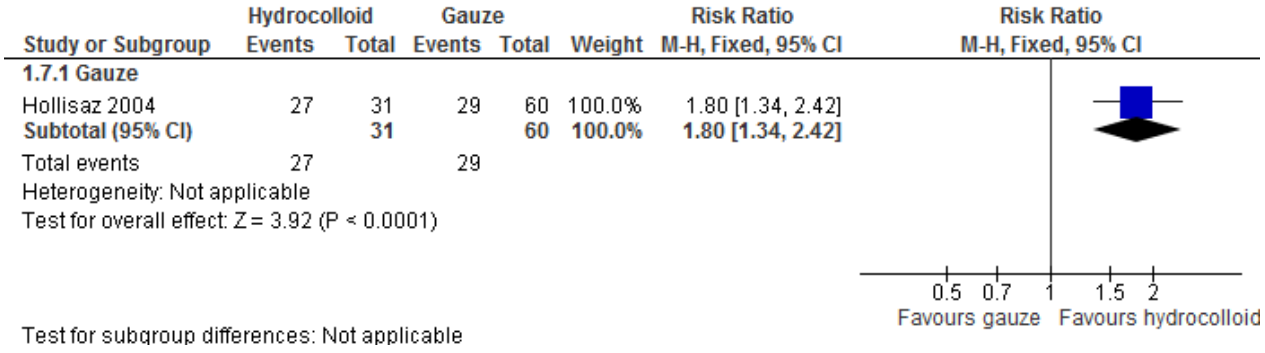


Figure 9 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers worsened (all stages)

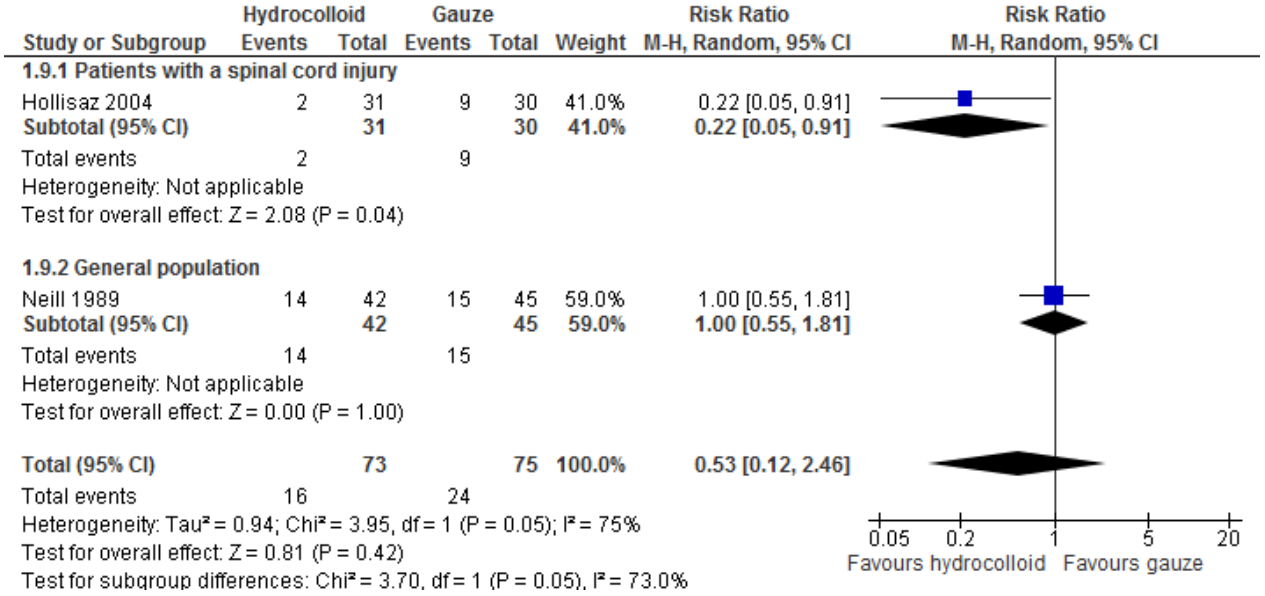
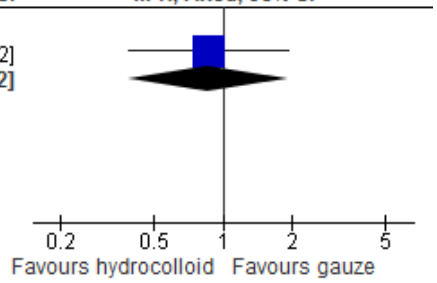


Figure 10 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers worsened (stage II)

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Gauze Events	Gauze Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.9.1 Gauze						
Neill 1989	7	25	11	34	100.0%	0.87 [0.39, 1.92]
Subtotal (95% CI)		**25**		**34**	**100.0%**	**0.87 [0.39, 1.92]**
Total events	7		11			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.36 (P = 0.72)



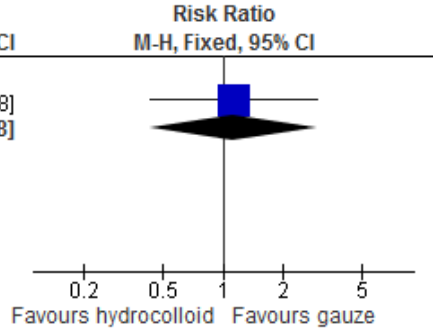
Test for subgroup differences: Not applicable

Figure 11 – Hydrocolloid dressing versus gauze dressing – proportion of ulcers worsened (stage III)

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Gauze Events	Gauze Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.10.1 Gauze						
Neill 1989	7	17	4	11	100.0%	1.13 [0.43, 2.98]
Subtotal (95% CI)		**17**		**11**	**100.0%**	**1.13 [0.43, 2.98]**
Total events	7		4			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.25 (P = 0.80)

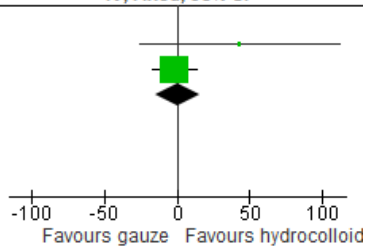


Test for subgroup differences: Not applicable

Figure 12 – Hydrocolloid dressing versus gauze dressing – mean percentage reduction in ulcer area

Study or Subgroup	Hydrocolloid Mean	SD	Total	Gauze Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.11.1 Gauze								
Chang 1998	34	102.45	17	-9	102.45	17	4.8%	43.00 [-25.87, 111.87]
Mulder 1993	3.3	32.7	21	5.1	14.8	20	95.2%	-1.80 [-17.22, 13.62]
Subtotal (95% CI)			**38**			**37**	**100.0%**	**0.34 [-14.71, 15.38]**

Heterogeneity: Chi² = 1.55, df = 1 (P = 0.21); I² = 35%
Test for overall effect: Z = 0.04 (P = 0.96)

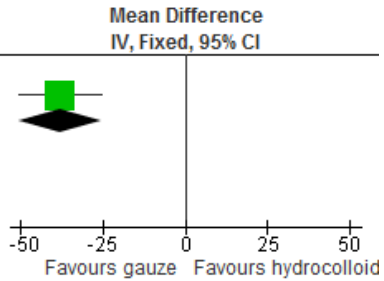


Test for subgroup differences: Not applicable

Figure 13 – Hydrocolloid dressing versus gauze dressing – mean percentage reduction in ulcer volume

Study or Subgroup	Hydrocolloid Mean	SD	Total	Gauze Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.18.1 Gauze								
Matzen 1999	26	20	17	64	16	15	100.0%	-38.00 [-50.49, -25.51]
Subtotal (95% CI)			**17**			**15**	**100.0%**	**-38.00 [-50.49, -25.51]**

Heterogeneity: Not applicable
Test for overall effect: Z = 5.96 (P < 0.00001)

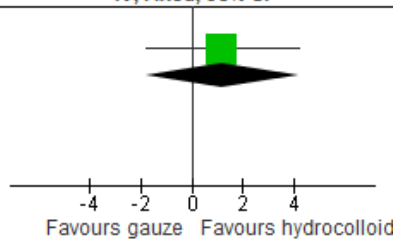


Test for subgroup differences: Not applicable

Figure 14 – Hydrocolloid dressing versus gauze dressing – mean healing speed (mm²/day)

Study or Subgroup	Hydrocolloid Mean	SD	Total	Gauze Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
1.19.1 Gauze								
Kim 1996	9.1	5.4	26	7.9	4.7	18	100.0%	1.20 [-1.80, 4.20]
Subtotal (95% CI)			**26**			**18**	**100.0%**	**1.20 [-1.80, 4.20]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.78 (P = 0.43)

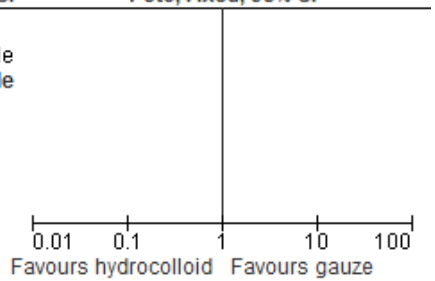


Test for subgroup differences: Not applicable

Figure 15 – Hydrocolloid dressing versus gauze dressing – proportion of patients with an infection

Study or Subgroup	Hydrocolloid Events	Total	Gauze Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.21.1 Gauze						
Chang 1998	0	17	0	17		Not estimable
Subtotal (95% CI)		**17**		**17**		**Not estimable**
Total events	0		0			

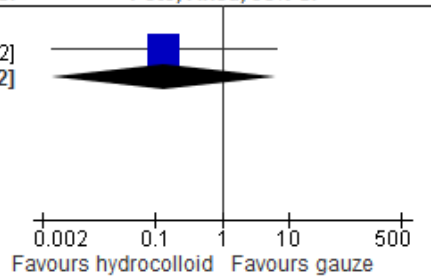
Heterogeneity: Not applicable
Test for overall effect: Not applicable



Test for subgroup differences: Not applicable

Study or Subgroup	Hydrocolloid Events	Total	Gauze Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.22.1 Gauze						
Chang 1998	0	17	1	17	100.0%	0.14 [0.00, 6.82]
Subtotal (95% CI)		**17**		**17**	**100.0%**	**0.14 [0.00, 6.82]**
Total events	0		1			

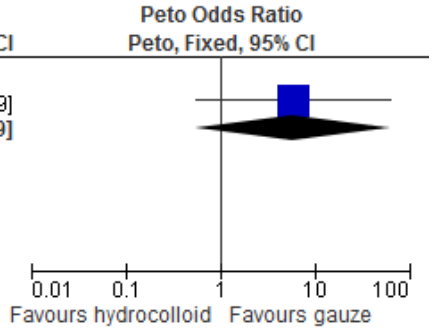
Heterogeneity: Not applicable
Test for overall effect: Z = 1.00 (P = 0.32)



Test for subgroup differences: Not applicable

Figure 16 – Hydrocolloid dressing versus gauze dressing – proportion of patients with hypergranulation

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Gauze Events	Gauze Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.23.1 Gauze						
Kim 1996	3	26	0	18	100.0%	5.90 [0.56, 62.29]
Subtotal (95% CI)		**26**		**18**	**100.0%**	**5.90 [0.56, 62.29]**
Total events	3		0			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.48 (P = 0.14)						



Test for subgroup differences: Not applicable

Figure 17 – Hydrocolloid dressing versus gauze dressing – proportion of patients with skin irritation

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Gauze Events	Gauze Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.25.1 Gauze						
Neill 1989	0	50	9	50	100.0%	0.11 [0.03, 0.44]
Subtotal (95% CI)		**50**		**50**	**100.0%**	**0.11 [0.03, 0.44]**
Total events	0		9			
Heterogeneity: Not applicable						
Test for overall effect: Z = 3.13 (P = 0.002)						

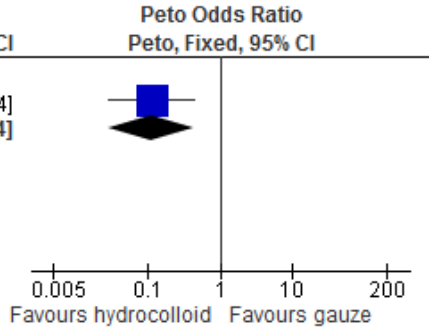
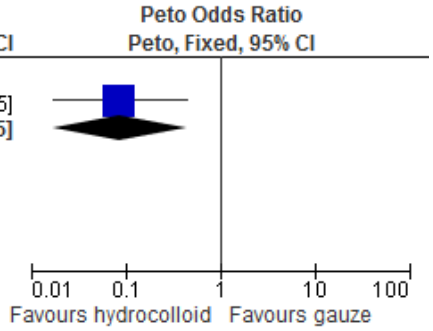


Figure 18 – Hydrocolloid dressing versus gauze dressing – proportion of patients with pain at dressing removal

Study or Subgroup	Hydrocolloid Events	Total	Gauze Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.25.1 Gauze						
Chang 1998	0	17	7	17	100.0%	0.09 [0.02, 0.45]
Subtotal (95% CI)		**17**		**17**	**100.0%**	**0.09 [0.02, 0.45]**
Total events	0		7			

Heterogeneity: Not applicable

Test for overall effect: Z = 2.92 (P = 0.003)



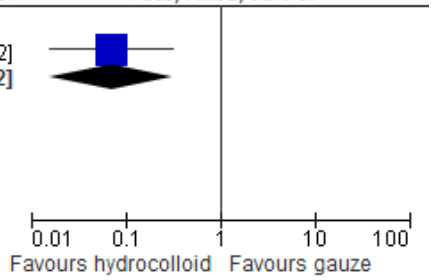
Test for subgroup differences: Not applicable

Figure 19 – Hydrocolloid dressing versus gauze dressing – proportion of patients with discomfort

Study or Subgroup	Hydrocolloid Events	Total	Gauze Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
1.28.1 Gauze						
Chang 1998	0	17	9	17	100.0%	0.07 [0.02, 0.32]
Subtotal (95% CI)		**17**		**17**	**100.0%**	**0.07 [0.02, 0.32]**
Total events	0		9			

Heterogeneity: Not applicable

Test for overall effect: Z = 3.45 (P = 0.0006)



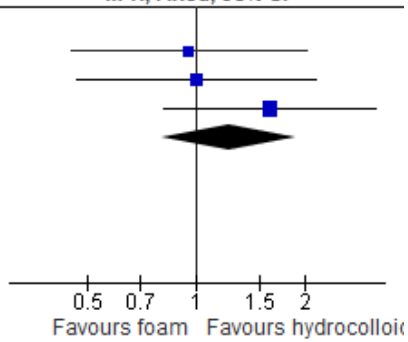
Test for subgroup differences: Not applicable

Figure 20 – Hydrocolloid dressing versus foam dressing – proportion of patients completely healed

Study or Subgroup	Hydrocolloid Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.1.2 Foam						
Bale 2005	5	9	7	12	25.0%	0.95 [0.45, 2.03]
Seeley 1999	8	20	8	20	33.3%	1.00 [0.47, 2.14]
Thomas 1997	16	48	10	48	41.7%	1.60 [0.81, 3.16]
Subtotal (95% CI)		**77**		**80**	**100.0%**	**1.24 [0.81, 1.90]**
Total events	29		25			

Heterogeneity: Chi² = 1.31, df = 2 (P = 0.52); I² = 0%

Test for overall effect: Z = 0.98 (P = 0.33)



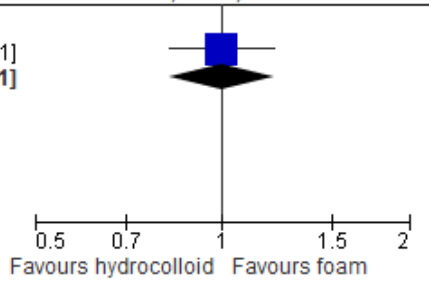
Test for subgroup differences: Not applicable

Figure 21 – Hydrocolloid dressing versus foam dressing – proportion of patients improved

Study or Subgroup	Hydrocolloid Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.2.1 Foam						
Thomas 1997	39	48	39	48	100.0%	1.00 [0.83, 1.21]
Subtotal (95% CI)		**48**		**48**	**100.0%**	**1.00 [0.83, 1.21]**
Total events	39		39			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.00 (P = 1.00)



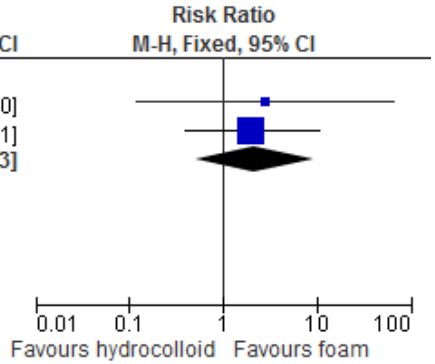
Test for subgroup differences: Not applicable

Figure 22 – Hydrocolloid dressing versus foam dressing – proportion of patients not changed

Study or Subgroup	Hydrocolloid Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.3.1 Foam						
Bale1997	1	31	0	29	20.5%	2.81 [0.12, 66.40]
Thomas 1997	4	48	2	48	79.5%	2.00 [0.38, 10.41]
Subtotal (95% CI)		**79**		**77**	**100.0%**	**2.17 [0.50, 9.33]**
Total events	5		2			

Heterogeneity: Chi² = 0.04, df = 1 (P = 0.85); I² = 0%

Test for overall effect: Z = 1.04 (P = 0.30)



Test for subgroup differences: Not applicable

Figure 23 – Hydrocolloid dressing versus foam dressing – proportion of patients worsened

Study or Subgroup	Hydrocolloid Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.4.1 Foam						
Bale1997	2	31	1	29	17.1%	1.87 [0.18, 19.55]
Thomas 1997	7	48	5	48	82.9%	1.40 [0.48, 4.10]
Subtotal (95% CI)		**79**		**77**	**100.0%**	**1.48 [0.56, 3.94]**
Total events	9		6			

Heterogeneity: Chi² = 0.05, df = 1 (P = 0.83); I² = 0%

Test for overall effect: Z = 0.79 (P = 0.43)

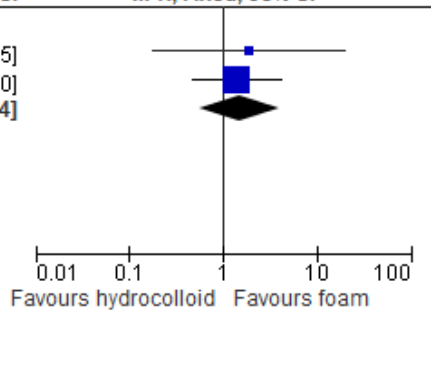
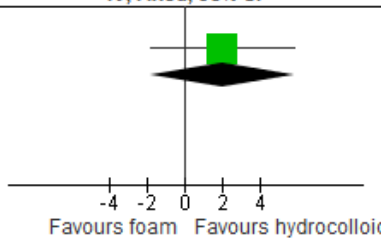


Figure 24 – Hydrocolloid dressing versus foam dressing – mean reduction in ulcer area

Study or Subgroup	Hydrocolloid Mean	SD	Total	Foam Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
2.5.2 Foam								
Seeley 1999	52	6.06	19	50	6.06	20	100.0%	2.00 [-1.81, 5.81]
Subtotal (95% CI)			**19**			**20**	**100.0%**	**2.00 [-1.81, 5.81]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.03 (P = 0.30)

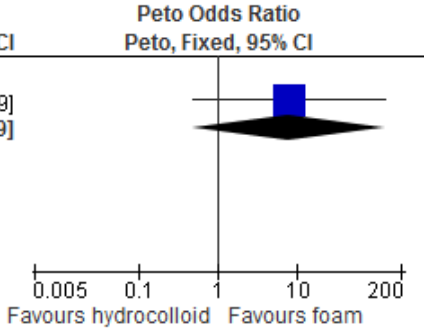


Test for subgroup differences: Not applicable

Figure 25 – Hydrocolloid dressing versus foam dressing – proportion of patients with bleeding

Study or Subgroup	Hydrocolloid Events	Total	Foam Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
2.7.1 Foam						
Thomas 1997	2	49	0	50	100.0%	7.70 [0.47, 124.89]
Subtotal (95% CI)		**49**		**50**	**100.0%**	**7.70 [0.47, 124.89]**
Total events	2		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.44 (P = 0.15)



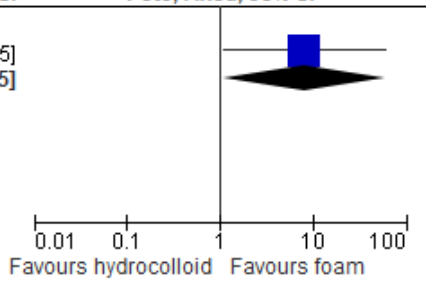
Test for subgroup differences: Not applicable

Figure 26 – Hydrocolloid dressing versus foam dressing – proportion of patients with maceration

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Foam Events	Foam Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
2.8.1 Foam						
Thomas 1997	4	49	0	50	100.0%	8.04 [1.10, 58.85]
Subtotal (95% CI)		**49**		**50**	**100.0%**	**8.04 [1.10, 58.85]**
Total events	4		0			

Heterogeneity: Not applicable

Test for overall effect: Z = 2.05 (P = 0.04)



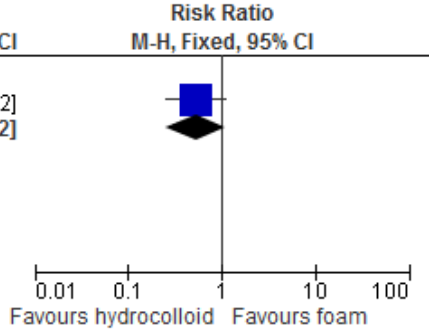
Test for subgroup differences: Not applicable

Figure 27 – Hydrocolloid dressing versus foam dressing – proportion of patients with inflammation or maceration

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Foam Events	Foam Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.9.1 Foam						
Seeley 1999	6	19	12	20	100.0%	0.53 [0.25, 1.12]
Subtotal (95% CI)		**19**		**20**	**100.0%**	**0.53 [0.25, 1.12]**
Total events	6		12			

Heterogeneity: Not applicable

Test for overall effect: Z = 1.67 (P = 0.09)

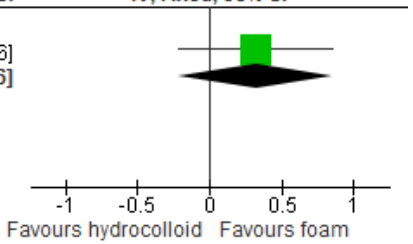


Test for subgroup differences: Not applicable

Figure 28 – Hydrocolloid dressing versus foam dressing – mean pain score at end of treatment

Study or Subgroup	Hydrocolloid Mean	SD	Total	Foam Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
2.10.1 Foam								
Seeley 1999	0.47	0.9	19	0.15	0.8	20	100.0%	0.32 [-0.22, 0.86]
Subtotal (95% CI)			**19**			**20**	**100.0%**	**0.32 [-0.22, 0.86]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.17 (P = 0.24)

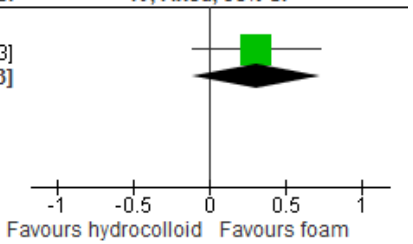


Test for subgroup differences: Not applicable

Figure 29 – Hydrocolloid dressing versus foam dressing – mean odour score at end of treatment

Study or Subgroup	Hydrocolloid Mean	SD	Total	Foam Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
2.11.1 Foam								
Seeley 1999	0.47	0.8	19	0.16	0.5	20	100.0%	0.31 [-0.11, 0.73]
Subtotal (95% CI)			**19**			**20**	**100.0%**	**0.31 [-0.11, 0.73]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.44 (P = 0.15)



Test for subgroup differences: Not applicable

Figure 30 – Hydrocolloid dressing versus foam dressing – proportion of patients with adverse events (unknown if dressing related)

Study or Subgroup	Hydrocolloid Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bale1997	2	31	3	29	38.3%	0.62 [0.11, 3.47]
Seeley 1999	3	20	5	20	61.7%	0.60 [0.17, 2.18]
Total (95% CI)		**51**		**49**	**100.0%**	**0.61 [0.22, 1.71]**
Total events	5		8			

Heterogeneity: Chi² = 0.00, df = 1 (P = 0.97); I² = 0%
Test for overall effect: Z = 0.94 (P = 0.35)

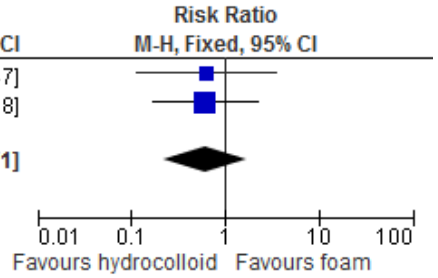
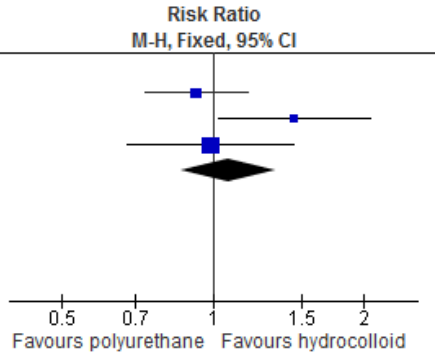


Figure 31 – Hydrocolloid dressing versus polyurethane film – proportion of patients completely healed

Study or Subgroup	Hydrocolloid Events	Total	Polyurethane Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.1.3 Polyurethane						
Banks 1994a	11	12	10	10	27.0%	0.93 [0.73, 1.17]
Banks 1994b	10	10	12	18	21.8%	1.45 [1.02, 2.06]
Brown-Etris 2008	22	37	21	35	51.2%	0.99 [0.68, 1.45]
Subtotal (95% CI)		**59**		**63**	**100.0%**	**1.07 [0.87, 1.33]**
Total events	43		43			

Heterogeneity: Chi² = 4.54, df = 2 (P = 0.10); I² = 56%
Test for overall effect: Z = 0.65 (P = 0.52)

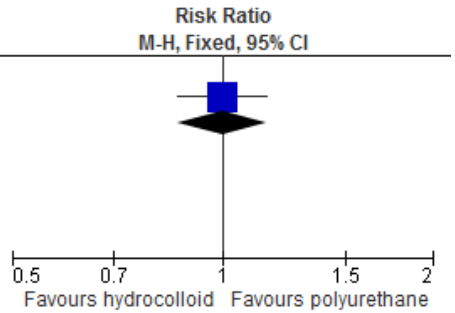


Test for subgroup differences: Not applicable

Figure 32 – Hydrocolloid dressing versus polyurethane film – proportion of patients improved

Study or Subgroup	Hydrocolloid Events	Total	Polyurethane Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
3.2.3 Polyurethane						
Banks 1994b	10	10	18	18	100.0%	1.00 [0.86, 1.16]
Subtotal (95% CI)		**10**		**18**	**100.0%**	**1.00 [0.86, 1.16]**
Total events	10		18			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)



Test for subgroup differences: Not applicable

Figure 33 – Hydrocolloid dressing versus polyurethane film – linear healing rate (cm/week)

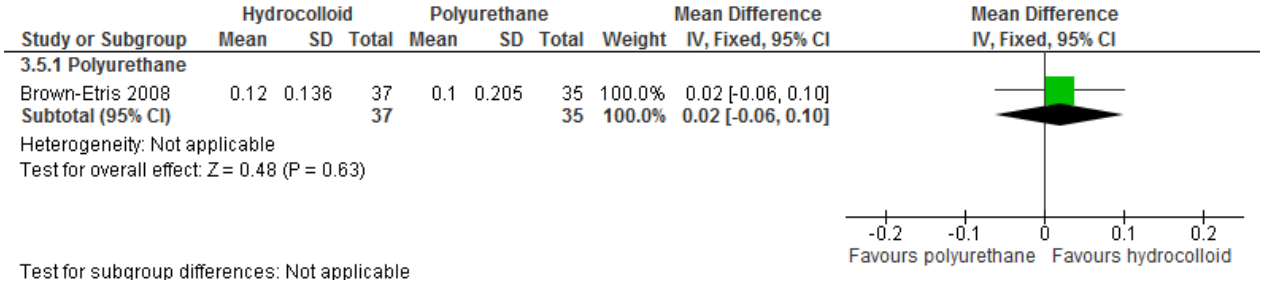


Figure 34 – Hydrocolloid dressing versus polyurethane film – mean odour score

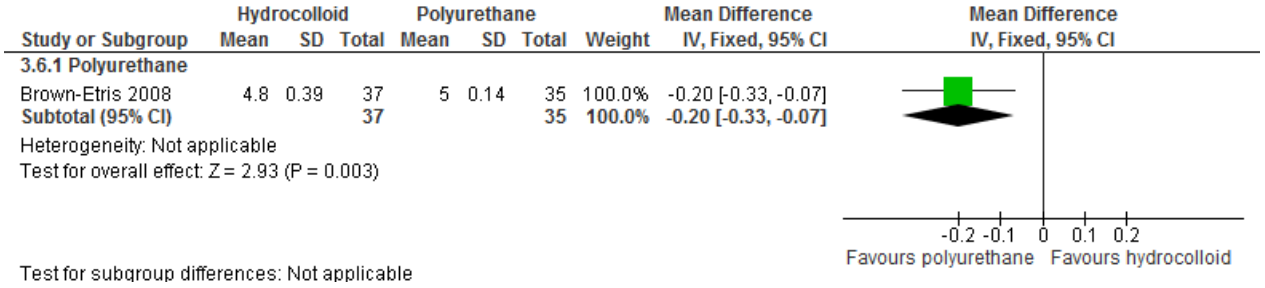


Figure 35 – Hydrocolloid dressing versus polyurethane film – mean comfort score

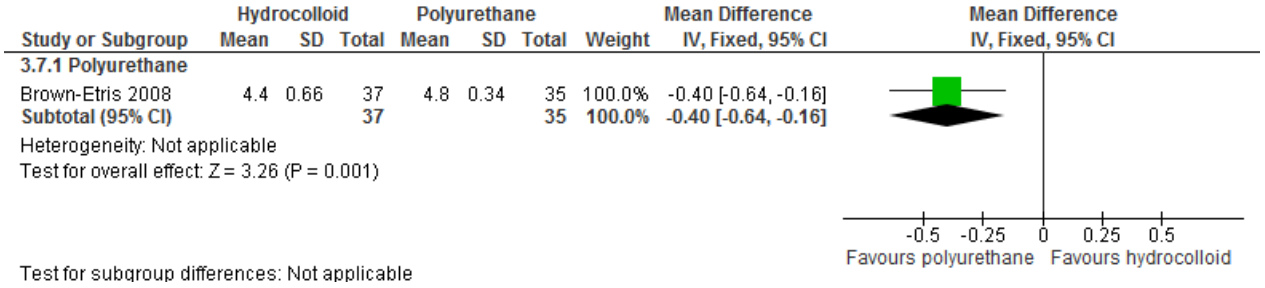


Figure 36 – Hydrocolloid dressing versus collagenase ointment – proportion of patients completely healed

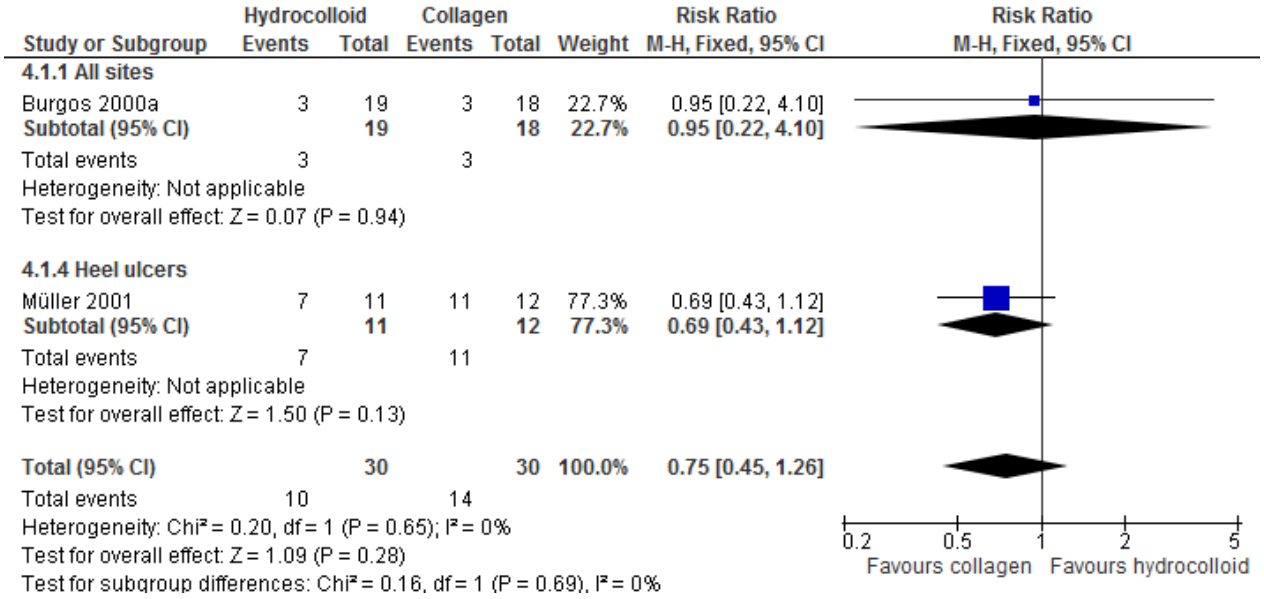


Figure 37 – Hydrocolloid dressing versus collagenase ointment– mean percentage reduction in ulcer area

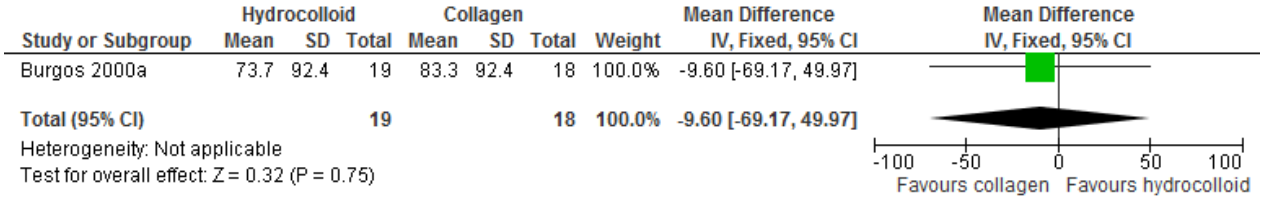


Figure 38 – Hydrocolloid dressing versus collagenase ointment– mean cm² reduction in ulcer area

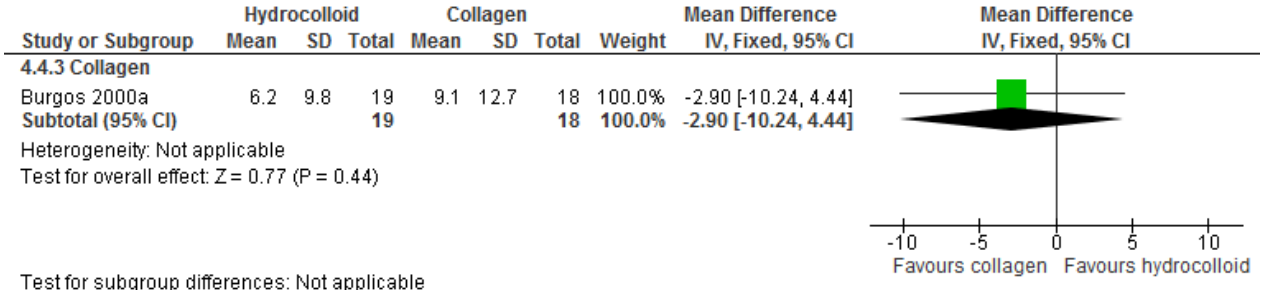


Figure 39 – Hydrocolloid dressing versus collagenase ointment – mean time to healing (weeks)

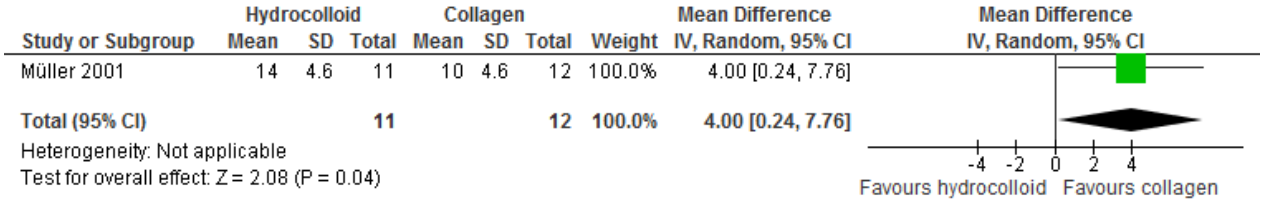


Figure 40 – Hydrocolloid dressing versus collagenase ointment – proportion of patients with adverse events

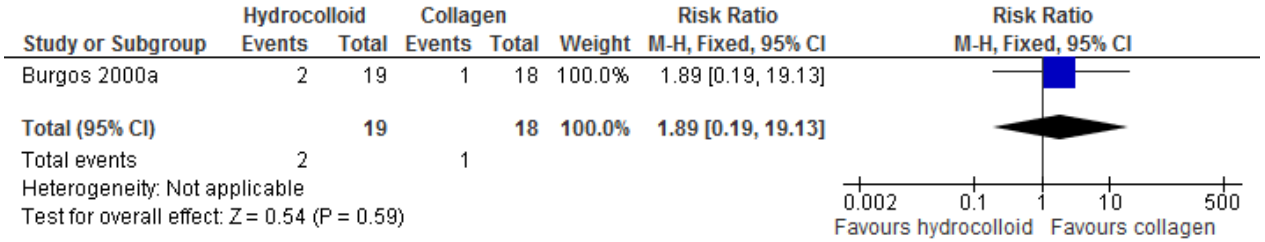


Figure 41 – Hydrocolloid dressing versus collagen dressing – proportion of patients completely healed

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Collagen Events	Collagen Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Graumlich 2003	15	30	18	35	100.0%	0.97 [0.60, 1.57]
Total (95% CI)		**30**		**35**	**100.0%**	**0.97 [0.60, 1.57]**
Total events	15		18			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.11 (P = 0.91)

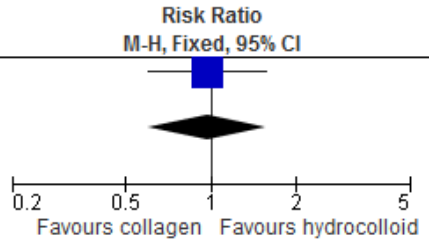


Figure 42 – Hydrocolloid dressing versus collagen dressing – mean percentage reduction in ulcer area

Study or Subgroup	Hydrocolloid Mean	Hydrocolloid SD	Hydrocolloid Total	Collagen Mean	Collagen SD	Collagen Total	Weight	Mean Difference IV, Fixed, 95% CI
Graumlich 2003	9	73.98	30	33	73.98	35	100.0%	-24.00 [-60.08, 12.08]
Total (95% CI)			**30**			**35**	**100.0%**	**-24.00 [-60.08, 12.08]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.30 (P = 0.19)

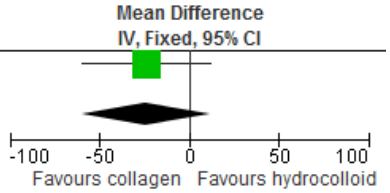


Figure 43 – Hydrocolloid dressing versus collagen dressing – mean healing speed (mm²/day)

Study or Subgroup	Hydrocolloid Mean	Hydrocolloid SD	Hydrocolloid Total	Collagen Mean	Collagen SD	Collagen Total	Weight	Mean Difference IV, Fixed, 95% CI
4.5.2 Collagen								
Graumlich 2003	6	16	35	6	19	35	100.0%	0.00 [-8.23, 8.23]
Subtotal (95% CI)			**35**			**35**	**100.0%**	**0.00 [-8.23, 8.23]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)

Test for subgroup differences: Not applicable

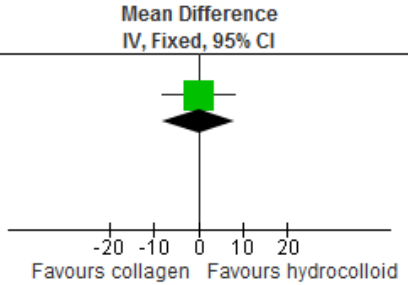


Figure 44 – Hydrocolloid dressing versus collagen dressing – mean time to healing (weeks)

Study or Subgroup	Hydrocolloid Mean	SD	Total	Collagen Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Graumlich 2003	6	2.68	30	5	2.91	35	100.0%	1.00 [-0.36, 2.36]
Total (95% CI)			**30**			**35**	**100.0%**	**1.00 [-0.36, 2.36]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.44 (P = 0.15)

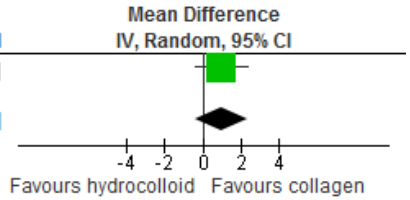
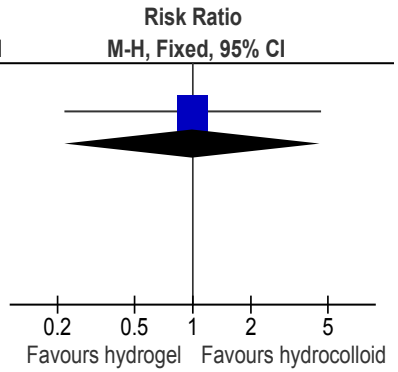


Figure 45 – Hydrocolloid dressing versus hydrogel dressing – proportion of patients completely healed

Study or Subgroup	Hydrocolloid Events	Total	Hydrogel Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
5.1.5 Hydrogel						
Motta 1999	2	5	2	5	100.0%	1.00 [0.22, 4.56]
Subtotal (95% CI)		**5**		**5**	**100.0%**	**1.00 [0.22, 4.56]**
Total events	2		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)

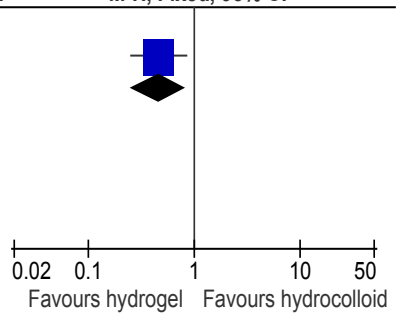


Test for subgroup differences: Not applicable

Figure 46 – Hydrocolloid dressing versus hydrogel dressing – proportion of ulcers completely healed

Study or Subgroup	Hydrocolloid Events	Total	Hydrogel Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
5.2.2 Hydrogel						
Darkovich 1990	12	67	24	62	100.0%	0.46 [0.25, 0.84]
Subtotal (95% CI)		**67**		**62**	**100.0%**	**0.46 [0.25, 0.84]**
Total events	12		24			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.51 (P = 0.01)



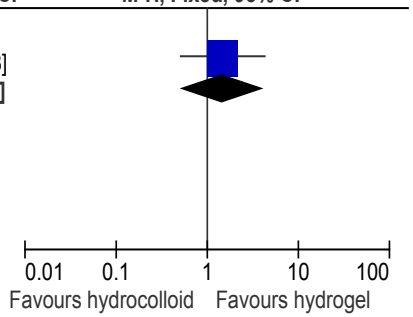
Test for subgroup differences: Not applicable

Figure 47 – Hydrocolloid dressing versus hydrogel dressing – proportion of ulcers not changed

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Hydrogel Events	Hydrogel Total	Weight	Risk Ratio M-H, Fixed, 95% CI
5.3.1 Hydrogel						
Darkovich 1990	8	67	5	62	100.0%	1.48 [0.51, 4.28]
Subtotal (95% CI)		**67**		**62**	**100.0%**	**1.48 [0.51, 4.28]**
Total events	8		5			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.72 (P = 0.47)



Test for subgroup differences: Not applicable

Figure 48 – Hydrocolloid dressing versus hydrogel dressing – proportion of ulcers worsened

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Hydrogel Events	Hydrogel Total	Weight	Risk Ratio M-H, Fixed, 95% CI
5.4.2 Hydrogel						
Darkovich 1990	7	67	1	62	100.0%	6.48 [0.82, 51.16]
Subtotal (95% CI)		**67**		**62**	**100.0%**	**6.48 [0.82, 51.16]**
Total events	7		1			

Heterogeneity: Not applicable

Test for overall effect: Z = 1.77 (P = 0.08)

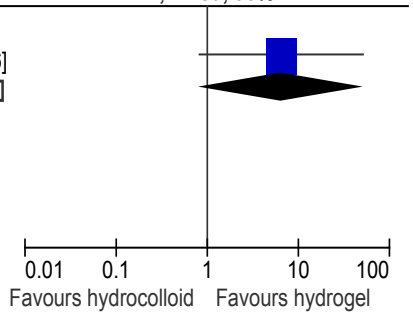


Figure 49 – Hydrocolloid dressing versus hydrogel dressing – mean percentage reduction in ulcer area (stage II)

Study or Subgroup	Hydrocolloid Mean	SD	Total	Hydrogel Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
5.6.1 Hydrogel								
Darkovich 1990	34	47.7	36	64	47.7	35	100.0%	-30.00 [-52.19, -7.81]
Subtotal (95% CI)			**36**			**35**	**100.0%**	**-30.00 [-52.19, -7.81]**

Heterogeneity: Not applicable

Test for overall effect: Z = 2.65 (P = 0.008)

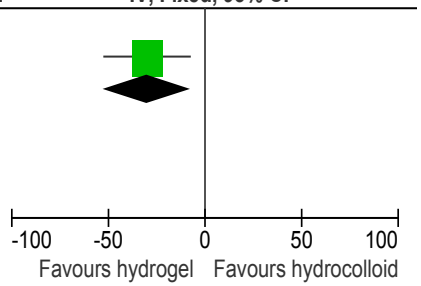


Figure 50 – Hydrocolloid dressing versus hydrogel dressing – mean healing rate (cm/day)

Study or Subgroup	Hydrocolloid Mean	SD	Total	Hydrogel Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
5.8.1 Hydrogel								
Motta 1999	0.35	0.43	5	0.15	0.22	5	100.0%	0.20 [-0.22, 0.62]
Subtotal (95% CI)			**5**			**5**	**100.0%**	**0.20 [-0.22, 0.62]**

Heterogeneity: Not applicable

Test for overall effect: Z = 0.93 (P = 0.35)

Test for subgroup differences: Not applicable

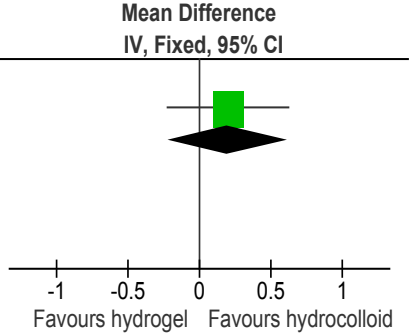
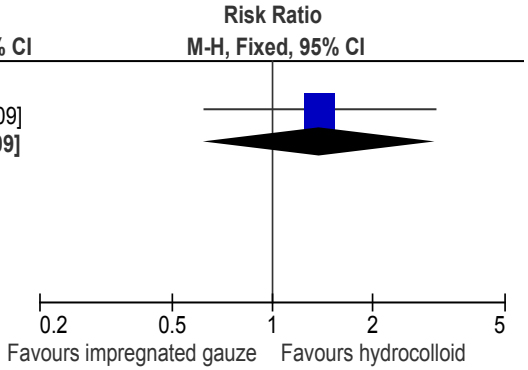


Figure 51 – Hydrocolloid dressing versus impregnated gauze dressing – proportion of patients completely healed

Study or Subgroup	Hydrocolloid Events	Total	Impregnated gauze Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
6.1.6 Impregnated gauze						
Winter 1990	5	6	3	5	100.0%	1.39 [0.62, 3.09]
Subtotal (95% CI)		**6**		**5**	**100.0%**	**1.39 [0.62, 3.09]**
Total events	5		3			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.80 (P = 0.42)



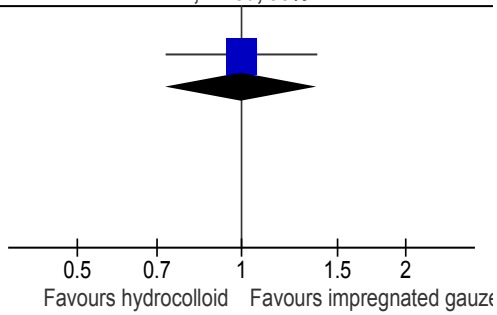
Test for subgroup differences: Not applicable

Figure 52 – Hydrocolloid dressing versus impregnated gauze dressing – proportion of patients improved

Study or Subgroup	Hydrocolloid Events	Total	Impregnated gauze Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
6.2.2 Impregnated gauze						
Winter 1990	6	6	5	5	100.0%	1.00 [0.73, 1.37]
Subtotal (95% CI)		**6**		**5**	**100.0%**	**1.00 [0.73, 1.37]**
Total events	6		5			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.00 (P = 1.00)



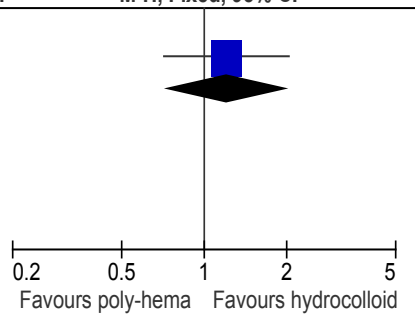
Test for subgroup differences: Not applicable

Figure 53 – Hydrocolloid dressing versus poly-hema dressing – proportion of patients completely healed

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Poly-hema Events	Poly-hema Total	Weight	Risk Ratio M-H, Fixed, 95% CI
7.1.7 Poly-hema						
Brod 1990	10	16	14	27	100.0%	1.21 [0.71, 2.04]
Subtotal (95% CI)		**16**		**27**	**100.0%**	**1.21 [0.71, 2.04]**
Total events	10		14			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.70 (P = 0.49)



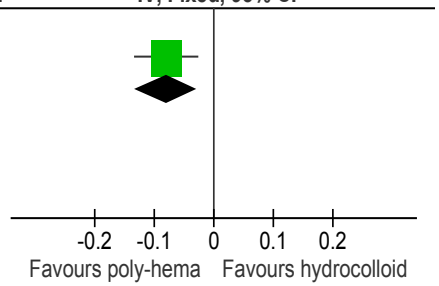
Test for subgroup differences: Not applicable

Figure 54 – Hydrocolloid dressing versus poly-hema dressing – absolute rate of healing (cm²/week)

Study or Subgroup	Hydrocolloid Mean	Hydrocolloid SD	Hydrocolloid Total	Poly-hema Mean	Poly-hema SD	Poly-hema Total	Weight	Mean Difference IV, Fixed, 95% CI
7.3.1 Poly-hema								
Brod 1990	0.1	0.085	16	0.18	0.085	27	100.0%	-0.08 [-0.13, -0.03]
Subtotal (95% CI)			**16**			**27**	**100.0%**	**-0.08 [-0.13, -0.03]**

Heterogeneity: Not applicable

Test for overall effect: Z = 2.98 (P = 0.003)



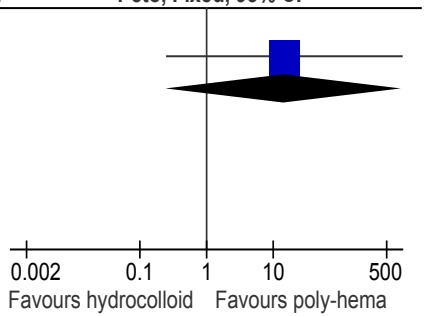
Test for subgroup differences: Not applicable

Figure 55 – Hydrocolloid dressing versus poly-hema dressing – proportion of patients with adverse events

Study or Subgroup	Hydrocolloid Events	Total	Poly-hema Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
7.4.1 Poly-hema						
Brod 1990	1	16	0	27	100.0%	14.69 [0.25, 847.55]
Subtotal (95% CI)		**16**		**27**	**100.0%**	**14.69 [0.25, 847.55]**
Total events	1		0			

Heterogeneity: Not applicable

Test for overall effect: Z = 1.30 (P = 0.19)



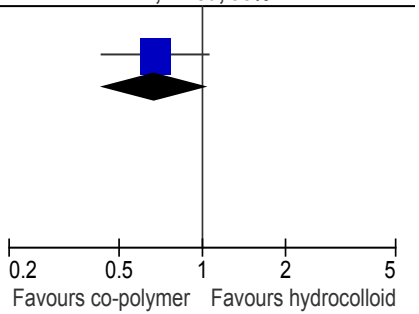
Test for subgroup differences: Not applicable

Figure 56 – Hydrocolloid dressing versus co-polymer (amino acid) dressing – proportion of patients completely healed

Study or Subgroup	Hydrocolloid Events	Total	Co-polymer Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
8.1.8 Copolymer (amino acid)						
Hondé 1994	23	88	31	80	100.0%	0.67 [0.43, 1.05]
Subtotal (95% CI)		**88**		**80**	**100.0%**	**0.67 [0.43, 1.05]**
Total events	23		31			

Heterogeneity: Not applicable

Test for overall effect: Z = 1.73 (P = 0.08)



Test for subgroup differences: Not applicable

Figure 57 – Hydrocolloid dressing versus co-polymer (amino acid) dressing – proportion of patients with an infection

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Co-polymer Events	Co-polymer Total	Weight	Risk Ratio M-H, Fixed, 95% CI
8.3.3 Copolymer (amino acid)						
Hondé 1994	6	88	6	80	100.0%	0.91 [0.31, 2.70]
Subtotal (95% CI)		**88**		**80**	**100.0%**	**0.91 [0.31, 2.70]**
Total events	6		6			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.17 (P = 0.86)

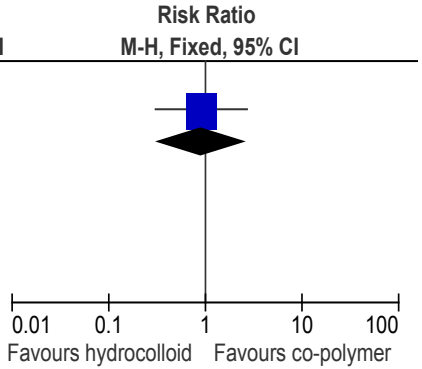


Figure 58 – Hydrocolloid dressing versus phenytoin cream – proportion of patients completely healed

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Phenytoin Events	Phenytoin Total	Weight	Risk Ratio M-H, Fixed, 95% CI
9.1.9 Phenytoin cream						
Hollisaz 2004	20	28	8	27	100.0%	2.41 [1.29, 4.51]
Subtotal (95% CI)		**28**		**27**	**100.0%**	**2.41 [1.29, 4.51]**
Total events	20		8			

Heterogeneity: Not applicable

Test for overall effect: Z = 2.75 (P = 0.006)

Test for subgroup differences: Not applicable

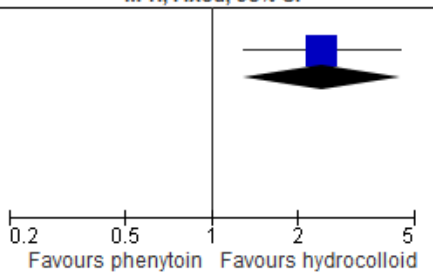
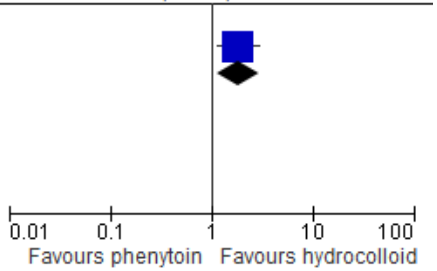


Figure 59 – Hydrocolloid dressing versus phenytoin cream – proportion of ulcers completely healed (all stages – all sites)

Study or Subgroup	Hydrocolloid Events	Total	Phenytoin Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
9.2.3 Phenytoin cream						
Hollisaz 2004	23	31	12	30	100.0%	1.85 [1.14, 3.01]
Subtotal (95% CI)		**31**		**30**	**100.0%**	**1.85 [1.14, 3.01]**
Total events	23		12			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.50 (P = 0.01)

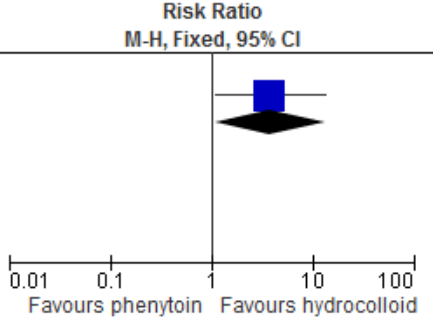


Test for subgroup differences: Not applicable

Figure 60 – Hydrocolloid dressing versus phenytoin cream – proportion of ulcers completely healed (stage I – all sites)

Study or Subgroup	Hydrocolloid Events	Total	Phenytoin Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
9.3.2 Phenytoin cream						
Hollisaz 2004	11	13	2	9	100.0%	3.81 [1.10, 13.21]
Subtotal (95% CI)		**13**		**9**	**100.0%**	**3.81 [1.10, 13.21]**
Total events	11		2			

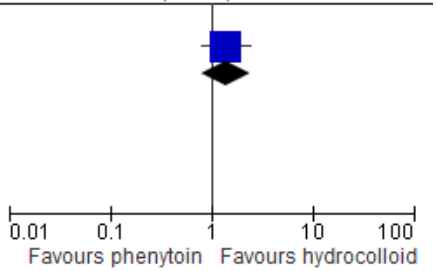
Heterogeneity: Not applicable
Test for overall effect: Z = 2.11 (P = 0.04)



Test for subgroup differences: Not applicable

Figure 61 – Hydrocolloid dressing versus phenytoin cream – proportion of ulcers completely healed (stage II – all sites)

Study or Subgroup	Hydrocolloid Events	Total	Phenytoin Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
9.4.2 Phenytoin cream						
Hollisaz 2004	12	18	10	21	100.0%	1.40 [0.80, 2.44]
Subtotal (95% CI)		**18**		**21**	**100.0%**	**1.40 [0.80, 2.44]**
Total events	12		10			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.19 (P = 0.23)						



Test for subgroup differences: Not applicable

Figure 62 – Hydrocolloid dressing versus phenytoin cream – proportion of ulcers completely healed (all stages – sacral)

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
9.5.2 Phenytoin cream						
Hollisaz 2004	4	7	2	5	100.0%	1.43 [0.41, 4.99]
Subtotal (95% CI)		**7**		**5**	**100.0%**	**1.43 [0.41, 4.99]**
Total events	4		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.56 (P = 0.58)						

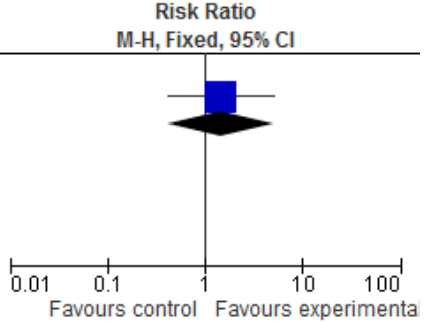
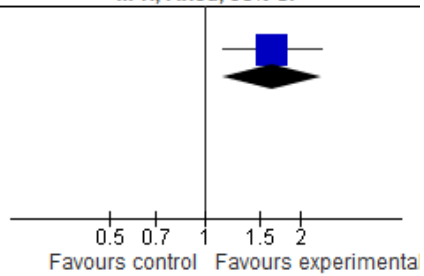


Figure 63 – Hydrocolloid dressing versus phenytoin cream – proportion of ulcers improved

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
9.6.3 Phenytoin cream						
Hollisaz 2004	27	31	16	30	100.0%	1.63 [1.14, 2.34]
Subtotal (95% CI)		**31**		**30**	**100.0%**	**1.63 [1.14, 2.34]**
Total events	27		16			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.66 (P = 0.008)						



Test for subgroup differences: Not applicable

Figure 64 – Hydrocolloid dressing versus phenytoin cream – proportion of ulcers worsened

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Pheyntoin Events	Pheyntoin Total	Weight	Risk Ratio M-H, Fixed, 95% CI
9.7.3 Phenytoin cream						
Hollisaz 2004	2	31	2	30	100.0%	0.97 [0.15, 6.44]
Subtotal (95% CI)		**31**		**30**	**100.0%**	**0.97 [0.15, 6.44]**
Total events	2		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.03 (P = 0.97)						

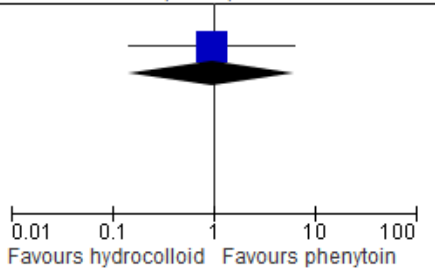


Figure 65 – Hydrocolloid dressing versus alginate dressing – proportion of patients 40% healed

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Alginate Events	Alginate Total	Weight	Risk Ratio M-H, Fixed, 95% CI
10.1.1 Alginate						
Belmin 2002	31	53	43	57	100.0%	0.78 [0.59, 1.02]
Subtotal (95% CI)		**53**		**57**	**100.0%**	**0.78 [0.59, 1.02]**
Total events	31		43			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.84 (P = 0.07)						
Total (95% CI)		**53**		**57**	**100.0%**	**0.78 [0.59, 1.02]**
Total events	31		43			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.84 (P = 0.07)						
Test for subgroup differences: Not applicable						

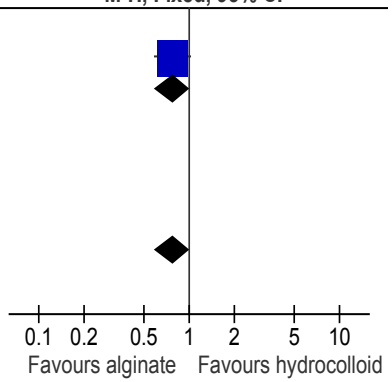


Figure 66 – Hydrocolloid dressing versus alginate dressing – mean percentage reduction in ulcer area

Study or Subgroup	Hydrocolloid Mean	Hydrocolloid SD	Hydrocolloid Total	Alginate Mean	Alginate SD	Alginate Total	Weight	Mean Difference IV, Fixed, 95% CI
10.2.3 Alginate								
Belmin 2002	42.6	49.1	53	69.1	33.9	57	100.0%	-26.50 [-42.38, -10.62]
Subtotal (95% CI)			**53**			**57**	**100.0%**	**-26.50 [-42.38, -10.62]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.27 (P = 0.001)								
Test for subgroup differences: Not applicable								

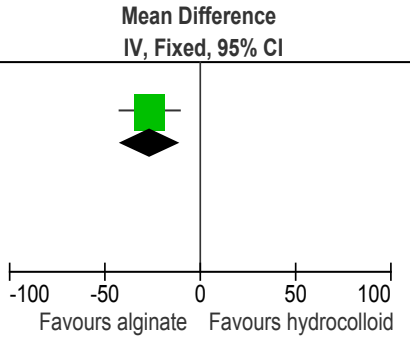
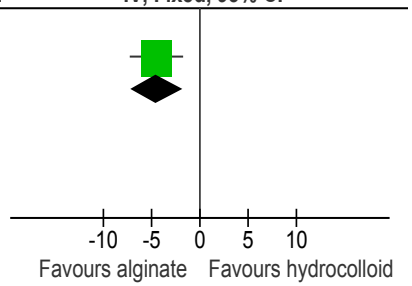


Figure 67 – Hydrocolloid dressing versus alginate dressing – mean cm² reduction in ulcer area

Study or Subgroup	Hydrocolloid Mean	SD	Total	Alginate Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
10.3.2 Alginate								
Belmin 2002	5.2	7.2	53	9.7	7.1	57	100.0%	-4.50 [-7.17, -1.83]
Subtotal (95% CI)			**53**			**57**	**100.0%**	**-4.50 [-7.17, -1.83]**

Heterogeneity: Not applicable

Test for overall effect: Z = 3.30 (P = 0.0010)



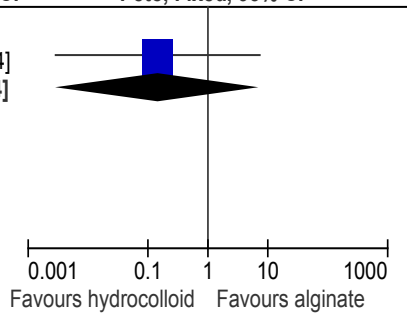
Test for subgroup differences: Not applicable

Figure 68 – Hydrocolloid dressing versus alginate dressing – proportion of patients with an infection

Study or Subgroup	Hydrocolloid Events	Total	Alginate Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
10.4.2 Alginate						
Belmin 2002	0	53	1	57	100.0%	0.15 [0.00, 7.34]
Subtotal (95% CI)		**53**		**57**	**100.0%**	**0.15 [0.00, 7.34]**
Total events	0		1			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.96 (P = 0.33)



Test for subgroup differences: Not applicable

Figure 69 – Hydrocolloid dressing versus alginate dressing – proportion of patients with skin irritation

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Alginate Events	Alginate Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
10.5.2 Alginate						
Belmin 2002	0	53	2	57	100.0%	0.14 [0.01, 2.31]
Subtotal (95% CI)		**53**		**57**	**100.0%**	**0.14 [0.01, 2.31]**
Total events	0		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.37 (P = 0.17)						

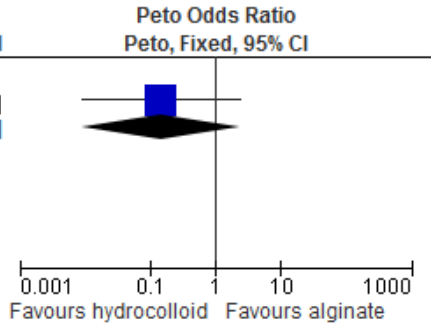
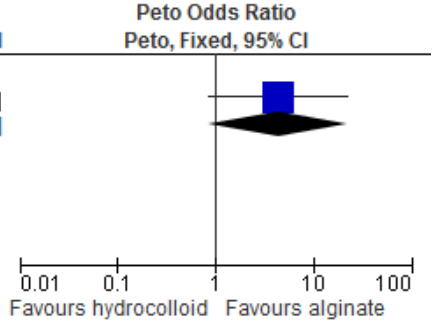


Figure 70 – Hydrocolloid dressing versus alginate dressing – proportion of patients with hypergranulation

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Alginate Events	Alginate Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
10.6.3 Alginate						
Belmin 2002	5	53	1	57	100.0%	4.37 [0.85, 22.53]
Subtotal (95% CI)		**53**		**57**	**100.0%**	**4.37 [0.85, 22.53]**
Total events	5		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.76 (P = 0.08)						



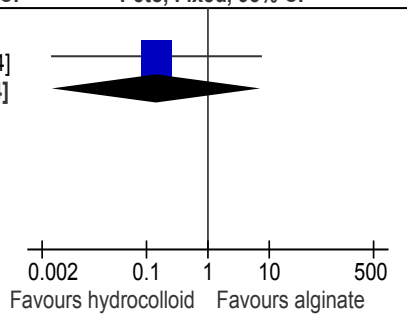
Test for subgroup differences: Not applicable

Figure 71 – Hydrocolloid dressing versus alginate dressing – proportion of patients with maceration

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Alginate Events	Alginate Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
10.7.2 Alginate						
Belmin 2002	0	53	1	57	100.0%	0.15 [0.00, 7.34]
Subtotal (95% CI)		**53**		**57**	**100.0%**	**0.15 [0.00, 7.34]**
Total events	0		1			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.96 (P = 0.33)



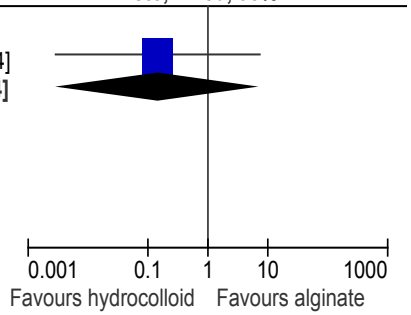
Test for subgroup differences: Not applicable

Figure 72 – Hydrocolloid dressing versus alginate dressing – proportion of patients with bleeding

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Alginate Events	Alginate Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
10.8.2 Alginate						
Belmin 2002	0	53	1	57	100.0%	0.15 [0.00, 7.34]
Subtotal (95% CI)		**53**		**57**	**100.0%**	**0.15 [0.00, 7.34]**
Total events	0		1			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.96 (P = 0.33)



Test for subgroup differences: Not applicable

Figure 73 – Hydrocolloid dressing versus alginate dressing – incidence of pain at dressing removal

Study or Subgroup	Hydrocolloid Events	Total	Alginate Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Belmin 2002	411	1314	316	887	100.0%	0.88 [0.78, 0.99]
Total (95% CI)		**1314**		**887**	**100.0%**	**0.88 [0.78, 0.99]**
Total events	411		316			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.14 (P = 0.03)

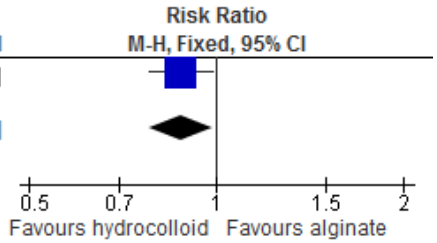


Figure 74 – Hydrocolloid dressing versus alginate dressing – incidence of strong odour at dressing removal

Study or Subgroup	Hydrocolloid Events	Total	Alginate Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Belmin 2002	173	1314	178	887	100.0%	0.66 [0.54, 0.79]
Total (95% CI)		**1314**		**887**	**100.0%**	**0.66 [0.54, 0.79]**
Total events	173		178			

Heterogeneity: Not applicable
Test for overall effect: Z = 4.32 (P < 0.0001)

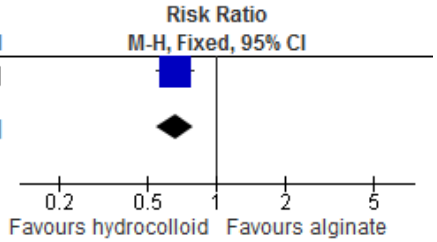


Figure 75 – Hydrocolloid dressing versus alginate dressing – incidence of mild odour at dressing removal

Study or Subgroup	Hydrocolloid Events	Total	Alginate Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Belmin 2002	382	1314	361	887	100.0%	0.71 [0.64, 0.80]
Total (95% CI)		**1314**		**887**	**100.0%**	**0.71 [0.64, 0.80]**
Total events	382		361			

Heterogeneity: Not applicable
Test for overall effect: Z = 5.69 (P < 0.00001)

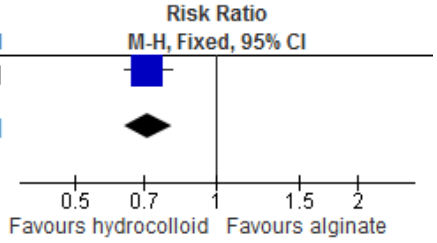


Figure 76 – Hydrocolloid dressing versus charcoal dressing – proportion of patients worsened

Study or Subgroup	Hydrocolloid Events	Total	Charcoal Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
11.1.2 Charcoal						
Kerihuel 2010	1	30	0	29	100.0%	7.15 [0.14, 360.38]
Subtotal (95% CI)		**30**		**29**	**100.0%**	**7.15 [0.14, 360.38]**
Total events	1		0			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.98 (P = 0.33)						

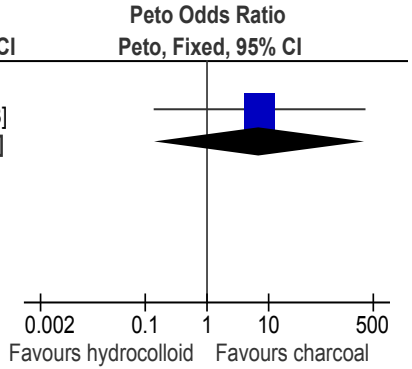


Figure 77 – Hydrocolloid dressing versus charcoal dressing – proportion of patients with maceration

Study or Subgroup	Hydrocolloid Events	Total	Charcoal Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
11.4.3 Charcoal						
Kerihuel 2010	2	30	0	29	100.0%	7.40 [0.45, 121.22]
Subtotal (95% CI)		**30**		**29**	**100.0%**	**7.40 [0.45, 121.22]**
Total events	2		0			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.40 (P = 0.16)						

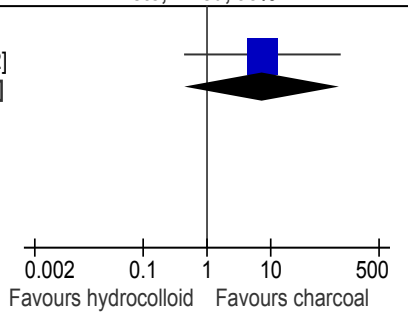


Figure 78 – Hydrocolloid dressing versus charcoal dressing – proportion of patients with an infection

Study or Subgroup	Hydrocolloid Events	Total	Charcoal Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
11.5.4 Charcoal						
Kerihuel 2010	2	30	1	29	100.0%	1.93 [0.19, 20.18]
Subtotal (95% CI)		**30**		**29**	**100.0%**	**1.93 [0.19, 20.18]**
Total events	2		1			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.55 (P = 0.58)

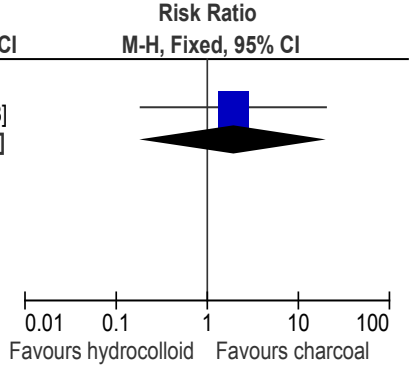


Figure 79 – Hydrocolloid dressing versus charcoal dressing – proportion of patients with hypergranulation

Study or Subgroup	Hydrocolloid Events	Total	Chacoal Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
11.6.4 Charcoal						
Kerihuel 2010	1	30	0	29	100.0%	7.15 [0.14, 360.38]
Subtotal (95% CI)		**30**		**29**	**100.0%**	**7.15 [0.14, 360.38]**
Total events	1		0			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.98 (P = 0.33)

Test for subgroup differences: Not applicable

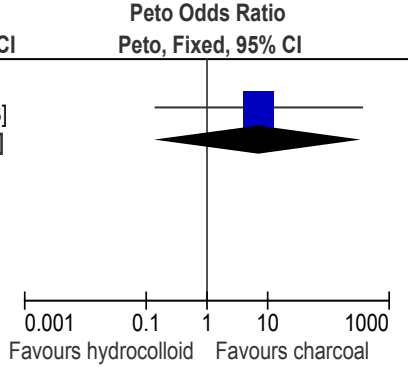


Figure 80 – Hydrocolloid dressing versus charcoal dressing – proportion of patients with skin irritation and eczema

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Charcoal Events	Charcoal Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
11.7.3 Charcoal						
Kerihuel 2010	1	30	0	29	100.0%	7.15 [0.14, 360.38]
Subtotal (95% CI)		**30**		**29**	**100.0%**	**7.15 [0.14, 360.38]**
Total events	1		0			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.98 (P = 0.33)

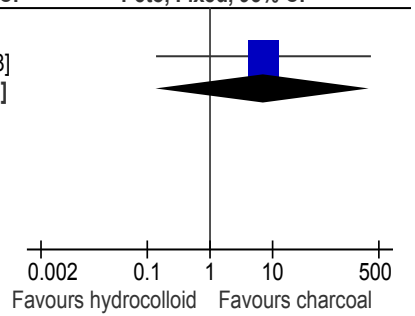
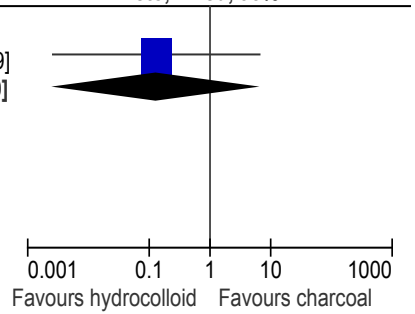


Figure 81 – Hydrocolloid dressing versus charcoal dressing – proportion of patients with pruritus

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Charcoal Events	Charcoal Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
11.9.1 Charcoal						
Kerihuel 2010	0	30	1	29	100.0%	0.13 [0.00, 6.59]
Subtotal (95% CI)		**30**		**29**	**100.0%**	**0.13 [0.00, 6.59]**
Total events	0		1			

Heterogeneity: Not applicable

Test for overall effect: Z = 1.02 (P = 0.31)



Test for subgroup differences: Not applicable

Figure 82 – Hydrocolloid dressing versus charcoal dressing – proportion of patients with pain at dressing removal

Study or Subgroup	Hydrocolloid Events	Hydrocolloid Total	Charcoal Events	Charcoal Total	Weight	Risk Ratio M-H, Fixed, 95% CI
11.11.2 Charcoal						
Kerihuel 2010	19	30	19	29	100.0%	0.97 [0.66, 1.41]
Subtotal (95% CI)		**30**		**29**	**100.0%**	**0.97 [0.66, 1.41]**
Total events	19		19			

Heterogeneity: Not applicable

Test for overall effect: Z = 0.18 (P = 0.86)

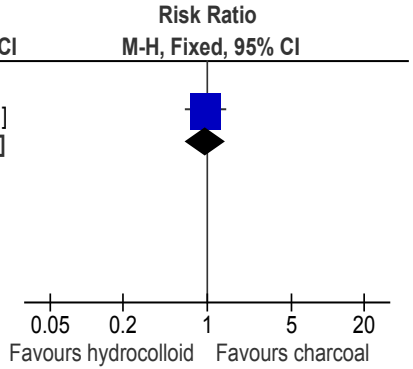


Figure 83 – Hydrocolloid dressing versus phenytoin ointment – mean time to healing (days)

Study or Subgroup	Hydrocolloid Mean	Hydrocolloid SD	Hydrocolloid Total	Phenytoin ointment Mean	Phenytoin ointment SD	Phenytoin ointment Total	Weight	Mean Difference IV, Fixed, 95% CI
12.1.1 Phenytoin ointment								
Rhodes 2001	51.8	19.6	13	35.3	14.3	15	100.0%	16.50 [3.62, 29.38]
Subtotal (95% CI)			**13**			**15**	**100.0%**	**16.50 [3.62, 29.38]**

Heterogeneity: Not applicable

Test for overall effect: Z = 2.51 (P = 0.01)

Test for subgroup differences: Not applicable

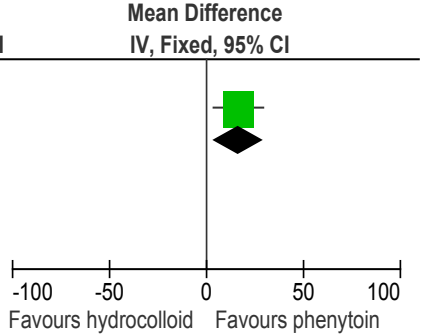
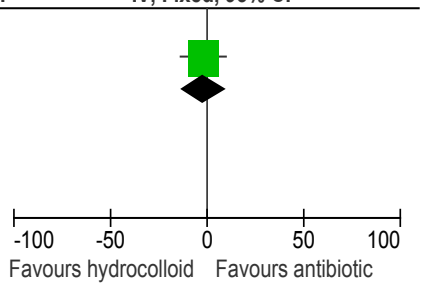


Figure 84 – Hydrocolloid dressing versus antibiotic ointment – mean time to healing (days)

Study or Subgroup	Hydrocolloid Mean	SD	Total	Antibiotic Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
13.1.2 Antiobtic ointment								
Rhodes 2001	51.8	19.6	13	53.8	8.5	11	100.0%	-2.00 [-13.78, 9.78]
Subtotal (95% CI)			**13**			**11**	**100.0%**	**-2.00 [-13.78, 9.78]**

Heterogeneity: Not applicable

Test for overall effect: Z = 0.33 (P = 0.74)



Test for subgroup differences: Not applicable

Figure 85 – Hydrocolloid dressing: triangular shape versus oval shape – proportion of patients completely healed

Study or Subgroup	Triangular Events	Total	Oval Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Day 1995	17	47	11	49	100.0%	1.61 [0.85, 3.07]
Total (95% CI)		**47**		**49**	**100.0%**	**1.61 [0.85, 3.07]**
Total events	17		11			

Heterogeneity: Not applicable

Test for overall effect: Z = 1.45 (P = 0.15)

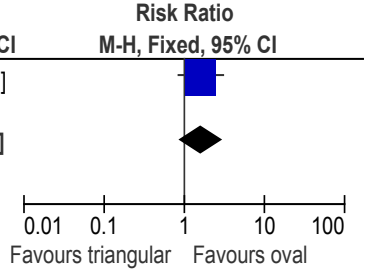


Figure 86 – Hydrocolloid dressing: triangular shape versus oval shape – proportion of patients improved

Study or Subgroup	Triangular Events	Total	Oval Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Day 1995	41	47	31	49	100.0%	1.38 [1.08, 1.75]
Total (95% CI)		**47**		**49**	**100.0%**	**1.38 [1.08, 1.75]**
Total events	41		31			

Heterogeneity: Not applicable

Test for overall effect: Z = 2.63 (P = 0.009)

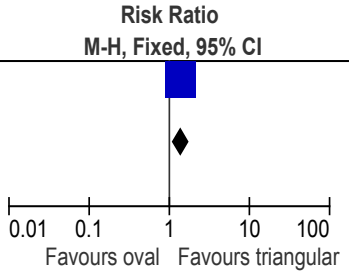


Figure 87 – Hydrocolloid dressing: triangular shape versus oval shape – proportion of patients not changed

Study or Subgroup	Triangular Events	Triangular Total	Oval Events	Oval Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Day 1995	4	47	3	49	100.0%	1.39 [0.33, 5.88]
Total (95% CI)		**47**		**49**	**100.0%**	**1.39 [0.33, 5.88]**
Total events	4		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.45 (P = 0.65)

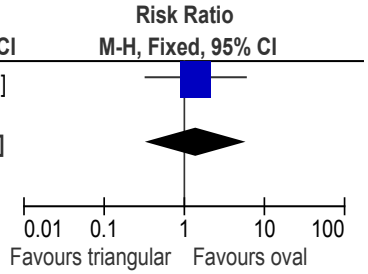


Figure 88 – Hydrocolloid dressing: triangular shape versus oval shape – proportion of patients worsened

Study or Subgroup	Triangular Events	Triangular Total	Oval Events	Oval Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Day 1995	2	47	15	49	100.0%	0.14 [0.03, 0.58]
Total (95% CI)		**47**		**49**	**100.0%**	**0.14 [0.03, 0.58]**
Total events	2		15			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.72 (P = 0.006)

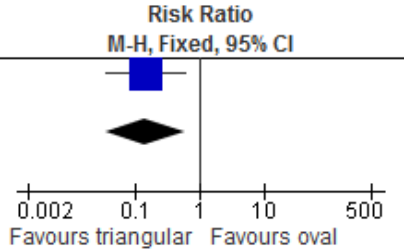


Figure 89 – Hydrocolloid dressing: triangular shape versus oval shape – mean percentage reduction in ulcer length

Study or Subgroup	Triangular Mean	Triangular SD	Triangular Total	Oval Mean	Oval SD	Oval Total	Weight	Mean Difference IV, Fixed, 95% CI
Day 1995	32	34.15	47	17	34.15	49	100.0%	15.00 [1.33, 28.67]
Total (95% CI)			**47**			**49**	**100.0%**	**15.00 [1.33, 28.67]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.15 (P = 0.03)

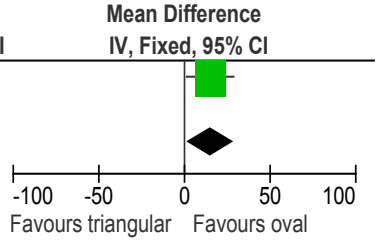


Figure 90 – Hydrocolloid dressing: triangular shape versus oval shape – mean pain at dressing change

	Triangular			Oval				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Day 1995	2.1	2.1	47	4.3	1.75	49	100.0%	-2.20 [-2.97, -1.43]	
Total (95% CI)			**47**			**49**	**100.0%**	**-2.20 [-2.97, -1.43]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 5.56 (P < 0.00001)

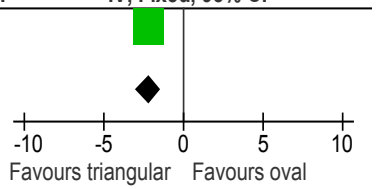


Figure 91 – Hydrocolloid dressing: triangular shape versus oval shape – proportion of patients with ulcer pain

	Triangular		Oval			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Day 1995	8	47	15	49	100.0%	0.56 [0.26, 1.19]	
Total (95% CI)		**47**		**49**	**100.0%**	**0.56 [0.26, 1.19]**	
Total events	8		15				

Heterogeneity: Not applicable
Test for overall effect: Z = 1.52 (P = 0.13)

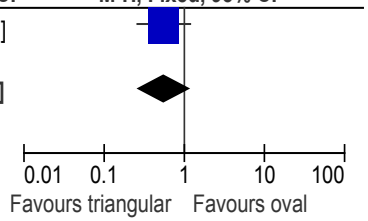


Figure 92 – Hydrocolloid dressing: triangular shape versus oval shape – proportion of patients with adverse events

	Triangular		Oval			Peto Odds Ratio	Peto Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	Peto, Fixed, 95% CI	Peto, Fixed, 95% CI
Day 1995	0	47	4	49	100.0%	0.13 [0.02, 0.97]	
Total (95% CI)		**47**		**49**	**100.0%**	**0.13 [0.02, 0.97]**	
Total events	0		4				

Heterogeneity: Not applicable
Test for overall effect: Z = 1.99 (P = 0.05)

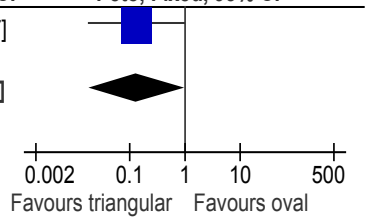


Figure 93 – Hydrocolloid dressing: Comfeel® versus Comfeel®Plus – proportion of patients with dressing intolerance

Study or Subgroup	Comfeel Events	Comfeel Total	ComfeelPlus Events	ComfeelPlus Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Routkovsky-Norval 1996	2	31	3	30	100.0%	0.65 [0.12, 3.59]
Total (95% CI)		**31**		**30**	**100.0%**	**0.65 [0.12, 3.59]**
Total events	2		3			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.50 (P = 0.62)						

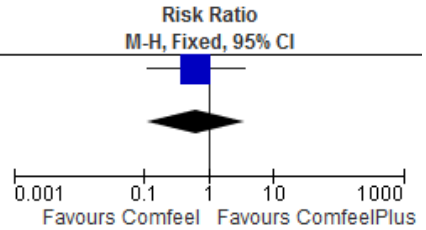


Figure 94 – Hydrocolloid dressing: Comfeel® versus Comfeel®Plus – proportion of patients reporting the dressing as good to excellent for comfort at dressing change

Study or Subgroup	Comfeel Events	Comfeel Total	ComfeelPlus Events	ComfeelPlus Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Routkovsky-Norval 1996	142	167	150	166	100.0%	0.94 [0.87, 1.02]
Total (95% CI)		**167**		**166**	**100.0%**	**0.94 [0.87, 1.02]**
Total events	142		150			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.48 (P = 0.14)						

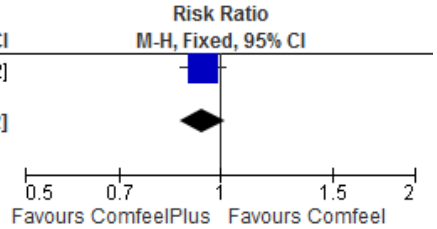


Figure 95 – Hydrocolloid dressing: SingaDress® versus Comfeel®Plus – proportion of patients completely healed

Study or Subgroup	SingaDress Events	SingaDress Total	ComfeelPlus Events	ComfeelPlus Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Seaman 2000	6	17	1	18	100.0%	6.35 [0.85, 47.44]
Total (95% CI)		**17**		**18**	**100.0%**	**6.35 [0.85, 47.44]**
Total events	6		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.80 (P = 0.07)						

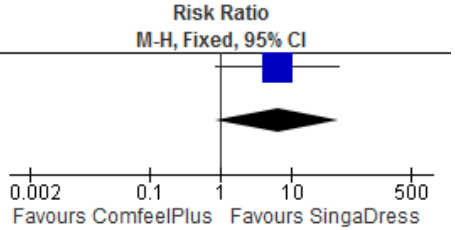


Figure 96 – Gauze dressing versus foam dressing – proportion of patients completely healed

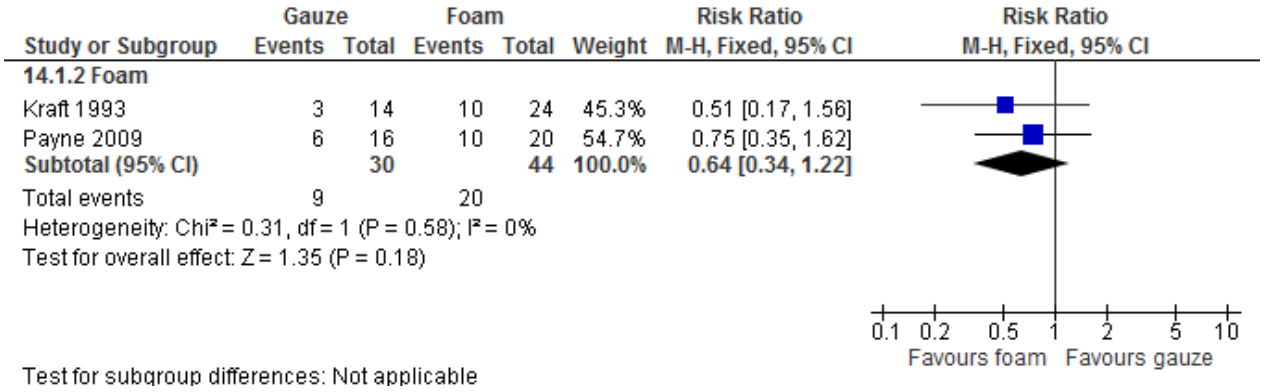


Figure 97 – Gauze dressing versus polyurethane film – proportion of ulcers completely healed (all stages)

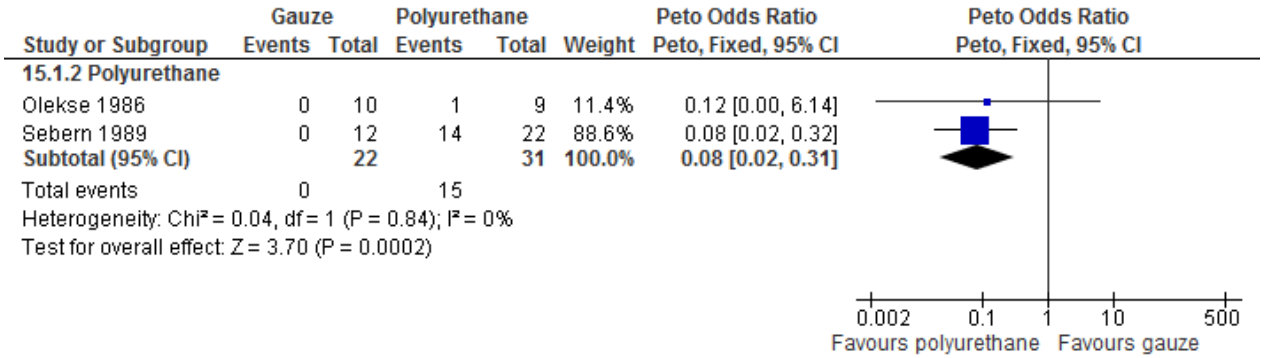


Figure 98 – Gauze dressing versus polyurethane film – proportion of ulcers completely healed (stage II)

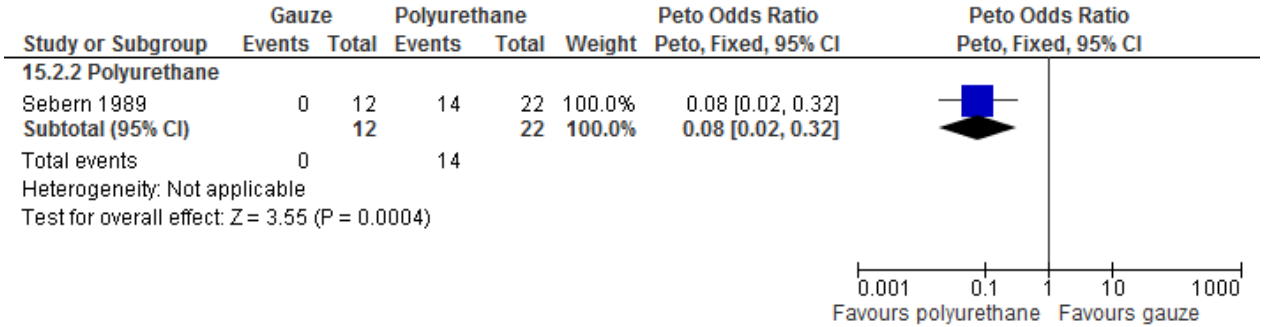


Figure 99 – Gauze dressing versus polyurethane film – proportion of ulcers worsened

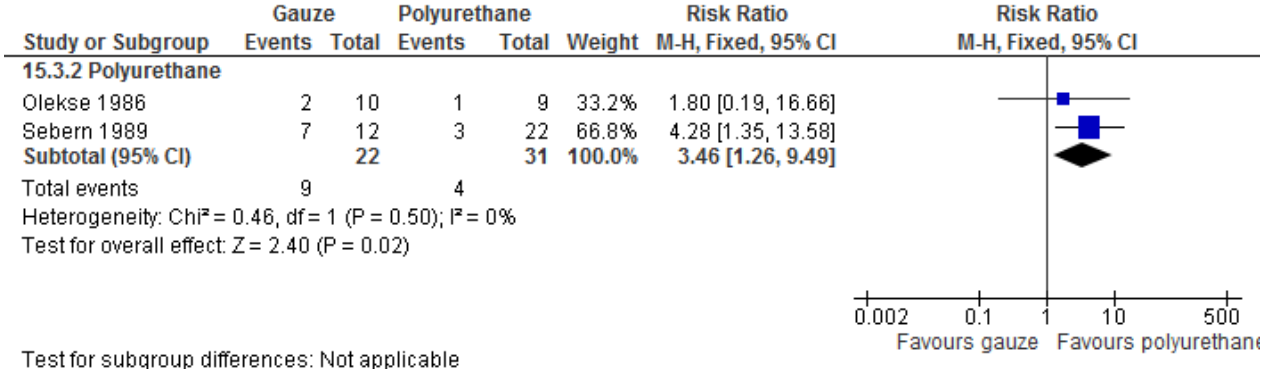


Figure 100 – Gauze dressing versus polyurethane dressing – proportion of ulcers decreased in ulcer stage (stage II)

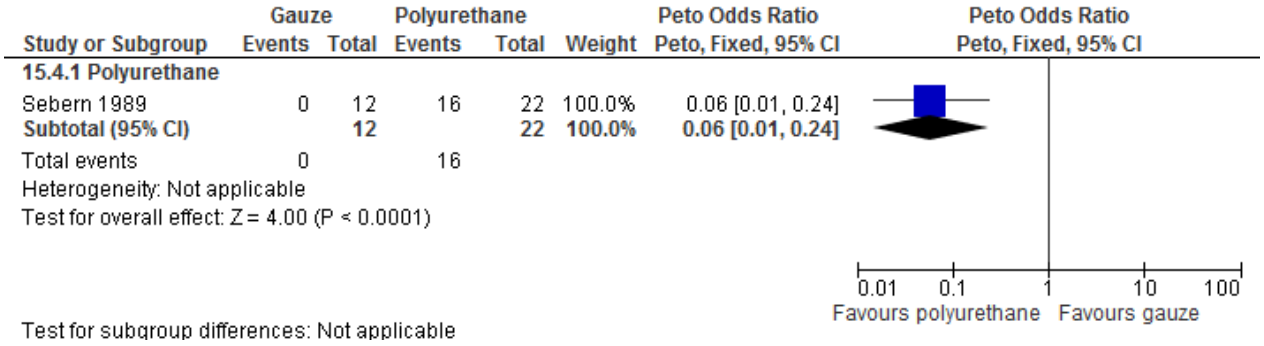


Figure 101 – Gauze dressing versus polyurethane film – proportion of ulcers increased in ulcer stage (stage II)

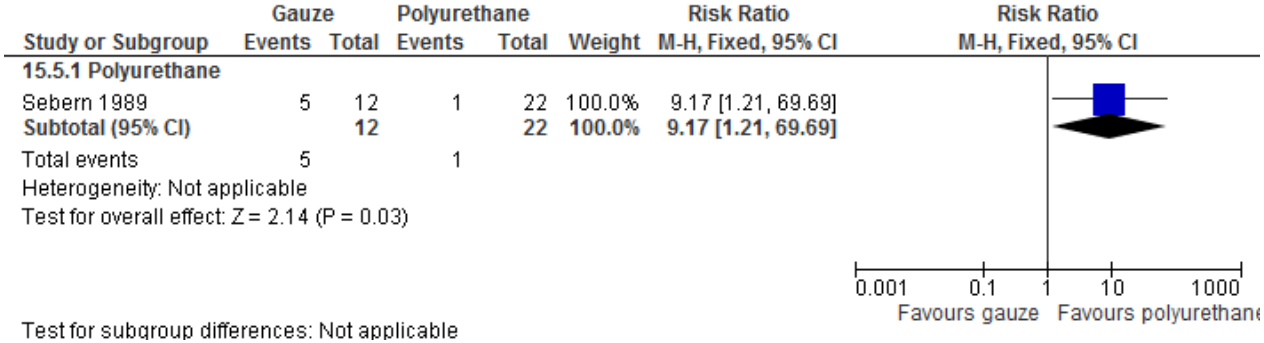
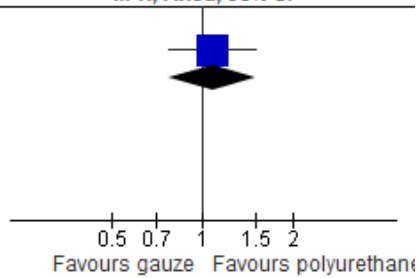


Figure 102 – Gauze dressing versus polyurethane film – proportion of patients with maceration

Study or Subgroup	Gauze Events	Gauze Total	Polyurethane Events	Polyurethane Total	Weight	Risk Ratio M-H, Fixed, 95% CI
15.9.1 Polyurethane						
Sebern 1989	10	12	17	22	100.0%	1.08 [0.77, 1.51]
Subtotal (95% CI)		**12**		**22**	**100.0%**	**1.08 [0.77, 1.51]**
Total events	10		17			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.44 (P = 0.66)

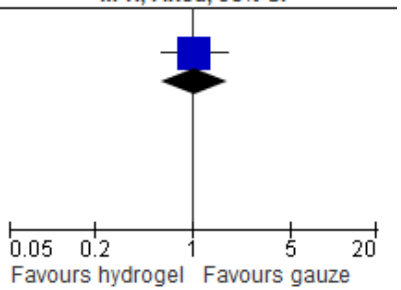


Test for subgroup differences: Not applicable

Figure 103 – Gauze dressing versus hydrogel – proportion of patients completely healed

Study or Subgroup	Gauze Events	Gauze Total	Hydrogel Events	Hydrogel Total	Weight	Risk Ratio M-H, Fixed, 95% CI
16.1.3 Hydrogel						
Thomas 1998	9	14	10	16	100.0%	1.03 [0.60, 1.77]
Subtotal (95% CI)		**14**		**16**	**100.0%**	**1.03 [0.60, 1.77]**
Total events	9		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.10 (P = 0.92)



Test for subgroup differences: Not applicable

Figure 104 – Gauze dressing versus hydrogel – proportion of patients worsened

Study or Subgroup	Gauze Events	Gauze Total	Hydrogel Events	Hydrogel Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Thomas 1998	1	19	1	22	100.0%	1.16 [0.08, 17.28]
Total (95% CI)		**19**		**22**	**100.0%**	**1.16 [0.08, 17.28]**
Total events	1		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.11 (P = 0.92)

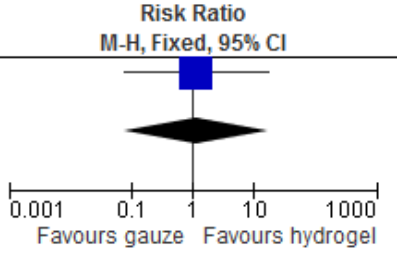


Figure 105 – Gauze dressing versus hydrogel – mean percentage reduction in ulcer area

Study or Subgroup	Gauze Mean	Gauze SD	Gauze Total	Hydrogel Mean	Hydrogel SD	Hydrogel Total	Weight	Mean Difference IV, Fixed, 95% CI
16.3.1 Hydrogel								
Mulder 1993	5.1	14.8	20	8	14.8	20	100.0%	-2.90 [-12.07, 6.27]
Subtotal (95% CI)			**20**			**20**	**100.0%**	**-2.90 [-12.07, 6.27]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.62 (P = 0.54)

Test for subgroup differences: Not applicable

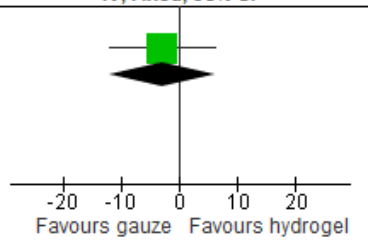


Figure 106 – Gauze dressing versus hydrogel – mean healing rate (cm²/day)

Study or Subgroup	Gauze Mean	Gauze SD	Gauze Total	Hydrogel Mean	Hydrogel SD	Hydrogel Total	Weight	Mean Difference IV, Fixed, 95% CI
16.5.2 Hydrogel								
Kaya 2005	0.12	0.16	15	0.09	0.05	12	100.0%	0.03 [-0.06, 0.12]
Subtotal (95% CI)			**15**			**12**	**100.0%**	**0.03 [-0.06, 0.12]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.69 (P = 0.49)

Test for subgroup differences: Not applicable

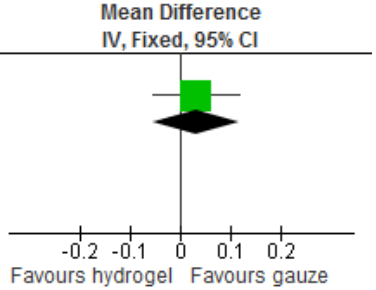


Figure 107 – Gauze dressing versus hydrogel – mean time to healing (weeks)

Study or Subgroup	Gauze Mean	Gauze SD	Gauze Total	Hydrogel Mean	Hydrogel SD	Hydrogel Total	Weight	Mean Difference IV, Fixed, 95% CI
Thomas 1998	5.2	2.4	14	5.3	2.3	16	100.0%	-0.10 [-1.79, 1.59]
Total (95% CI)			**14**			**16**	**100.0%**	**-0.10 [-1.79, 1.59]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.12 (P = 0.91)

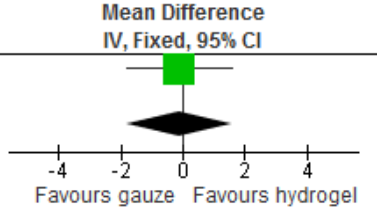
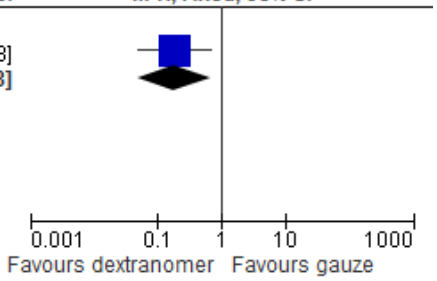


Figure 108 – Gauze dressing versus dextranomer – proportion of ulcers improved

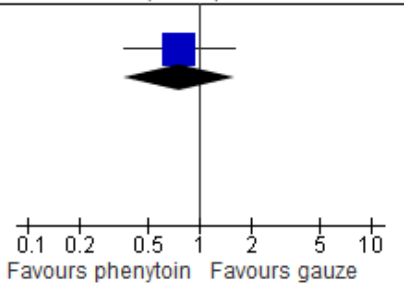
Study or Subgroup	Gauze Events	Gauze Total	Dextranomer Events	Dextranomer Total	Weight	Risk Ratio M-H, Fixed, 95% CI
17.1.1 Dextranomer						
Ljungberg 2009	2	15	11	15	100.0%	0.18 [0.05, 0.68]
Subtotal (95% CI)		**15**		**15**	**100.0%**	**0.18 [0.05, 0.68]**
Total events	2		11			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.52 (P = 0.01)						



Test for subgroup differences: Not applicable

Figure 109 – Gauze dressing versus phenytoin cream – proportion of patients completely healed

Study or Subgroup	Gauze Events	Gauze Total	Phenytoin Events	Phenytoin Total	Weight	Risk Ratio M-H, Fixed, 95% CI
18.1.1 Phenytoin cream						
Hollisaz 2004	8	27	11	28	100.0%	0.75 [0.36, 1.58]
Subtotal (95% CI)		**27**		**28**	**100.0%**	**0.75 [0.36, 1.58]**
Total events	8		11			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.75 (P = 0.46)						



Test for subgroup differences: Not applicable

Figure 110 – Gauze dressing versus phenytoin cream – proportion of ulcers completely healed (all stages – all sites)

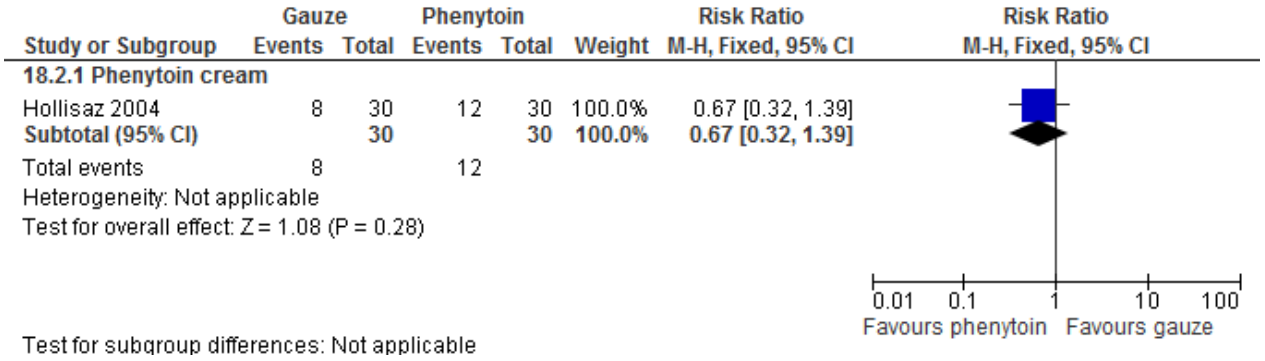


Figure 111 – Gauze dressing versus phenytoin cream – proportion of ulcers completely healed (stage I – all sites)

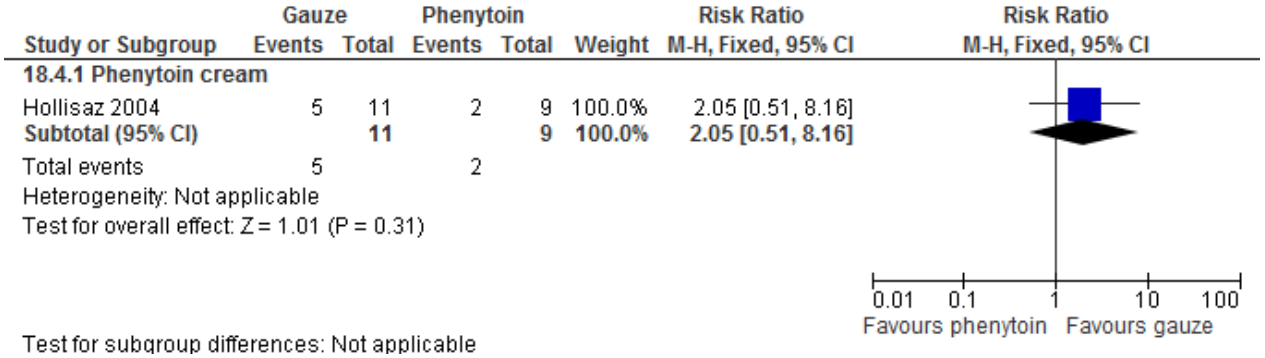


Figure 112 – Gauze dressing versus phenytoin cream – proportion of ulcers completely healed (stage II – all sites)

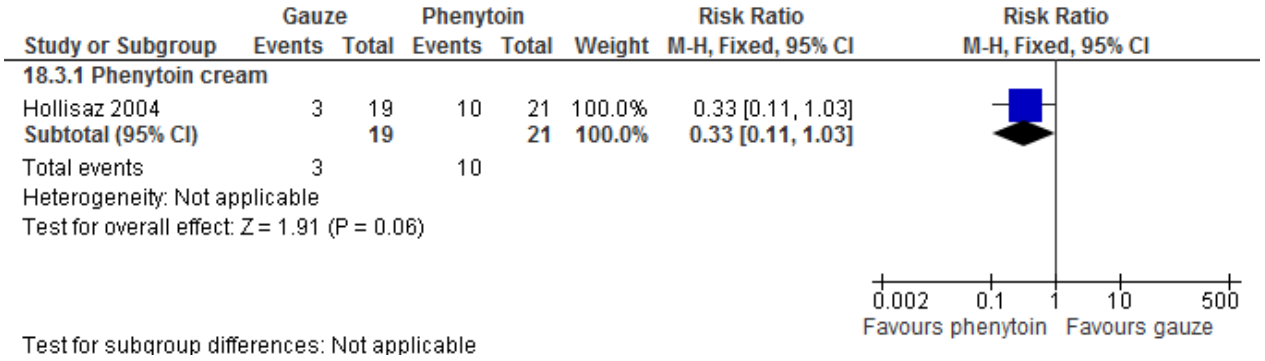


Figure 113 – Gauze dressing versus phenytoin cream – proportion of ulcers completely healed (all stages – sacral)

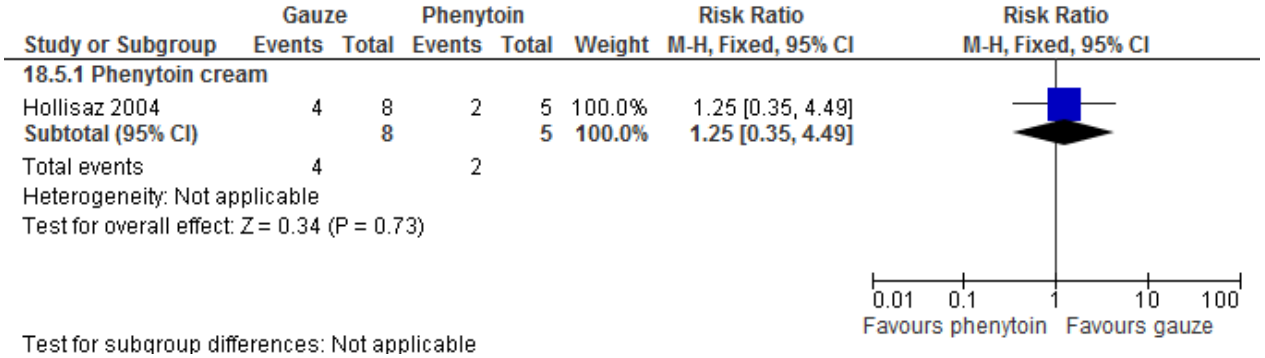


Figure 114 – Gauze dressing versus phenytoin cream – proportion of ulcers improved

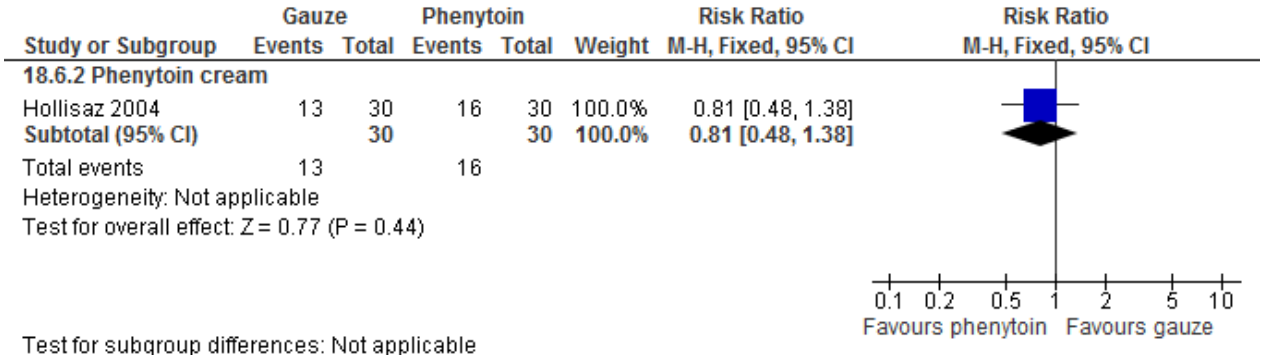


Figure 115 – Gauze dressing versus phenytoin cream – proportion of ulcers worsened

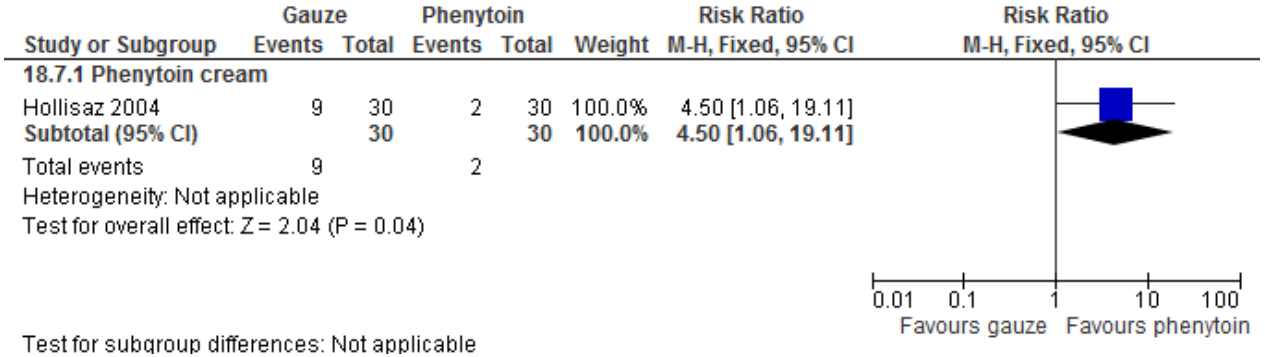
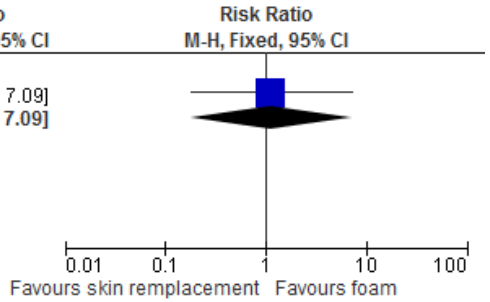


Figure 116 – Foam dressing versus skin replacement – proportion of patients completely healed

Study or Subgroup	Foam Events	Foam Total	Skin remplacement Events	Skin remplacement Total	Weight	Risk Ratio M-H, Fixed, 95% CI
19.1.1 Skin replacement						
Payne 2004	2	16	2	18	100.0%	1.13 [0.18, 7.09]
Subtotal (95% CI)		**16**		**18**	**100.0%**	**1.13 [0.18, 7.09]**
Total events	2		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.13 (P = 0.90)

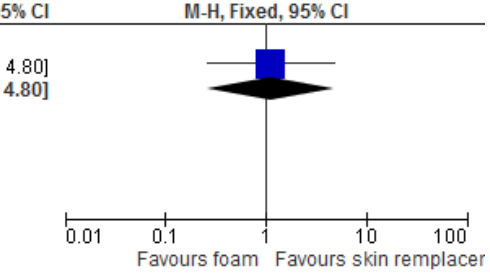


Test for subgroup differences: Not applicable

Figure 117 – Foam dressing versus skin replacement – proportion of patients with an infection

Study or Subgroup	Foam Events	Foam Total	Skin remplacement Events	Skin remplacement Total	Weight	Risk Ratio M-H, Fixed, 95% CI
19.6.1 Skin replacement						
Payne 2004	3	16	3	18	100.0%	1.13 [0.26, 4.80]
Subtotal (95% CI)		**16**		**18**	**100.0%**	**1.13 [0.26, 4.80]**
Total events	3		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.16 (P = 0.87)

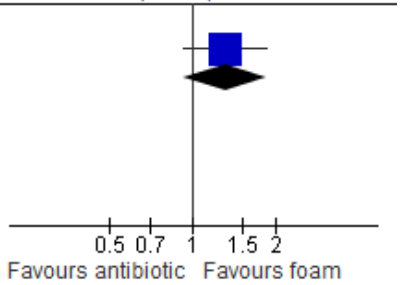


Test for subgroup differences: Not applicable

Figure 118 – Foam dressing versus antibiotic ointment – proportion of patients completely healed

Study or Subgroup	Foam Events	Foam Total	Antibiotic Events	Antibiotic Total	Weight	Risk Ratio M-H, Fixed, 95% CI
20.1.4 Antibiotic ointment						
Yastrub 2004	18	21	15	23	100.0%	1.31 [0.93, 1.86]
Subtotal (95% CI)		**21**		**23**	**100.0%**	**1.31 [0.93, 1.86]**
Total events	18		15			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.55 (P = 0.12)



Test for subgroup differences: Not applicable

Figure 119 – Foam dressing: Allevyn® versus Biatain® – proportion of patients completely healed

Study or Subgroup	Allevyn Events	Allevyn Total	Biatian Events	Biatian Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Amoine 2005	11	14	5	18	100.0%	2.83 [1.28, 6.25]
Total (95% CI)		**14**		**18**	**100.0%**	**2.83 [1.28, 6.25]**
Total events	11		5			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.57 (P = 0.01)

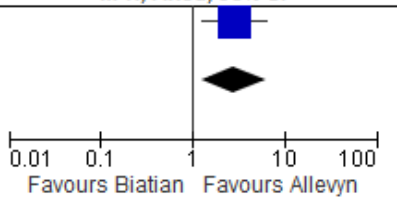


Figure 120 – Foam dressing: Allevyn® versus Biatain® – mean comfort score at dressing removal

Study or Subgroup	Allevyn Mean	Allevyn SD	Allevyn Total	Biatian Mean	Biatian SD	Biatian Total	Weight	Mean Difference IV, Fixed, 95% CI
Amoine 2005	1.84	0.26	14	2.11	0.26	18	100.0%	-0.27 [-0.45, -0.09]
Total (95% CI)			**14**			**18**	**100.0%**	**-0.27 [-0.45, -0.09]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.91 (P = 0.004)

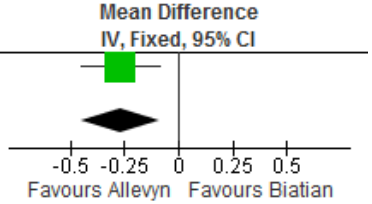


Figure 121 – Foam dressing: Allevyn® versus Biatain® – proportion of patients with dressing related adverse events

Study or Subgroup	Allevyn Events	Allevyn Total	Biatian Events	Biatian Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Amoine 2005	1	14	4	18	100.0%	0.32 [0.04, 2.57]
Total (95% CI)		**14**		**18**	**100.0%**	**0.32 [0.04, 2.57]**
Total events	1		4			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.07 (P = 0.28)

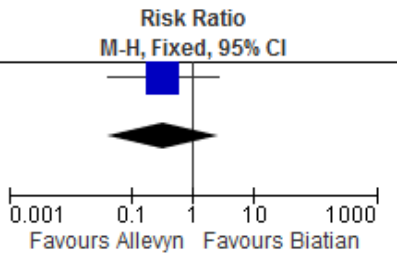


Figure 122 – Foam dressing: Mepilex® versus Tielle® – proportion of patients completely healed

Study or Subgroup	Mepilex Events	Mepilex Total	Tielle Events	Tielle Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Meaume 2003	8	18	10	20	100.0%	0.89 [0.45, 1.75]
Total (95% CI)		**18**		**20**	**100.0%**	**0.89 [0.45, 1.75]**
Total events	8		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.34 (P = 0.73)

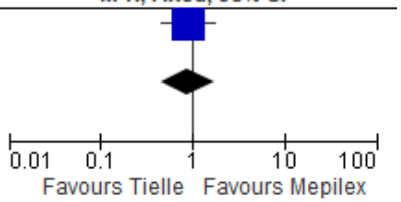


Figure 123 – Foam dressing: Mepilex® versus Tielle® – proportion of patients improved

Study or Subgroup	Mepilex Events	Mepilex Total	Tielle Events	Tielle Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Meaume 2003	15	18	19	20	100.0%	0.88 [0.70, 1.10]
Total (95% CI)		**18**		**20**	**100.0%**	**0.88 [0.70, 1.10]**
Total events	15		19			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.12 (P = 0.26)

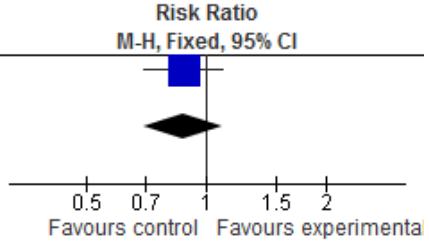


Figure 124 – Foam dressing: Mepilex® versus Tielle® – proportion of patients worsened

Study or Subgroup	Mepilex Events	Mepilex Total	Tielle Events	Tielle Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Meaume 2003	2	18	1	20	100.0%	2.22 [0.22, 22.49]
Total (95% CI)		**18**		**20**	**100.0%**	**2.22 [0.22, 22.49]**
Total events	2		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.68 (P = 0.50)

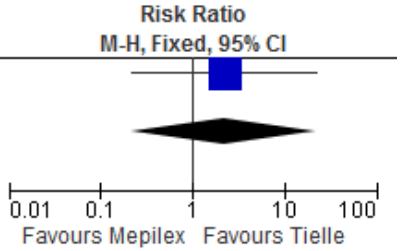


Figure 125 – Foam dressing: Mepilex® versus Tielle® – proportion of patients with maceration

Study or Subgroup	Mepilex Events	Mepilex Total	Tielle Events	Tielle Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Meaume 2003	0	18	3	20	100.0%	0.13 [0.01, 1.38]
Total (95% CI)		**18**		**20**	**100.0%**	**0.13 [0.01, 1.38]**
Total events	0		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.69 (P = 0.09)

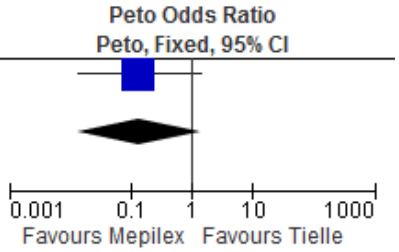


Figure 126 – Foam dressing: Mepilex® versus Tielle® – proportion of patients reporting odour

Study or Subgroup	Mepilex Events	Mepilex Total	Tielle Events	Tielle Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Meaume 2003	0	18	3	20	100.0%	0.13 [0.01, 1.38]
Total (95% CI)		**18**		**20**	**100.0%**	**0.13 [0.01, 1.38]**
Total events	0		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.69 (P = 0.09)

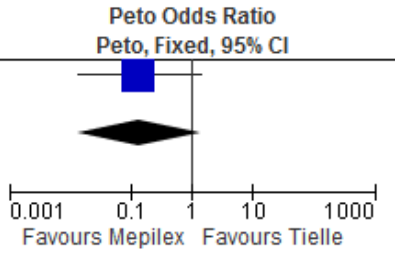


Figure 127 – Foam dressing: Mepilex® versus Tielle® – proportion of patients with adverse events

Study or Subgroup	Mepilex Events	Mepilex Total	Tielle Events	Tielle Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Meaume 2003	1	18	3	20	100.0%	0.37 [0.04, 3.25]
Total (95% CI)		**18**		**20**	**100.0%**	**0.37 [0.04, 3.25]**
Total events	1		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.90 (P = 0.37)

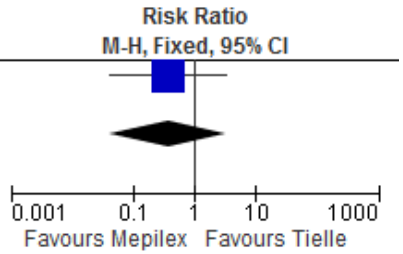
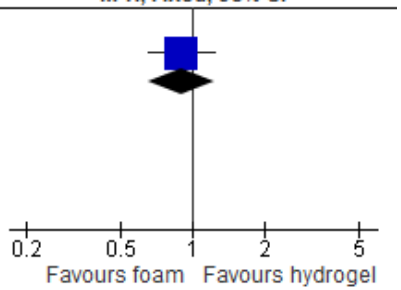


Figure 128 – Hydrogel dressing versus foam dressing – proportion of ulcers completely healed (all stages)

Study or Subgroup	Hydrogel Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
21.1.2 Foam						
Sopata 2002	15	20	15	18	100.0%	0.90 [0.65, 1.25]
Subtotal (95% CI)		**20**		**18**	**100.0%**	**0.90 [0.65, 1.25]**
Total events	15		15			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.63 (P = 0.53)

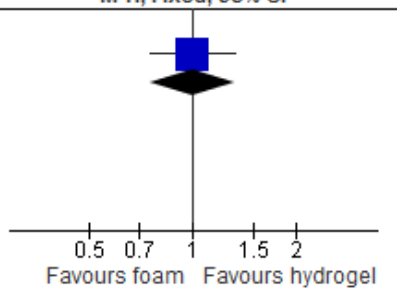


Test for subgroup differences: Not applicable

Figure 129 – Hydrogel dressing versus foam dressing – proportion of ulcers completely healed (stage II)

Study or Subgroup	Hydrogel Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
21.2.1 Foam						
Sopata 2002	6	6	6	6	100.0%	1.00 [0.75, 1.34]
Subtotal (95% CI)		**6**		**6**	**100.0%**	**1.00 [0.75, 1.34]**
Total events	6		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)

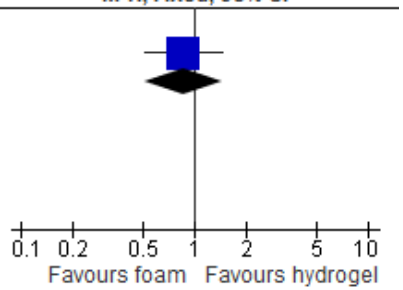


Test for subgroup differences: Not applicable

Figure 130 – Hydrogel dressing versus foam dressing – proportion of ulcers completely healed (stage III)

Study or Subgroup	Hydrogel Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
21.3.1 Foam						
Sopata 2002	9	14	9	12	100.0%	0.86 [0.52, 1.43]
Subtotal (95% CI)		**14**		**12**	**100.0%**	**0.86 [0.52, 1.43]**
Total events	9		9			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.59 (P = 0.55)

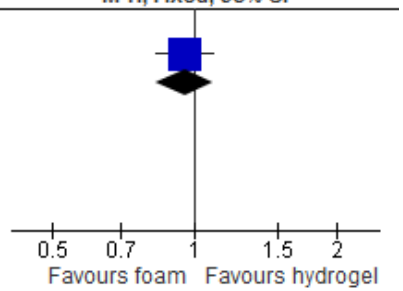


Test for subgroup differences: Not applicable

Figure 131 – Hydrogel dressing versus foam dressing – proportion of ulcers improved (all stages)

Study or Subgroup	Hydrogel Events	Total	Foam Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
21.4.2 Foam						
Sopata 2002	19	20	18	18	100.0%	0.95 [0.83, 1.10]
Subtotal (95% CI)		**20**		**18**	**100.0%**	**0.95 [0.83, 1.10]**
Total events	19		18			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.67 (P = 0.51)



Test for subgroup differences: Not applicable

Figure 132 – Hydrogel dressing versus foam dressing – proportion of ulcers improved (stage II)

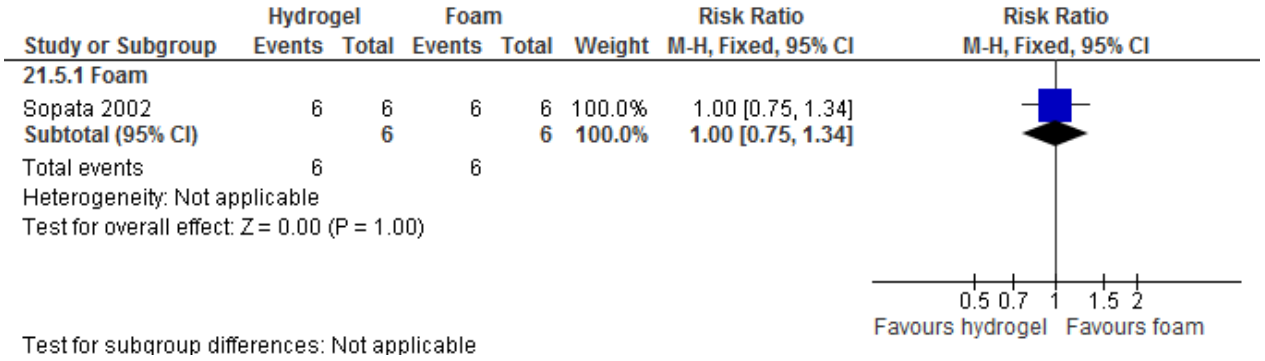


Figure 133 – Hydrogel dressing versus foam dressing – proportion of ulcers improved (stage III)

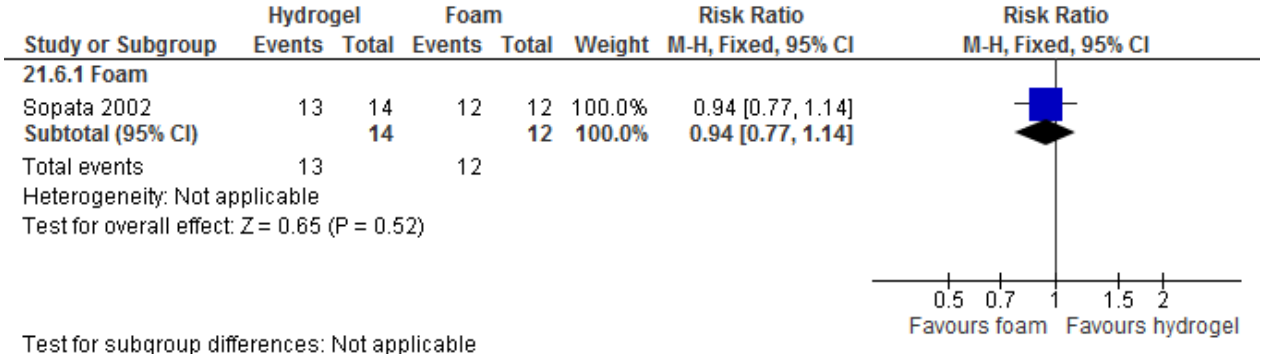
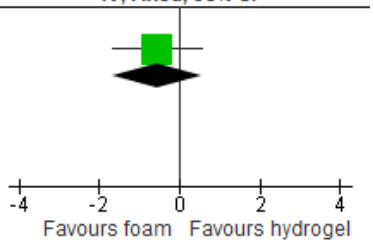


Figure 134 – Hydrogel dressing versus foam dressing – mean rate of healing of healed ulcers (cm²/day) (grade II)

Study or Subgroup	Hydrogel Mean	SD	Total	Foam Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
21.7.1 Foam								
Sopata 2002	0.67	0.37	6	1.23	1.33	6	100.0%	-0.56 [-1.66, 0.54]
Subtotal (95% CI)			**6**			**6**	**100.0%**	**-0.56 [-1.66, 0.54]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.99 (P = 0.32)

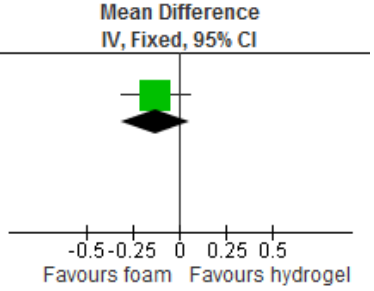


Test for subgroup differences: Not applicable

Figure 135 – Hydrogel dressing versus foam dressing – mean rate of healing of healed ulcers (cm²/day) (grade III)

Study or Subgroup	Hydrogel Mean	SD	Total	Foam Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
21.8.1 Foam								
Sopata 2002	0.31	0.21	14	0.44	0.27	12	100.0%	-0.13 [-0.32, 0.06]
Subtotal (95% CI)			**14**			**12**	**100.0%**	**-0.13 [-0.32, 0.06]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.35 (P = 0.18)

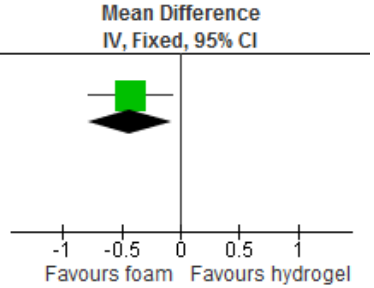


Test for subgroup differences: Not applicable

Figure 136 – Hydrogel dressing versus foam dressing – mean rate of healing of improved ulcers (cm²/day) (grade III)

Study or Subgroup	Hydrogel Mean	SD	Total	Foam Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
21.9.1 Foam								
Sopata 2002	0.27	0.11	14	0.7	0.63	12	100.0%	-0.43 [-0.79, -0.07]
Subtotal (95% CI)			**14**			**12**	**100.0%**	**-0.43 [-0.79, -0.07]**

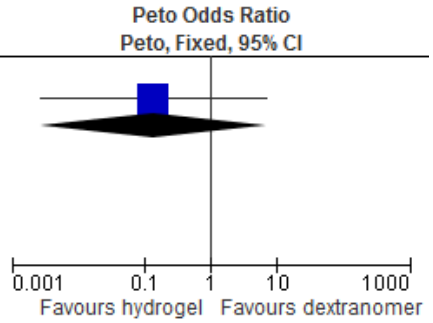
Heterogeneity: Not applicable
Test for overall effect: Z = 2.33 (P = 0.02)



Test for subgroup differences: Not applicable

Figure 137 – Hydrogel dressing versus dextranomer – proportion of patients reporting pain at dressing application

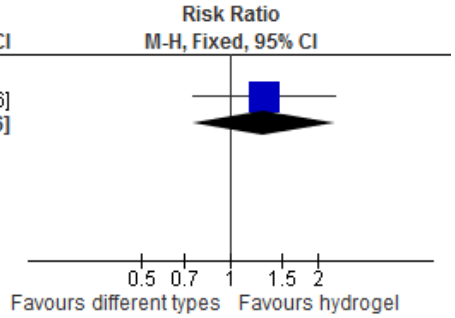
Study or Subgroup	Hydrogel Events	Hydrogel Total	Dextranomer Events	Dextranomer Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
22.2.1 Dextranomer						
Colin 1996	0	67	1	68	100.0%	0.14 [0.00, 6.92]
Subtotal (95% CI)		**67**		**68**	**100.0%**	**0.14 [0.00, 6.92]**
Total events	0		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.99 (P = 0.32)						



Test for subgroup differences: Not applicable

Figure 138 – Hydrogel, foam dressing or transparent film versus different types of dressing – proportion of patients completely healed

Study or Subgroup	Hydrogel Events	Hydrogel Total	Different types Events	Different types Total	Weight	Risk Ratio M-H, Fixed, 95% CI
23.1.3 Different type of dressings						
Small 2002	15	23	9	18	100.0%	1.30 [0.75, 2.26]
Subtotal (95% CI)		**23**		**18**	**100.0%**	**1.30 [0.75, 2.26]**
Total events	15		9			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.95 (P = 0.34)						



Test for subgroup differences: Not applicable

Figure 139 – Hydrogel, foam dressing or transparent film dressing versus different types of dressing – proportion of patients reporting the application of the dressing as comfortable

Study or Subgroup	Hydrogel Events	Hydrogel Total	Different types Events	Different types Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Small 2002	14	14	6	7	100.0%	1.19 [0.84, 1.68]
Total (95% CI)		**14**		**7**	**100.0%**	**1.19 [0.84, 1.68]**
Total events	14		6			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.98 (P = 0.32)						

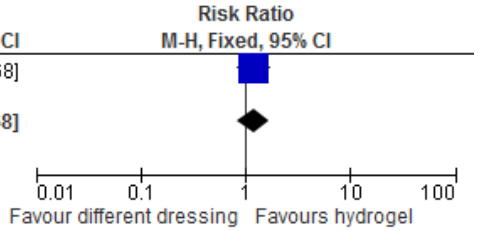


Figure 140 – Hydrogel, foam dressing or transparent film dressing versus different types of dressing – proportion of patients reporting discomfort at dressing removal

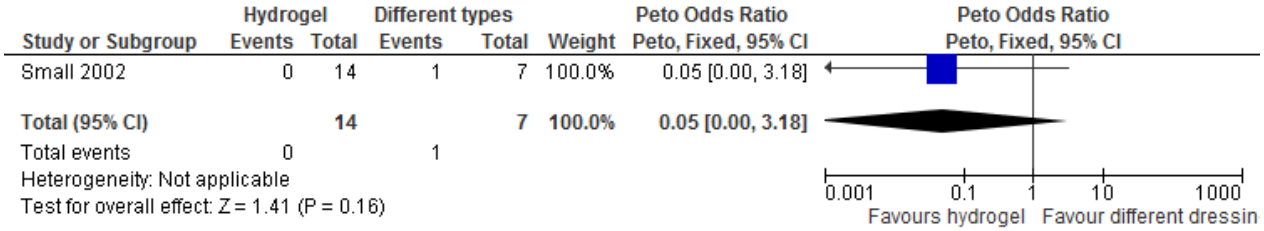


Figure 141 – Hydrogel dressing: Sterigel® versus Intrasite® – proportion of patients with intermittent ulcer pain

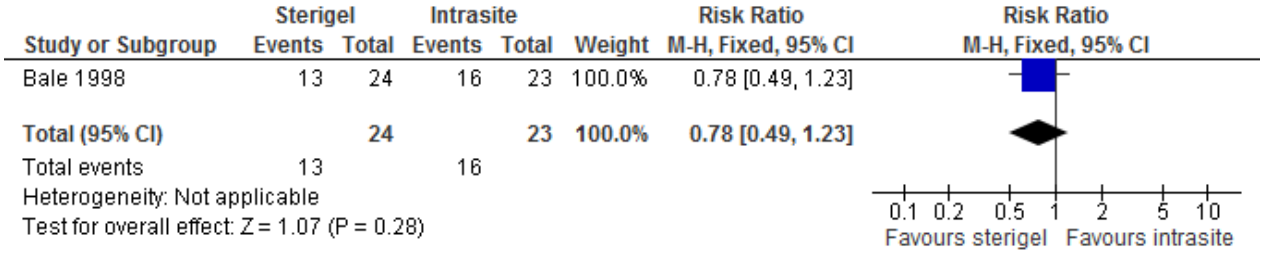


Figure 142 – Hydrogel dressing: Sterigel® versus Intrasite® – proportion of patients with continuous ulcer pain

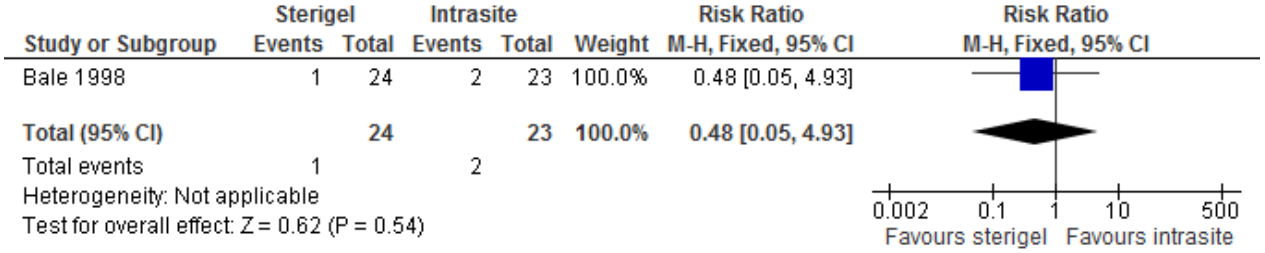


Figure 143 – Hydrogel dressing: Sterigel® versus Intrasite® – proportion of patients with slight pain at dressing removal

Study or Subgroup	Sterigel Events	Sterigel Total	Intrasite Events	Intrasite Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bale 1998	5	22	6	20	100.0%	0.76 [0.27, 2.10]
Total (95% CI)		**22**		**20**	**100.0%**	**0.76 [0.27, 2.10]**
Total events	5		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.53 (P = 0.59)

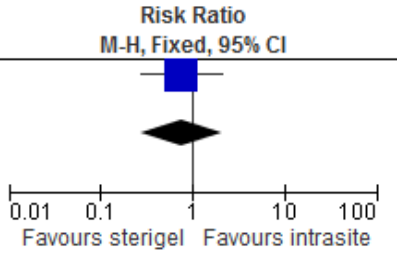


Figure 144 – Hydrogel dressing: Sterigel® versus Intrasite® – proportion of patients with severe pain at dressing removal

Study or Subgroup	Sterigel Events	Sterigel Total	Intrasite Events	Intrasite Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Bale 1998	0	22	1	20	100.0%	0.12 [0.00, 6.20]
Total (95% CI)		**22**		**20**	**100.0%**	**0.12 [0.00, 6.20]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.05 (P = 0.29)

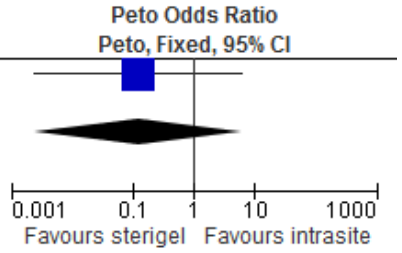


Figure 145 – Hydrogel dressing: Sterigel® versus Intrasite® – proportion of patients with discomfort

Study or Subgroup	Sterigel Events	Sterigel Total	Intrasite Events	Intrasite Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Bale 1998	0	22	1	20	100.0%	0.12 [0.00, 6.20]
Total (95% CI)		**22**		**20**	**100.0%**	**0.12 [0.00, 6.20]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.05 (P = 0.29)

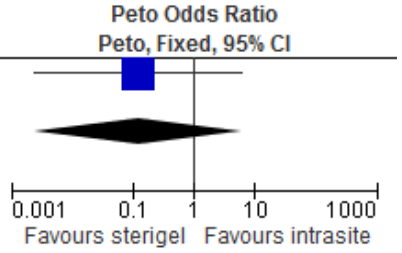


Figure 146 – Hydrogel dressing: Sterigel® versus Intrasite® – proportion of patients with maceration

Study or Subgroup	Sterigel Events	Sterigel Total	Intrasite Events	Intrasite Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bale 1998	8	21	9	17	100.0%	0.72 [0.36, 1.46]
Total (95% CI)		**21**		**17**	**100.0%**	**0.72 [0.36, 1.46]**
Total events	8		9			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.91 (P = 0.36)

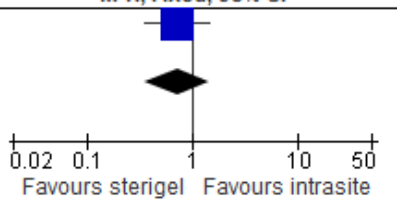


Figure 147 – Protease modulating matrix versus impregnated gauze dressing – proportion of patients completely healed

Study or Subgroup	Collagen Events	Collagen Total	Impregnated gauze Events	Impregnated gauze Total	Weight	Risk Ratio M-H, Fixed, 95% CI
24.1.2 Impregnated gauze						
Nisi 2005	36	40	28	40	100.0%	1.29 [1.02, 1.61]
Subtotal (95% CI)		**40**		**40**	**100.0%**	**1.29 [1.02, 1.61]**
Total events	36		28			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.16 (P = 0.03)

Test for subgroup differences: Not applicable

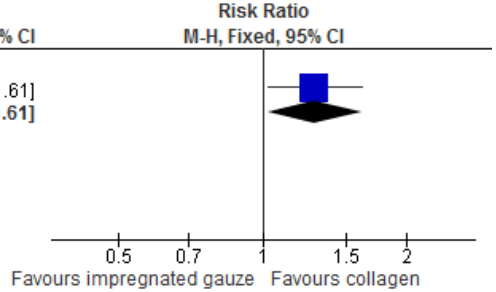


Figure 148 – Protease modulating matrix versus impregnated gauze dressing – proportion of patients with adverse events

Study or Subgroup	Collagen Events	Collagen Total	Impregnated gauze Events	Impregnated gauze Total	Weight	Risk Ratio M-H, Fixed, 95% CI
24.2.2 Impregnated gauze						
Nisi 2005	0	40	0	40		Not estimable
Subtotal (95% CI)		**40**		**40**		**Not estimable**
Total events	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable

Test for subgroup differences: Not applicable

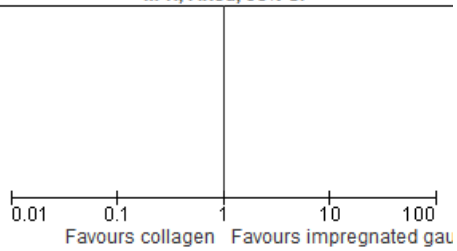
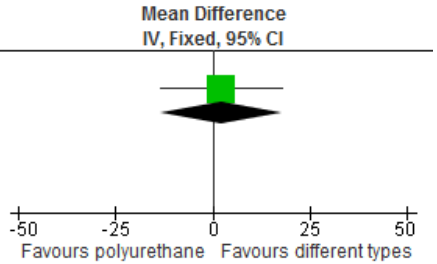


Figure 149 – Polyurethane film versus different types of dressing – mean time to healing (days) (all stages)

Study or Subgroup	Polyurethane Mean	SD	Total	Different types Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
28.1.1 Different types of dressing								
Bito 2012	59.8	29.4	35	57.5	33.5	29	100.0%	2.30 [-13.31, 17.91]
Subtotal (95% CI)			**35**			**29**	**100.0%**	**2.30 [-13.31, 17.91]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.29 (P = 0.77)

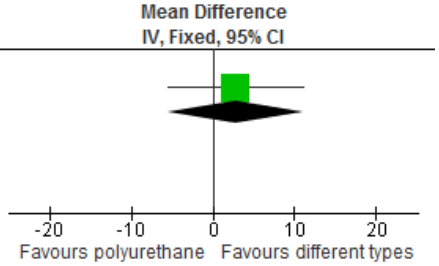


Test for subgroup differences: Not applicable

Figure 150 – Polyurethane film versus different types of dressing – mean time to healing (days) (stage II)

Study or Subgroup	Polyurethane Mean	SD	Total	Different types Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
28.2.1 Different type of dressings								
Bito 2012	18.8	5.3	4	16	9.4	8	100.0%	2.80 [-5.53, 11.13]
Subtotal (95% CI)			**4**			**8**	**100.0%**	**2.80 [-5.53, 11.13]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.66 (P = 0.51)

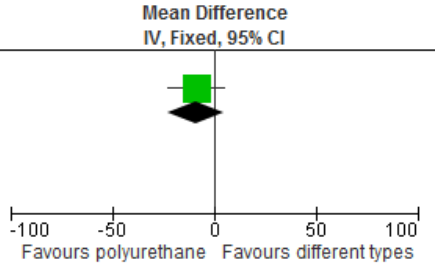


Test for subgroup differences: Not applicable

Figure 151 – Polyurethane film versus different types of dressing – mean time to healing (days) (stage III)

Study or Subgroup	Polyurethane Mean	SD	Total	Different types Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
28.3.1 Different type of dressings								
Bito 2012	63.2	27.8	31	71.8	23	21	100.0%	-8.60 [-22.48, 5.28]
Subtotal (95% CI)			**31**			**21**	**100.0%**	**-8.60 [-22.48, 5.28]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.21 (P = 0.22)



Test for subgroup differences: Not applicable

Figure 152 – Polyurethane film versus different types of dressing – mean difference in PUSH score

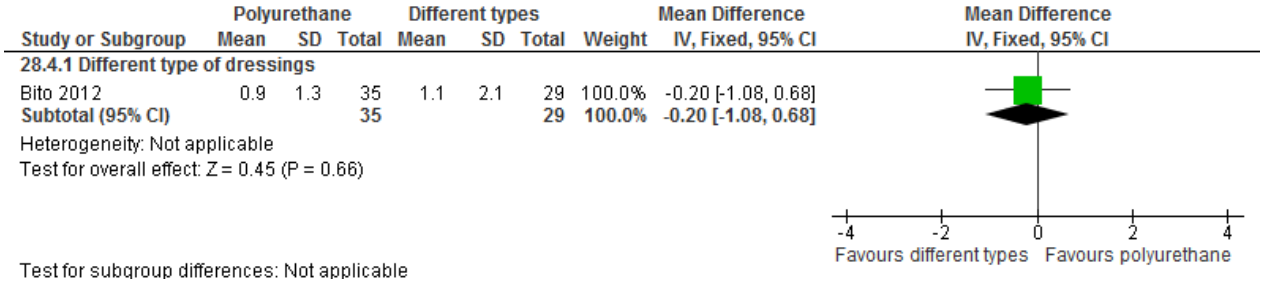


Figure 153 – Polyurethane film versus different types of dressing – proportion of patients with systemic worsening

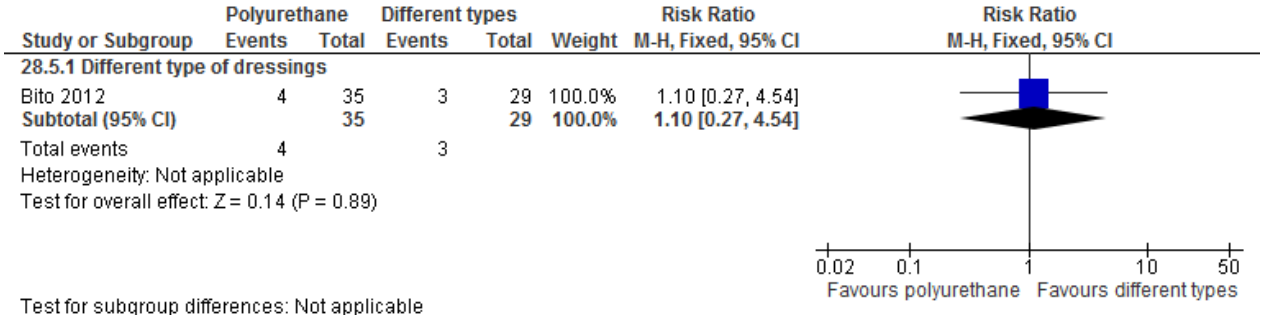


Figure 154 – Polyurethane film versus different types of dressing – proportion of patients with localized adverse events

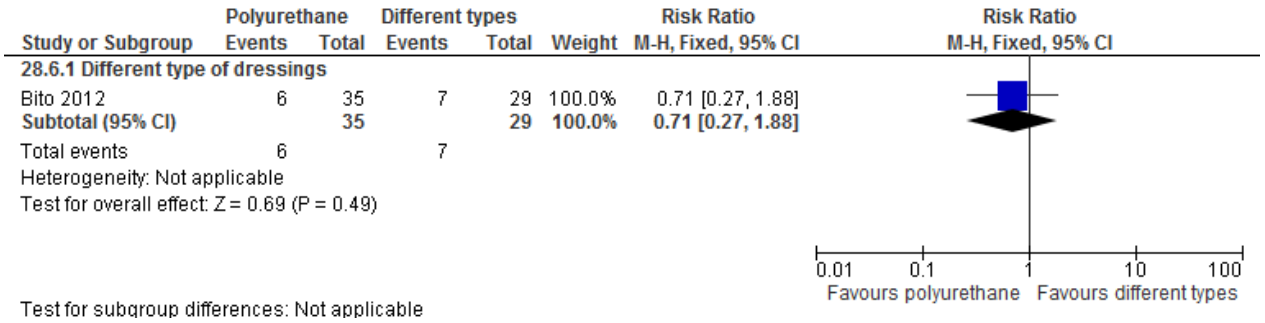
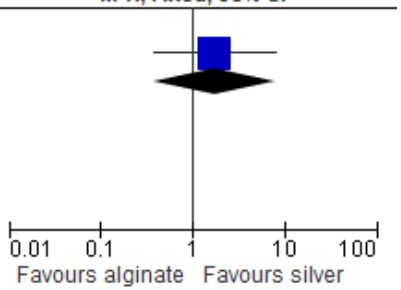


Figure 155 – Alginate dressing versus silver alginate dressing – proportion of patients worsened

Study or Subgroup	Alginate Events	Alginate Total	Silver Events	Silver Total	Weight	Risk Ratio M-H, Fixed, 95% CI
29.1.1 Silver alginate						
Meaume 2005	4	15	2	13	100.0%	1.73 [0.38, 7.98]
Subtotal (95% CI)		**15**		**13**	**100.0%**	**1.73 [0.38, 7.98]**
Total events	4		2			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.71 (P = 0.48)

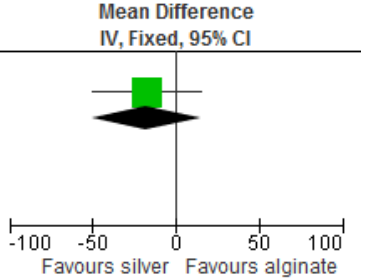


Test for subgroup differences: Not applicable

Figure 156 – Alginate dressing versus silver alginate dressing – mean percentage reduction in ulcer area

Study or Subgroup	Alginate Mean	Alginate SD	Alginate Total	Silver Mean	Silver SD	Silver Total	Weight	Mean Difference IV, Fixed, 95% CI
29.2.2 Silver alginate								
Meaume 2005	13.9	50.3	15	31.6	38.1	13	100.0%	-17.70 [-50.52, 15.12]
Subtotal (95% CI)			**15**			**13**	**100.0%**	**-17.70 [-50.52, 15.12]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.06 (P = 0.29)

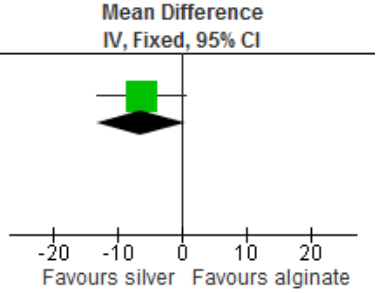


Test for subgroup differences: Not applicable

Figure 157 – Alginate dressing versus silver alginate dressing – absolute cm² decrease in ulcer area

Study or Subgroup	Alginate Mean	Alginate SD	Alginate Total	Silver Mean	Silver SD	Silver Total	Weight	Mean Difference IV, Fixed, 95% CI
29.3.1 Silver alginate								
Meaume 2005	0.8	10	15	7.2	9	13	100.0%	-6.40 [-13.44, 0.64]
Subtotal (95% CI)			**15**			**13**	**100.0%**	**-6.40 [-13.44, 0.64]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.78 (P = 0.07)



Test for subgroup differences: Not applicable

Figure 158 – Alginate dressing versus silver alginate dressing – mean rate of healing (cm²/day)

	Alginate			Silver				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
29.4.1 Silver alginate									
Meaume 2005	0.03	0.36	15	0.26	0.32	13	100.0%	-0.23 [-0.48, 0.02]	
Subtotal (95% CI)			**15**			**13**	**100.0%**	**-0.23 [-0.48, 0.02]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 1.79 (P = 0.07)

Test for subgroup differences: Not applicable

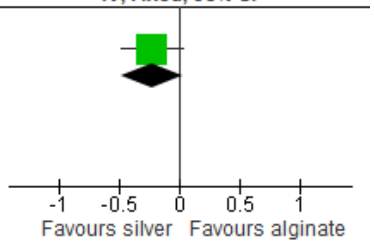


Figure 159 – Alginate dressing versus silver alginate dressing – proportion of patients with an infection

	Alginate		Silver			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
29.5.2 Silver alginate							
Meaume 2005	2	15	1	13	100.0%	1.73 [0.18, 16.99]	
Subtotal (95% CI)		**15**		**13**	**100.0%**	**1.73 [0.18, 16.99]**	
Total events	2		1				

Heterogeneity: Not applicable
Test for overall effect: Z = 0.47 (P = 0.64)

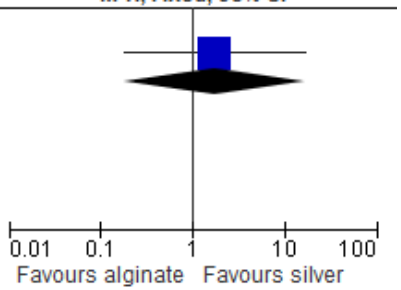


Figure 160 – Alginate dressing versus silver alginate dressing – mean mASEPSIS index at end of treatment

	Alginate			Silver				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
29.7.1 Silver alginate									
Meaume 2005	115.3	80.2	15	81.8	45.1	13	100.0%	33.50 [-13.92, 80.92]	
Subtotal (95% CI)			**15**			**13**	**100.0%**	**33.50 [-13.92, 80.92]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 1.38 (P = 0.17)

Test for subgroup differences: Not applicable

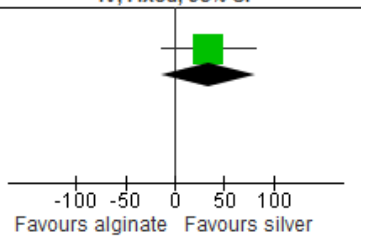
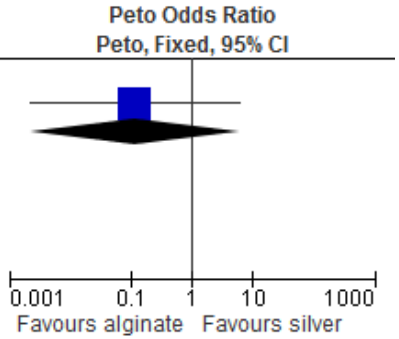


Figure 161 – Alginate dressing versus silver alginate dressing – proportion of patients with poor acceptability and/or tolerability

Study or Subgroup	Alginate Events	Alginate Total	Silver Events	Silver Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
29.8.1 Silver alginate						
Meaume 2005	0	15	1	13	100.0%	0.12 [0.00, 5.91]
Subtotal (95% CI)		**15**		**13**	**100.0%**	**0.12 [0.00, 5.91]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.07 (P = 0.28)

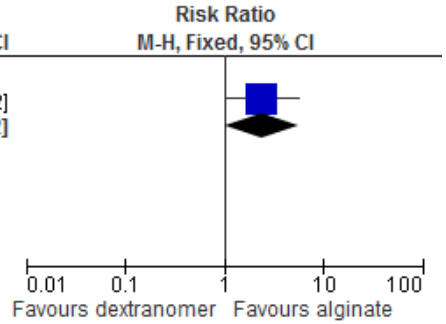


Test for subgroup differences: Not applicable

Figure 162 – Alginate dressing versus dextranomer – proportion of patients with > 75% reduction in ulcer area

Study or Subgroup	Alginate Events	Alginate Total	Dextranomer Events	Dextranomer Total	Weight	Risk Ratio M-H, Fixed, 95% CI
30.1.1 Dextranomer						
Sayag 1996	15	47	6	45	100.0%	2.39 [1.02, 5.62]
Subtotal (95% CI)		**47**		**45**	**100.0%**	**2.39 [1.02, 5.62]**
Total events	15		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.00 (P = 0.05)



Test for subgroup differences: Not applicable

Figure 163 – Alginate dressing versus dextranomer – proportion of patients with > 40% reduction in ulcer area

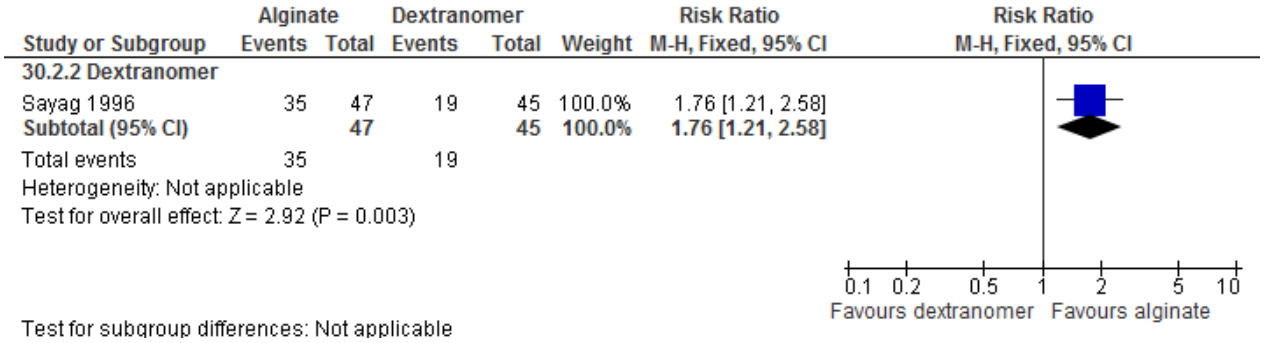


Figure 164 – Alginate dressing versus dextranomer – proportion of patients worsened or stagnated

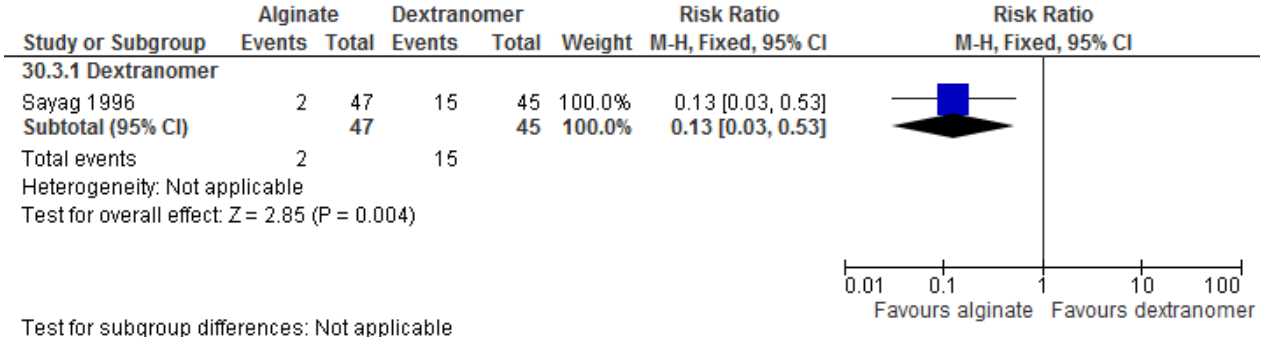


Figure 165 – Alginate dressing versus dextranomer – mean rate of healing in patients improved > 40% (cm²/week)

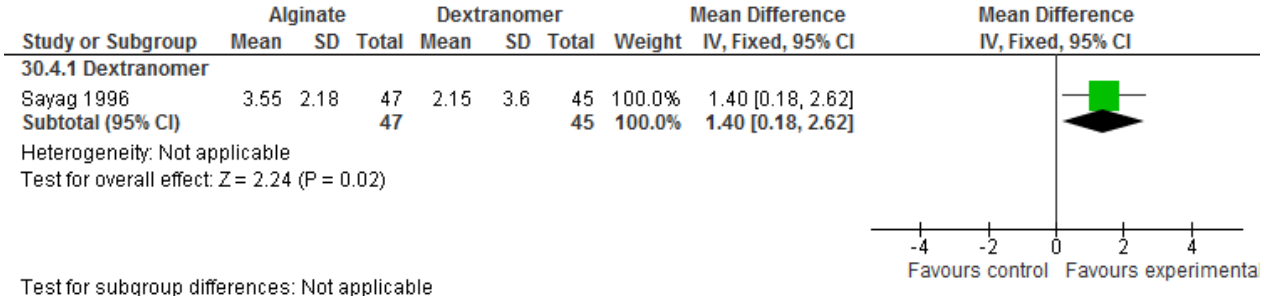


Figure 166 – Alginate dressing versus dextranomer – mean rate of healing (cm²/week)

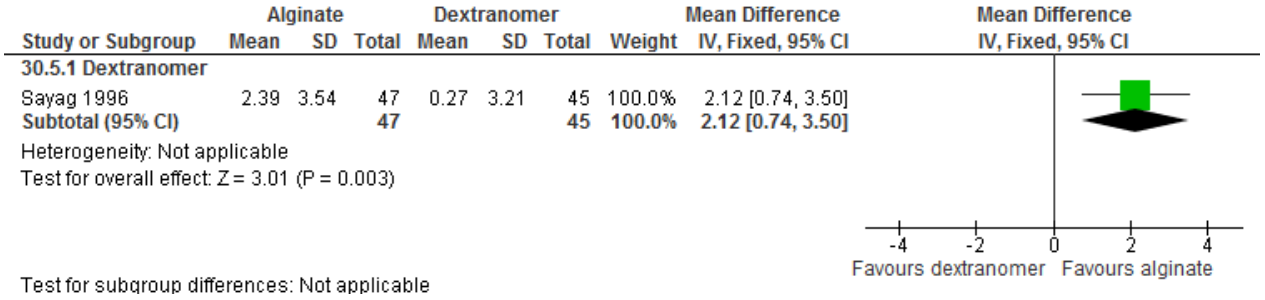


Figure 167 – Alginate dressing versus dextranomer – proportion of patients with an infection

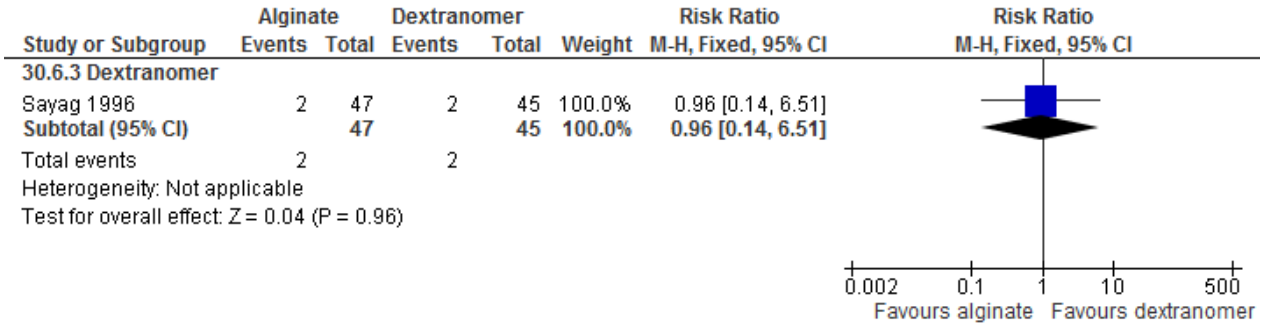


Figure 168 – Alginate dressing versus dextranomer – proportion of patients with hypergranulation

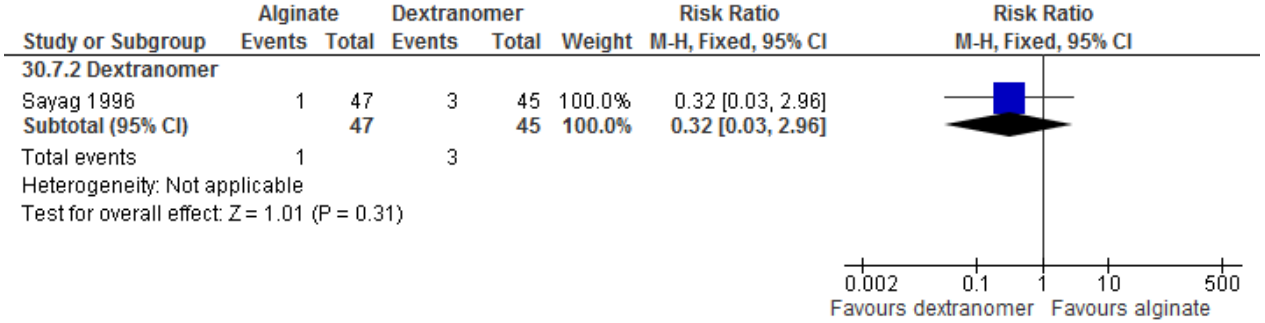


Figure 169 – Alginate dressing versus dextranomer – proportion of patients with skin irritation

Study or Subgroup	Alginate Events	Alginate Total	Dextranomer Events	Dextranomer Total	Weight	Risk Ratio M-H, Fixed, 95% CI
30.8.2 Dextranomer						
Sayag 1996	1	47	1	45	100.0%	0.96 [0.06, 14.85]
Subtotal (95% CI)		**47**		**45**	**100.0%**	**0.96 [0.06, 14.85]**
Total events	1		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.03 (P = 0.98)						

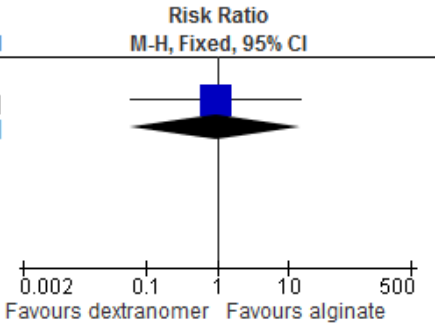


Figure 170 – Alginate dressing versus dextranomer – proportion of patients with bleeding

Study or Subgroup	Alginate Events	Alginate Total	Dextranomer Events	Dextranomer Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
30.9.2 Dextranomer						
Sayag 1996	0	47	3	45	100.0%	0.12 [0.01, 1.22]
Subtotal (95% CI)		**47**		**45**	**100.0%**	**0.12 [0.01, 1.22]**
Total events	0		3			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.79 (P = 0.07)						

Test for subgroup differences: Not applicable

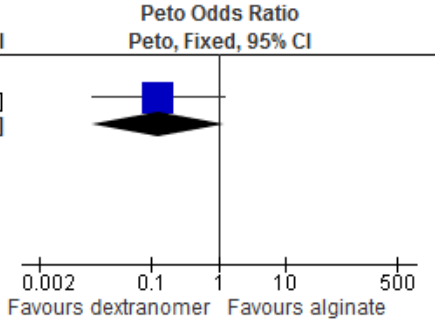
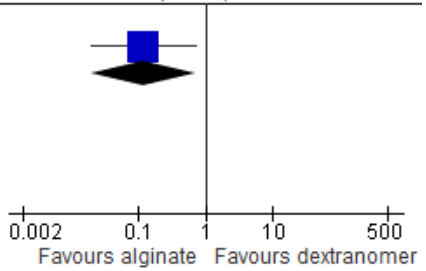


Figure 171 – Alginate dressing versus dextranomer – proportion of patients with pain

Study or Subgroup	Alginate Events	Alginate Total	Dextranomer Events	Dextranomer Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
30.10.1 Dextranomer						
Sayag 1996	0	47	5	45	100.0%	0.12 [0.02, 0.71]
Subtotal (95% CI)		**47**		**45**	**100.0%**	**0.12 [0.02, 0.71]**
Total events	0		5			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.34 (P = 0.02)

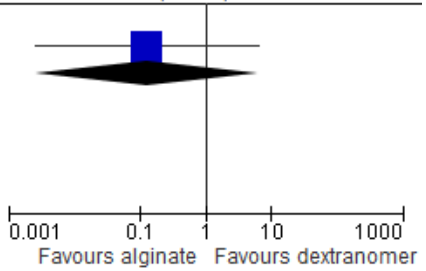


Test for subgroup differences: Not applicable

Figure 172 – Alginate dressing versus dextranomer – proportion of patients with pruritus

Study or Subgroup	Alginate Events	Alginate Total	Dextranomer Events	Dextranomer Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
30.11.1 Dextranomer						
Sayag 1996	0	47	1	45	100.0%	0.13 [0.00, 6.53]
Subtotal (95% CI)		**47**		**45**	**100.0%**	**0.13 [0.00, 6.53]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.02 (P = 0.31)



Test for subgroup differences: Not applicable

Figure 173 – Silver dressing versus silver cream – mean percentage reduction in ulcer area

Study or Subgroup	Dressing Mean	Dressing SD	Dressing Total	Cream Mean	Cream SD	Cream Total	Weight	Mean Difference IV, Fixed, 95% CI
Chuangsuwanich 2011	36.95	56.13	20	25.06	56.13	20	100.0%	11.89 [-22.90, 46.68]
Total (95% CI)			**20**			**20**	**100.0%**	**11.89 [-22.90, 46.68]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.67 (P = 0.50)

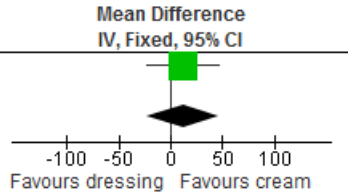


Figure 174 – Silver dressing versus silver cream –percentage reduction in PUSH score

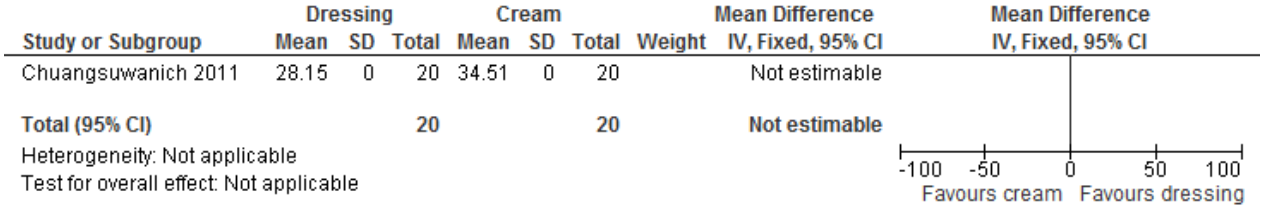


Figure 175 – Sugar versus dextranomer – proportion of patients completely healed

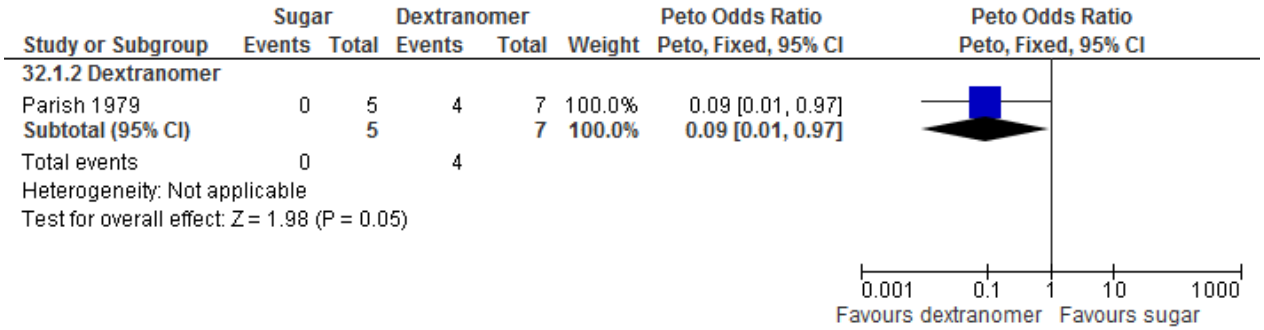


Figure 176 – Sugar versus dextranomer – proportion of patients improved

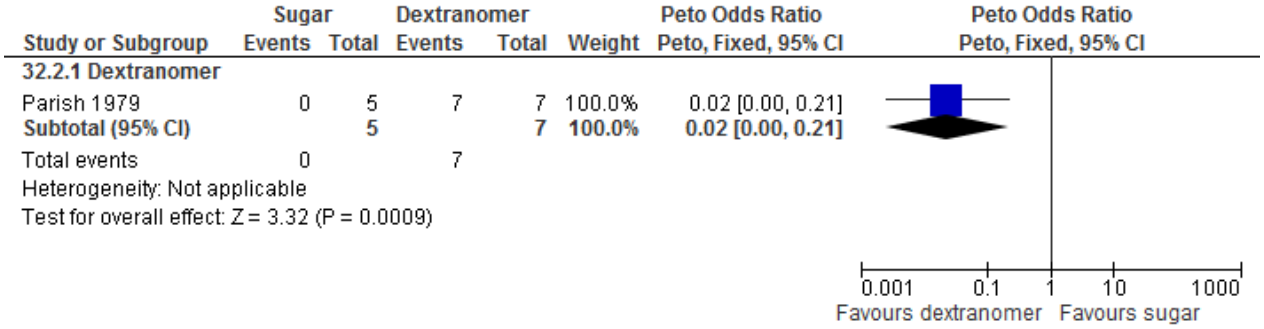


Figure 177 – Sugar versus dextranomer – proportion of ulcers completely healed

Study or Subgroup	Sugar Events	Sugar Total	Dextranomer Events	Dextranomer Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
32.3.1 Dextranomer						
Parish 1979	0	9	6	14	100.0%	0.12 [0.02, 0.77]
Subtotal (95% CI)		**9**		**14**	**100.0%**	**0.12 [0.02, 0.77]**
Total events	0		6			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.23 (P = 0.03)						

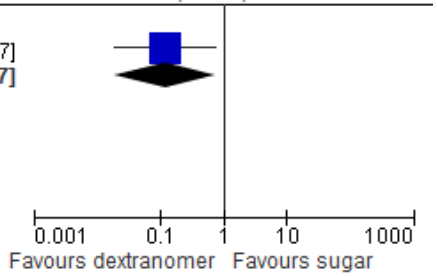


Figure 178 – Sugar versus dextranomer – proportion of ulcers improved

Study or Subgroup	Sugar Events	Sugar Total	Dextranomer Events	Dextranomer Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
32.4.1 Dextranomer						
Parish 1979	0	9	12	14	100.0%	0.04 [0.01, 0.19]
Subtotal (95% CI)		**9**		**14**	**100.0%**	**0.04 [0.01, 0.19]**
Total events	0		12			
Heterogeneity: Not applicable						
Test for overall effect: Z = 3.93 (P < 0.0001)						

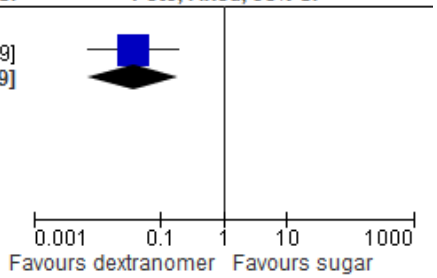


Figure 179 – Sugar versus different types of topical agents – proportion of patients completely healed

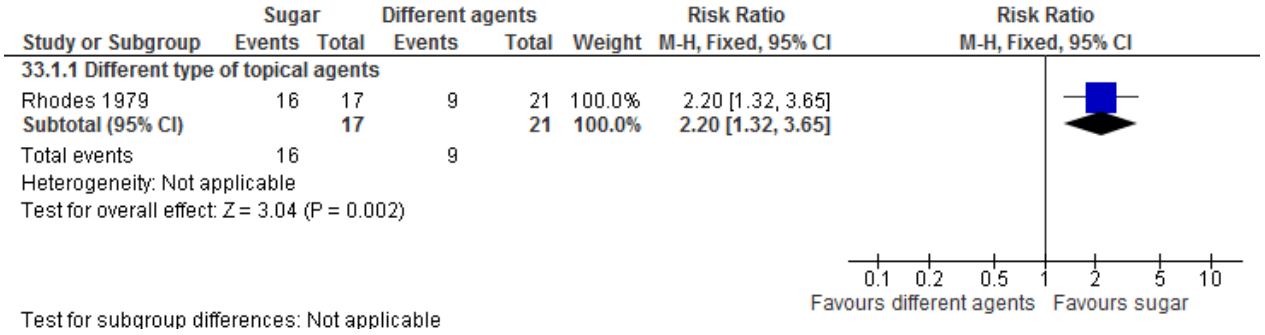


Figure 180 – Sugar versus different types of topical agents – mean healing index

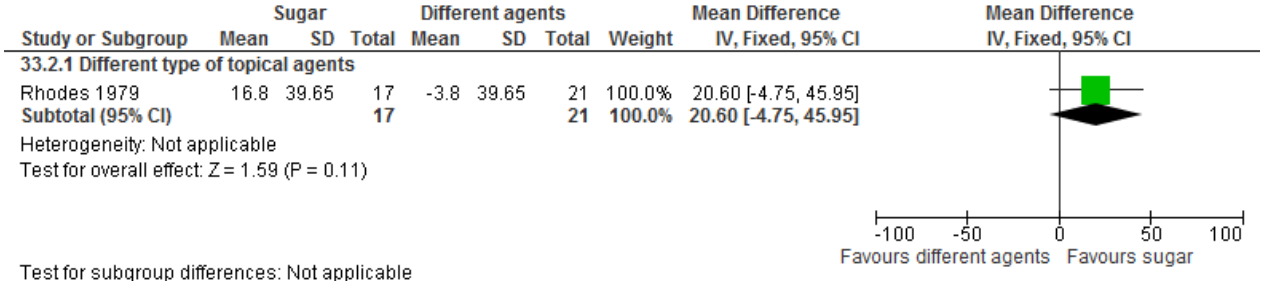


Figure 181 – Honey versus ethoxydiaminoacridine and nitrofurazone – proportion of ulcers completely healed

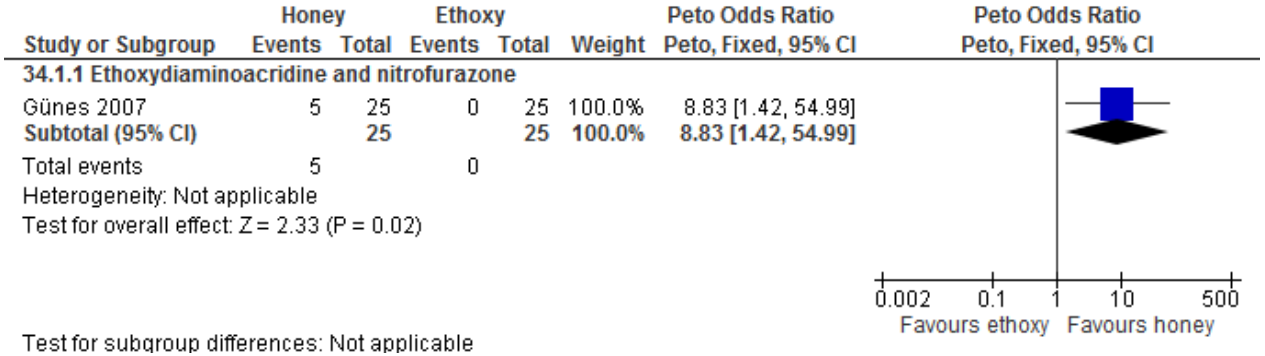


Figure 182 – Honey versus ethoxydiaminoacridine and nitrofurazone – mean percentage reduction in ulcer area

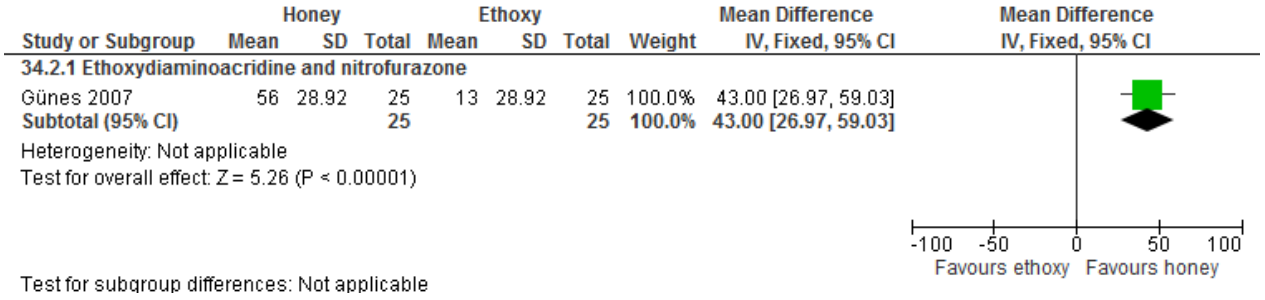


Figure 183 – Honey versus ethoxydiaminoacridine and nitrofurazone – mean percentage reduction in PUSH score

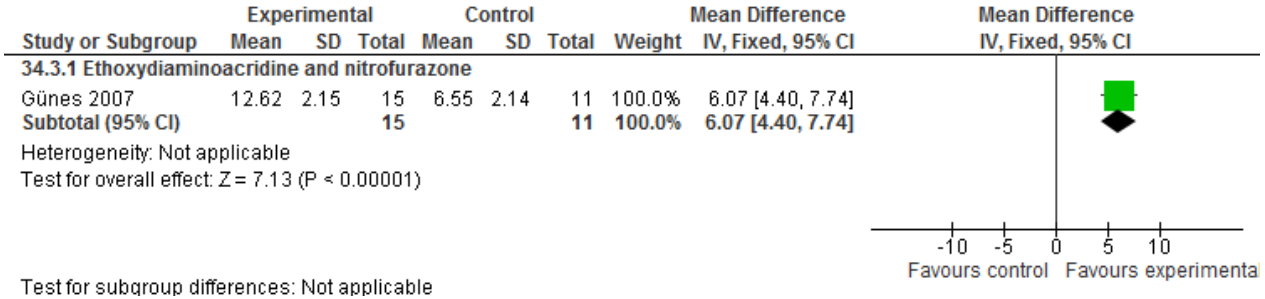


Figure 184 – Platelet gel versus other treatment – proportion of ulcers improved

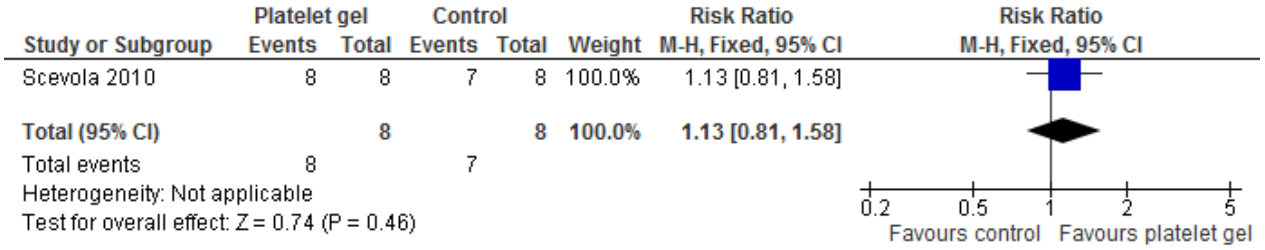


Figure 185 – Platelet gel versus other treatment – mean percentage reduction in ulcer volume

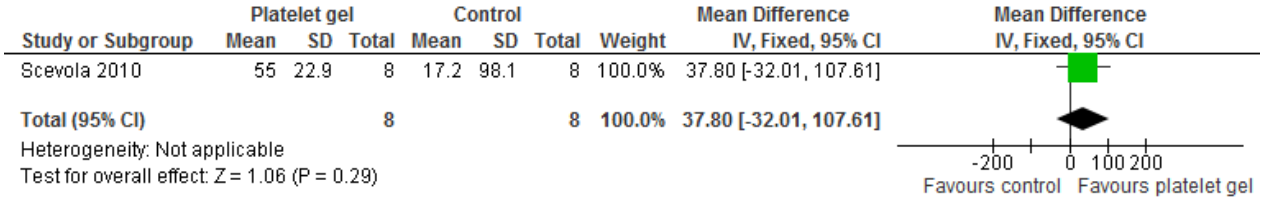


Figure 186 – Hyaluronic acid versus sodium hyaluronic – mean percentage reduction in ulcer area (stage I)

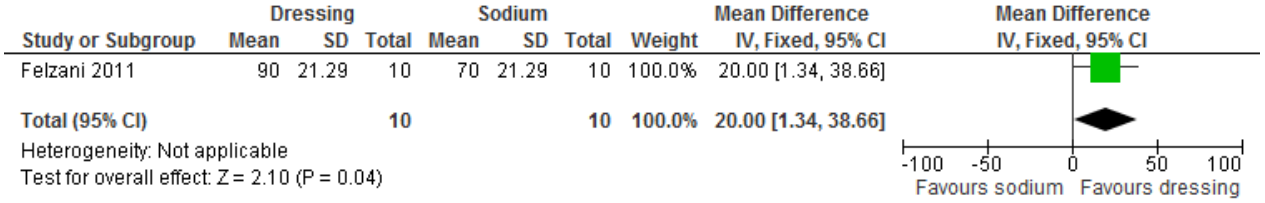


Figure 187 – Hyaluronic acid versus sodium hyaluronic – mean percentage reduction in ulcer area (stage II)

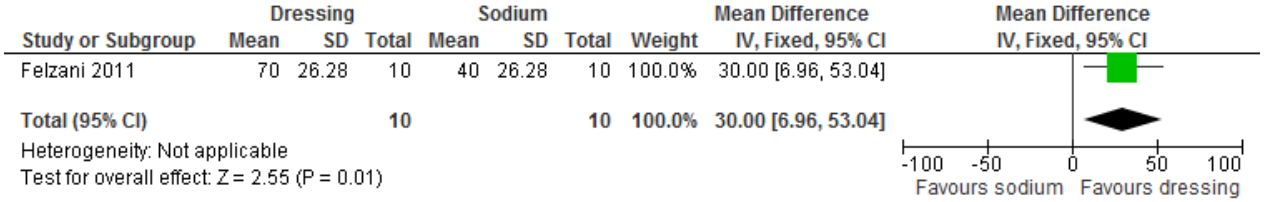


Figure 188 – Hyaluronic acid versus sodium hyaluronic – time to 50% reduction in ulcer diameter (days) (stage I)

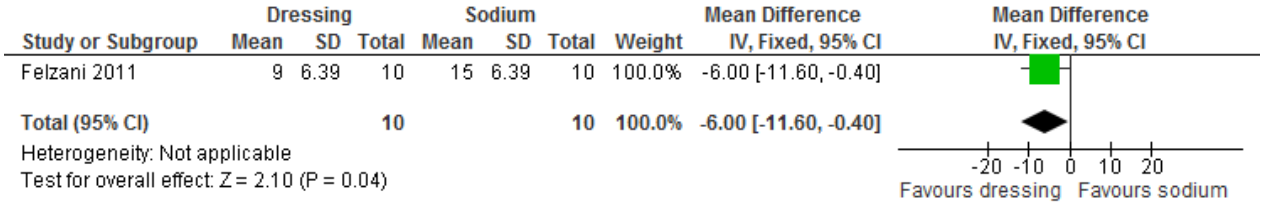


Figure 189 – Hyaluronic acid versus sodium hyaluronic – time to 50% reduction in ulcer diameter (days) (stage II)

Study or Subgroup	Dressing Mean	SD	Total	Sodium Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Felzani 2011	9.5	5.85	10	15	5.85	10	100.0%	-5.50 [-10.63, -0.37]
Total (95% CI)			**10**			**10**	**100.0%**	**-5.50 [-10.63, -0.37]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.10 (P = 0.04)

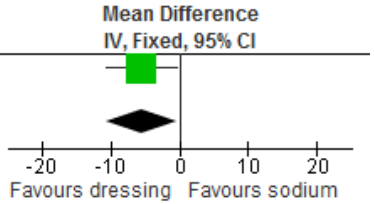


Figure 190 – Hyaluronic acid versus sodium hyaluronic – time to 50% reduction in ulcer diameter (days) (stage III)

Study or Subgroup	Dressing Mean	SD	Total	Sodium Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Felzani 2011	12.9	6.71	7	19.2	6.71	7	100.0%	-6.30 [-13.33, 0.73]
Total (95% CI)			**7**			**7**	**100.0%**	**-6.30 [-13.33, 0.73]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.76 (P = 0.08)

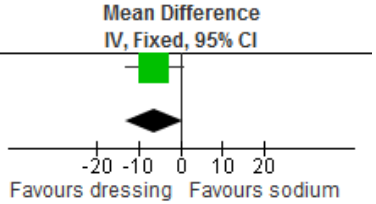


Figure 191 – Polyhexadine dressing versus polyhexadine swab – proportion of patients MRSA eradicated

Study or Subgroup	Dressing Events	Total	Swab Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Wild 2012	15	15	10	15	100.0%	1.48 [1.02, 2.13]
Total (95% CI)		**15**		**15**	**100.0%**	**1.48 [1.02, 2.13]**
Total events	15		10			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.09 (P = 0.04)

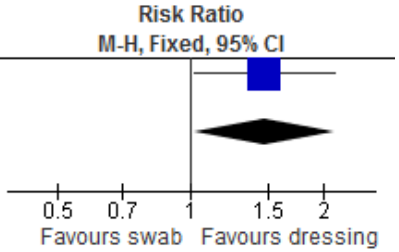


Figure 192 – Hydrofibre® versus resin salve – proportion of patients completely healed

Study or Subgroup	Hydrofibre Events	Total	Resin salve Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Sipponen 2008	4	9	12	13	100.0%	0.48 [0.23, 1.02]
Total (95% CI)		**9**		**13**	**100.0%**	**0.48 [0.23, 1.02]**
Total events	4		12			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.92 (P = 0.06)

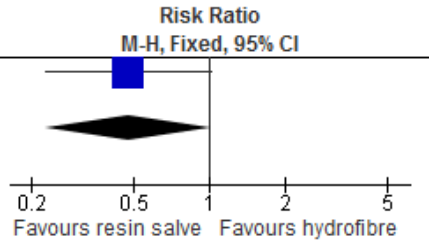


Figure 193 – Hydrofibre® versus resin salve – proportion of ulcers completely healed

Study or Subgroup	Hydrofibre Events	Total	Resin salve Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Sipponen 2008	4	11	17	18	100.0%	0.39 [0.17, 0.85]
Total (95% CI)		**11**		**18**	**100.0%**	**0.39 [0.17, 0.85]**
Total events	4		17			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.37 (P = 0.02)

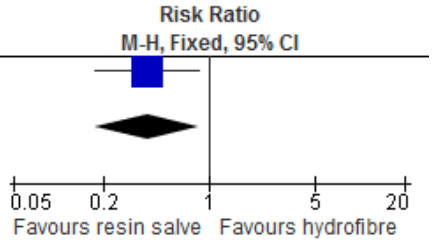


Figure 194 – Hydrofibre® versus resin salve – proportion of ulcers improved

Study or Subgroup	Hydrofibre Events	Total	Resin salve Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Sipponen 2008	10	11	18	18	100.0%	0.90 [0.72, 1.13]
Total (95% CI)		**11**		**18**	**100.0%**	**0.90 [0.72, 1.13]**
Total events	10		18			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.93 (P = 0.35)

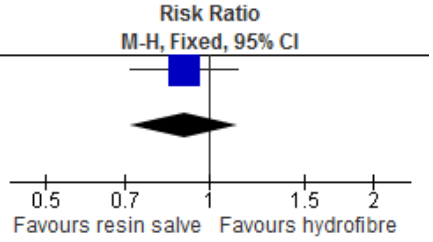


Figure 195 – Hydrofibre® versus resin salve – proportion of ulcers worsened

Study or Subgroup	Hydrofibre Events	Hydrofibre Total	Resin salve Events	Resin salve Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Sipponen 2008	1	11	0	18	100.0%	13.96 [0.25, 792.93]
Total (95% CI)		**11**		**18**	**100.0%**	**13.96 [0.25, 792.93]**
Total events	1		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.28 (P = 0.20)

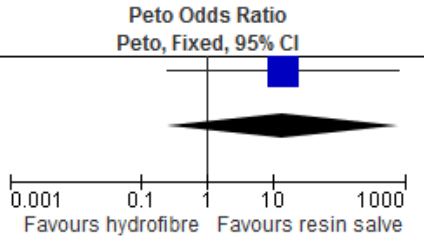


Figure 196 – Hydrofibre® versus resin salve – proportion of patients with allergic skin irritation

Study or Subgroup	Experimental Events	Experimental Total	Resin salve Events	Resin salve Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Sipponen 2008	0	16	1	21	100.0%	0.17 [0.00, 8.97]
Total (95% CI)		**16**		**21**	**100.0%**	**0.17 [0.00, 8.97]**
Total events	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.87 (P = 0.38)

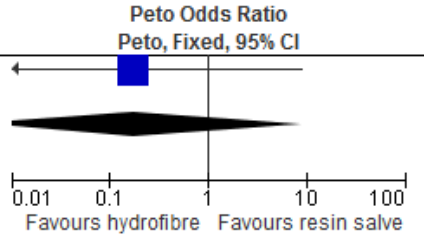
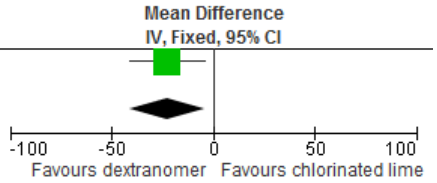


Figure 197 – Dextranomer versus chlorinated lime solution – Time to healing (defined as granulation and < 25% of original ulcer area) (days)

Study or Subgroup	Dextranomer Mean	Dextranomer SD	Dextranomer Total	Chlorinated lime Mean	Chlorinated lime SD	Chlorinated lime Total	Weight	Mean Difference IV, Fixed, 95% CI
Nasar 1982	39.3	17.67	6	61.8	13.86	5	100.0%	-22.50 [-41.14, -3.86]
Total (95% CI)			**6**			**5**	**100.0%**	**-22.50 [-41.14, -3.86]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.37 (P = 0.02)



5.3.5. Evidence tables

Table 52 – ALM 1989

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Alm (1989)** Title: **Care of pressure sores: a controlled study of the use of a hydrocolloid dressing compared with wet saline gauze compresses.** Journal: **Acta Dermato-Venereologica, 149; 1-10** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **stratified allocation based on Norton score** Blinding: **blinding of outcome assessor.** Addressing incomplete outcome data: **intention-to-treat analysis except the patients in which**	**Patient group:** Long stay patients PUs. **All patients** **Randomised N:** 50 patients and 56 PUs **Completed N:** 50 PUs for efficacy analysis and 51 PUs for safety analysis **Drop-outs:** 6 PUs for efficacy analysis (1 drop-out for unknown reason, 1 missing case report, 1 died during wash-out period, 2 in which protocol was violated, and 1 incomplete data)) and 5PUs for the safety analysis (1 drop-out for unknown reason, 1 missing case report, 1 died during wash-out period, and 2 in which protocol was violated) **Gender (m/f) (patients):** ±6/44 **Group 1** **Randomised N:** 31 PUs **Completed N:** 29 PUs	**Group 1:** Hydrocolloid dressing: sheet, paste and powder (Comfeel®, Coloplast A/S, Espergaerde, Denmerk). The dressing was changed when necessary. Th sheet is used solely or on top of the filled ulcer. Six ulcers were filled with paste and one with both paste and powder during the treatment period. Comfeel® sheet: consists of sodium carboxymethylcellulose particles embedded in an adhesive, elastic mass. The side which faces away from the ulcer is covered with a 0.3mm polyurethane film. Comfeel® paste: consists of sodium carboxymethylcellulose particles and guar cellulose particles suspended in a paste basis from vaseline, liquid paraffin and cetanol. Comfeel® powder: a dry mixture of sodium carboxymethylcellulose, guar cellulose and xanthan cellulose.	**Outcome 1:** Relative median percentage decrease in ulcer area by 6 weeks **Outcome 2:** Median percentage decrease in ulcer area by 8 weeks **Outcome 3:** Median ulcer depth at week 4 **Outcome 4:** Healing distribution function **Outcome 5:** proportion of patient reporting pain at dressing change	**Group 1:** 100.0 **Group 2:** 69.0 **P value:** 0.016 **Group 1:** figure unclear; not reported **Group 2:** figure unclear; not reported **P value:** 0.047 **P value:** 0.15 Treatment with hydrocolloid needed to be stopped in one patient (n=1/49) due to great pain.	**Funding:** / **Limitations:** no report on sequence allocation; allocation concealment by stratification; drop-outs unclear; partial statistical measure of difference between groups; no blinding of patients and nurses; no information on classification of PU and unclear if grade I PUs were included; information on pain unclear; no report on preventive measures or debridement. **Additional outcomes:**

protocol was violated, died in wash-out period, missing case-record and drop-out for unknown reason. Those were excluded. Statistical analysis: **Mean values, standard deviations and t-test were used when the values were apparently ,normally distributed. When values were normally distributed, median values and lower and upper hinges were calculated. The Mann-Whitney U-test was then used for probability evaluations. The statistical analysis was performed by means of the software package SYSTAT (Systat Inc., Illinois, USA). The healing outcome was analysed by means of the lifetest program SAS (SAS institute Inc., Cary, USA) The statistical analysis was performed by means of the software**	for the safety analysis and 28 or 29 PUs for the efficacy analysis (latter unclear). **Dropouts:** 2 for the safety analysis and 2 or 3 for the efficacy analysis (latter unclear). **Age (mean years (SD)):** 83.6 (9.2) **Norton score (mean (SD)):** 12 (2) **Duration PU (mean months (SD)):** 4.6 (10.9) **Ulcer location:** Heel: n=11 Sacrum: n=8 Malleolus: n=4 Gluteal region: n=3 Hip: n=4 Other: n=1 **Ulcer depth (median mm (IQR)):** 1.75 (0.30-3.00) **Ulcer area (median cm² (IQR)):** 2.02 (0.95-3.10) **Granulated area (median cm² (IQR)):** 0.32 (0.051-1.68) **Group 2** **Randomised N:** 25 PUs **Completed N:** 22 PUs for the safety analysis and 21 or 22 PUs for the efficacy analysis (latter unclear).	**Group 2:** wet saline gauze dressings which was changed twice daily. **Both groups:** after randomization all ulcers were dressed with wet saline gauze dressings for one week (wash-out period).	Granulation tissue was larger in G1 than G2 Nursing time: G1 versus G2, p<0.0001 **Notes:** /

package SYSTAT (Systat Inc., Illinois, USA). **The probability outcomes was analysed by the log rank test. A two-tailed p-value of ≤ 0.05 was accepted as statistical significance.** Baseline differences: **Difference was not measured statistically except for ulcer depth, ulcer area and granulated area, which were not significantly different. Groups were comparable based on the average.** Study power/sample size: **No a priori sample size calculation.** Setting: **Long-term ward.** Length of study: **six weeks of treatment and follow-up for a further 3 to 6 weeks** Assessment of PUs: **PUs classification not reported.** **Ulcer were photographed once a week. The area of the**	**Dropouts:** 3 for the safety analysis and 3 or 4 for the efficacy analysis (latter unclear). **Age (mean years (SD)):** 83.4 (9.4) **Norton score (mean (SD)):** 13 (3) **Duration PU (mean months (SD)):** 4.8 (6.4) **Ulcer location:** Heel: n=8 Sacrum: n=9 Malleolus: n=3 Gluteal region: n=2 Hip: n=1 Other: n=2 **Ulcer depth (median mm (IQR)):** 2.00 (1.00-5.00) **Ulcer area (median cm² (IQR)):** 2.44 (0.97-3.24) **Granulated area (median cm² (IQR)):** 0.25 (0.079-0.70) **Inclusion criteria:** having a PU. **Exclusion criteria:** Norton score <7	

ulcer which was not covered with epithelium was determined after projection of the slide from below onto a horizontal glass plate which was covered with matt drawing foil. The relevant area was measured on the image which appeared on the matt foil, suing a Haff digital planimeter type 320 E (Haff, Pfronten, GFR) and the real area was then calculated, taking the degree of magnification into consideration. The depth and degree of cleanness en the extend and intensity of maceration were assessed and classified on rating scales. Multiple ulcers: **50 patients with 56 ulcers. Ulcers are unit of analysis and randomization.**		

Table 53 – AMIONE 2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Amione (2005)** Title: **Comparison of Allevyn Adhesive and Biatain Adhesive in the management of pressure ulcers.** Journal: **Journal of Wound Care, 14 (8); 365-370.** Study type: **randomized controlled trial** Sequence generation: **block randomization** Allocation concealment: **stratified allocation based on baseline exudate level and treatment centre.** Blinding: **open trial** Addressing incomplete outcome data: **intention to treat analysis for outcomes in interest in this review. Per protocol analysis for some of the additional outcomes (marked with*)**	**Patient group:** Patients 18 years and older with a grade II or III PU (according to the EPUAP classification). **All patients** **Randomised N:** 32 **Completed N:** 28 **Drop-outs:** 4 (reasons unclearly reported) **Group 1** **Randomised N:** 14 **Completed N:** 13 **Dropouts:** 1 (had necrosis) **Age (median years; range):** 81.8; 31.2-94.8 **Gender (m/f):** 6/8 **Ulcer location:** Sacrum: n=8 Trochanter: n=1 Ischium: n=1 Heel: n=3 Other: n=1 **Ulcer grade:** Grade II: n=8 Grade III: n=6 **Incontinence** Urine: n=1 Faecal: n=0 Both: n=7	**Group 1:** Adhesive foam dressing (Allevyn®, Smith & Nephew Medical, Hull, UK). Ulcers were cleansed with sterile water or saline before application of the dressing. Dressings were changed when exudate came within 2cm of the edge, bit was not left in place for longer than seven days. Allevyn®: adhesive, polyurethane inner layer containing a low-allergy adhesive, hydrophilic, absorbent middle layer, and polyurethane outer layer. **Group 2:** Adhesive foam dressing (Biatain®, Coloplast, Peterborough, UK). Ulcers were cleansed with sterile water or saline before application of the dressing. Dressings were changed when exudate came within 2cm of the edge, bit was not left in place for longer than seven days. Biatain®: foam layer (with three-dimensional polymer structure), with a hydrocolloid-based adhesive, which is placed directly on	**Outcome 1:** Proportion of patient completely healed **Outcome 2:** Median percentage reduction in ulcer area **Outcome 3:** Mean (range) patient pain on dressing removal (1: none – 4: severe) **Outcome 4:** Mean (range) patient comfort on dressing removal (1: very comfortable – 4: very uncomfortable) **Outcome 4:** Proportion of patients with dressing related adverse events	**Group 1:** 11/14 **Group 2:** 5/18 **P value:** >0.05 **Group 1:** 38.2 (-97.6-99.4) **Group 2:** 45.8 (-56.9-90.0) **P value:** >0.05 **Group 1:** 1.01 (1.00-1.17) **Group 2:** 1.10 (1.00-2.17) **P value:** >0.05 **Group 1:** 1.84 (1.00-2.25) **Group 2:** 2.11 (1.00-2.17) **P value:** 0.006 **Group 1:** 1/14 (peri-erosion) **Group 2:** 4/18 (1 non-severe erythema, 2 erosion, 1 severe erythema)	**Funding:** Funded by Smith & nephew Wound Management Division, Hull, UK **Limitations:** no report; allocation concealment by stratification; insufficient sequence generation; no a priori sample size calculation; small sample size; no statistical measure of difference between groups; no blinding; no information on preventive measures and debridement **Additional outcomes:** Falling apart of dressing.* Ease of application and removal of

Statistical analysis: **For outcomes of interest for this review, difference between the two dressings were evaluated using the Mantel-Haenszel test. The level of significance was taken as p<0.05.** Baseline differences: **Difference was not measured statistically.** Study power/sample size: **No a priori sample size calculation.** Setting: **four wound care centres.** Length of study: **seven dressing with a maximum of six weeks of treatment** Assessment of PUs: **PUs were classified according to the EPUAP classification. Photographs were taken before and after dressing removal and before and after cleansing. Ulcers were traced after cleansing.** Multiple ulcers: **the largest ulcer was**	Any: n=8 **Ulcer area (median cm²; range):** 16.3; 0.7-44.3 **Group 2** **Randomised N:** 18 **Completed N:** 15 **Dropouts:** 3 (reason not clearly reported) **Age (median years; range):** 79.1; 30.1-93.6 **Gender (m/f):** 8/10 **Ulcer location:** Sacrum: n=7 Trochanter: n=3 Ischium: n=4 Heel: n=3 Other: n=1 **Ulcer grade:** Grade II: n=10 Grade III: n=8 **Incontinence** Urine: n=8 Faecal: n=1 Both: n=4 Any: n=13 **Ulcer area (median cm²; range):** 9.3 (0.6-80.8) **Inclusion criteria:** 18 years or older; PU grade II or III; slight to moderate exudate. **Exclusion criteria:** PU grade 0 (healed), I or IV; necrosis > 10%; ulcers	the wound. Semipermeable polyurethane film backing. **Both groups:** /	**Outcome 4:** Proportion of patients with non-dressing related adverse events	**Group 1:** 2/14 **Group 2:** 2/18	dressing, conformability of dressing on application and removal, adherence on application and removal. **Notes:** /

used in the study	caused by rheumatoid vasculitis, diabetes, cancer, venous leg ulceration; active cellulitis being treated with systematic antibiotics; ulcer > 14cm length; ulcer with cavity (as opposed to a crater); surrounding skin on which use of adhesive dressing is inappropriate; participation other trial; hypersensitivity to the dressing	

Table 54 – Bale 1997

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Bale (1997)** Title: **A comparison of two dressings in pressure sore management.** Journal: **Journal of Wound Care, 6 (10); 463-466.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **open randomisation list.** Blinding: **not reported.** Addressing incomplete outcome data: **not reported** Statistical analysis: **All parameters were assessed using the Mann Whitney test except the comparison of mean dressing wear time, which was analysed using the student t-test. All test were two-sided and the 5%**	**Patient group:** Patients with a stage II or III PU (according to the Stirling classification). **All patients** **Randomised N:** 60 **Completed N:** 20 **Drop-outs:** 40 (13 were discharged, 8 died, 5 had an adverse incident, 4 requested withdrawal, 4 had an unsuitable dressing, 3 had a deteriorating wound, 1 had a lack of progress, 2 had rolling dressings) **Group 1** **Randomised N:** 31 **Completed N:** 9 **Dropouts:** 22 (8 were discharged, 2 died, 2 had an adverse incident, 2 requested withdrawal, 3 had an unsuitable dressing, 2 had a deteriorating wound, 1 had a lack of progress, 2 had rolling dressings) **Age (median years):** 74 **Gender (m/f):** 15/16 **Ulcer location:**	**Group 1:** Hydrocolloid dressing (Granuflex®) **Group 2:** Polyurethane foam dressing (Allevyn®) **Both groups:** /	**Outcome 1:** Proportion of patient completely healed **Outcome 2:** Proportion of patient not changed **Outcome 3:** Proportion of patient worsened **Outcome 3:** Proportion of patient with adverse events (unknown if dressing related)	**Group 1:** 5/9 **Group 2:** 7/12 **Group 1:** 1/31 **Group 2:** 0/29 **Group 1:** 2/31 **Group 2:** 1/29 **Group 1:** 2/31 **Group 2:** 3/29	**Funding:** Funded by Smith & Nephew **Limitations:** no report on sequence allocation; allocation concealment by open randomisation list; no ITT analysis; no a priori sample size calculation; high dropout; no statistical measure of difference between groups; no report on blinding; no report on multiple ulcers; no information on preventive measures and debridement **Additional outcomes:** ease of application; absorbency of dressing; mean

level considered significant. Data were analysed using a statistical analysis system (SAS) Baseline differences: **Difference was not measured statistically. Groups were balanced** Study power/sample size: **No a priori sample size calculation.** Setting: **five centres.** Length of study: **30 days of treatment or until completely healed.** Assessment of PUs: **PUs were classified according to Stirling classification. Assessment not reported.** Multiple ulcers: **not reported**	Sacrum: n=13 Trochanter: n=1 Heel: n=11 Other: n=6 **Ulcer stage:** Stage II: n=22 Grade III: n=9 **Ulcer area (cm²):** < 5: n=10 5-9: n=6 10-19: n=9 ≥ 20: n=6 **Group 2** **Randomised N:** 29 **Completed N:** 11 **Dropouts:** 18 (5 were discharged, 6 died, 3 had an adverse incident, 2 requested withdrawal, 1 had an unsuitable dressing, 1 had a deteriorating wound) **Age (median years):** 73 **Gender (m/f):** 12/17 **Ulcer location:** Sacrum: n=18 Trochanter: n=1 Heel: n=5 Other: n=5 **Ulcer stage:** Stage II: n=23 Grade III: n=6 **Ulcer area (cm²):** < 5: n=14 5-9: n=6 10-19: n=4 ≥ 20: n=5		dressing wear time, ease of removal. **Notes:** /

	Inclusion criteria: 18 years or older; PU stage II or III with the largest diameter ≤ 11 cm; ulcer with no signs of infection; no history of poor compliance; no previous involvement in the study; not pregnant. **Exclusion criteria:** /				

Table 55 – Bale 1998

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Bale (1998)** Title: **A comparison of two amorphous hydrogels in the debridement of pressure sores.** Journal: **Journal of Wound Care, 7 (2); 65-68.** Study type: **randomized controlled trial** Sequence generation: **performed by allocating the next sequential number from a computer-generated random number list.**	**Patient group:** Patients with necrotic PUs. **All patients** **Randomised N:** 50 **Completed N:** 38 **Drop-outs:** 12 (3 patients in group 1 and 4 in group 2 died of causes unrelated to the study. 2 patients in group 1 were withdrawn from the study, 1 lost to follow-up and 1 requested to withdraw due to reasons unrelated to the study. 3 patients in group 2 were withdrawn because they developed a wound infection)	**Group 1:** application of an amorphous hydrogel (Sterigel®) manufactured from corn bran and compose of 2% w/w hemicellulose matrix and 20% propylenen glucol in purified water. **Group 2:** application of another amorphous hydrogel (Intrasite®) **Both groups**: A low-adherent dressing (Telfa) and a semipermeable film (Tegaderm) were used as secondary dressings in both groups. The gel was replaced daily in order to maximise its debridement capability. All other wound treatment	**Outcome 1:** Mean size of wounds at day 14 in (cm^2; range) **Outcome 2:** Proportion of patients experiencing no ulcer pain at end of study **Outcome 3:** Proportion of patients experiencing intermittent ulcer pain at end of study **Outcome 4:**	**Group 1:** 26.8 (21.5-40) **Group 2:** 8.7 (3-15.7) **P value:**0.08 **Group 1:** 10/24 **Group 2:** 5/23 **Relative risk:** 1.92 **95% CI:** 0.77-4.75 **Group 1:** 13/24 **Group 2:** 16/23 **Relative risk:** 0.78 **95% CI:**0.49-1.23 **Group 1:** 1/24	**Funding:** study was undertaken with financial support from Seton Healtcare **Limitations:** Unclear allocation concealment Relatively high drop-out **Additional outcomes:** In group 1, 14 patients achieved complete debridement of their wounds, 10 of these in 21 days or more. Of

Allocation concealment: **open randomisation list.** Blinding: **an independent assessor confirm or reject the subjective assessment recorded by the nurses not blinded.** Addressing incomplete outcome data: **not reported** Statistical analysis: **not reported** Baseline differences: **None** Study power/sample size: **With the inclusion of 50 patients, the study had a power of 80% to detect a difference equal to 23% of the standard deviation of the quantitative measurements; for qualitative measurements the study was capable of detecting a 36% difference in response rates at a significance level of 5%.** Setting: **Hospital and community settings in the UK.**	**Group 1** **Randomised N:** 26 **Completed N:** 21 **Dropouts:** 5 **Age (mean years; range):** 78; 20-93 **Gender (m/f):** 9/17 **PU grade:** Grade II: 2 Grade III: 20 Grade IV: 2 **Waterlow score mean (range):** 20.5 (13-35) **Ulcer area (mean cm^2; range):** 14.7; 6.6-49 **Ulcer depth (mean mm; range):** 5; 1-15 **Duration of wound mean (mean months; range):** 5.1 months; 5 days- 4 years **PU location:** Sacrum: 5 Ischial tuberosities: 2 Heel: 14 Foot: 2 Gaiter area: 1 Elbow: 1 Lateral malleolus: 0 Buttock: 1 **Group 2** **Randomised N:** 24 **Completed N:** 17 **Dropouts:** 7 **Age (mean years; range):** 77; 38-99 **Gender (m/f):** 10/14	was prohibited during the study	Proportion of patients experiencing continuous ulcer pain at end of study **Outcome 5:** Proportion of patients experiencing no pain on dressing removal at end of the study **Outcome 6:** Proportion of patients experiencing slight pain on dressing removal at end of the study **Outcome 7:** Proportion of patients experiencing severe pain on dressing removal at end of the study **Outcome 8:** Proportion of patients uncomfortable or very uncomfortable with dressing	**Group 2:** 2/23 **Group 1:** 17/22 **Group 2:** 13/20 **Group 1:** 5/22 **Group 2:** 6/20 **Relative risk:** 0.76 **95% CI:** 0.27-2.10 **P value:** 0.73 **Group 1:** 0/22 **Group 2:** 1/20 **Relative risk:** 0.30 **95% CI:** 0.01-7.07 **P value:** 0.38 **Group 1:** 0/22 **Group 2:** 1/20	the 7 remaining wounds 1 deteriorated, 1 remained the same and 5 improved. In group 2, 9 achieved complete debridement, 4 of these in 21 days or more. Of the remaining 8, 1 deteriorated, 3 remained the same and 4 improved. There were no differences in wound odor between the two groups. **Notes:** /

Length of study: **four weeks or until wound had debrided, whichever was sooner** Assessment of PUs: **PU classification not reported.** **The study nurse was asked at each assessment to assess the percentage of black (representing hard dry eshar), green (infection, yellow (slough) and red (healthy granulation tissue). The nurses unanimously considered that debridement was successful when there was 80% red granulation tissue present and no signs of necrosis. Photographs and tracings were also taken at each assessment. The photographs were sent for computerized wound analysis.** **Pain was measured by the patient selecting from three**	**PU grade:** Grade II: 0 Grade III: 21 Grade IV: 1 **Waterlow score (mean; range):** 20.4; 9-29 **Ulcer area (mean cm^2; range):** 9.4; 1-36 **Ulcer depth (mean mm; range):** 4.7; 2-10 **Duration of wound (mean months; range):** 4.7; 11 days- 4 years **PU location:** Sacrum: 4 Ischial tuberosities: 0 Heel: 19 Foot: 0 Gaiter area: 0 Elbow: 0 Lateral malleolus: 1 Buttock: 0 **Inclusion criteria:** presence of necrotic pressure ulcers **Exclusion criteria:** wound diameter > 8cm; disease resulting in immunosuppression; pregnant or nursing mothers; participation in another clinical trial 1 month prior to the study; already participated in the trial	**Outcome 9:** Proportion of patients experiencing maceration of the skin at the end of the study	**Group 1:** 8/21 **Group 2:** 9/17

options: none, intermittent and continuous; no measure of the severity of the pain was undertaken. Pain on removal of dressings was measured at the end of the study using three options: pain, slight pain and severe pain. Multiple ulcers: **not reported**					

Table 56 – BANKS 1994a

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Banks (1994a)** Title: **The use of two dressings for moderately exuding pressure sores.** Journal: **Journal of Wound Care, 3 (3); 132-134.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **not reported.**	**Patient group:** Inpatients with a grade II or III PU. **All patients** **Randomised N:** 29 **Completed N:** 22 **Drop-outs:** 7 (4 wound deterioration, 2 dressing/wound related problems, 2 were discharged) **Group 1** **Randomised N:** 13 **Completed N:** 10 **Dropouts:** 3 (1 wound deterioration, 1	**Group 1:** Semi-permeable polyurethane dressing (Spyrosorb®, C.V. Laboratories Ltd). Dressings were changed when the area discoloured by exudate was less than 1cm from the edge of the dressing and before exudate had leaked, with a maximum of seven days. Spyrosorb®: inner layer consists of porous, hydrophilic, pressure sensitive adhesive wound contact surface, the middle layer consists of an absorbent microporous polyurethane membrane, and	**Outcome 1:** Proportion of patient completely healed **Outcome 2:** Proportion of patient improved **Outcome 3:** Time to healing (median days) **Outcome 4:** Percentage of patient reporting painful removal of dressing	**Group 1:** 10/10 **Group 2:** 11/12 **Group 1:** 10/10 **Group 2:** 12/12 **Group 1:** 13.36 **Group 2:** 12.69 **P value:** > 0.05 **Group 1:** figure unclear **Group 2:** figure unclear **P value:** < 0.005	**Funding:** sponsored by C.V. Laboratories Ltd and Calgon Vestal Laboratories **Limitations:** no report on sequence generation; no report on allocation concealment; no ITT analysis; no a priori sample size calculation; small sample size; no report on blinding;

Blinding: **not reported.** Addressing incomplete outcome data: **drop-out were excluded.** Statistical analysis: **Survival analysis was used to compare the time of healing. The Mann-Whitney U test was used to compare ease of dressing removal, pain at removal, and comfort of dressings. No Further information.** Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **single centre, inpatients.** Length of study: **6 weeks of treatment or until completely healed.** Assessment of PUs: **PUs classification not reported. Wound size were carried out using a structured light method. Assessment took place at each**	dressing/wound related problems, 1 was discharged) **Age (median years; range):** 73; 40-88 **Gender (m/f):** 4/9 **Ulcer location:** Sacrum: n=4 Buttock: n=8 Other: n=1 **Duration PU (median days; range):** 7; 2-14 **Ulcer area (median cm²; range):** 1.4; 0.5-14.3 **Group 2** **Randomised N:** 16 **Completed N:** 12 **Dropouts:** 4 (3 wound deterioration, 1 dressing/wound related problems) **Age (median years; range):** 74; 40-95 **Gender (m/f):** 7/9 **Ulcer location:** Sacrum: n=6 Buttock: n=9 Other: n=1 **Duration PU (median days; range):** 5.5; 2-365 **Ulcer area (median cm²; range):** 2.4; 0.1-25.8 **Inclusion criteria:** 16 years or older; shallow,	the outer layer is vapourpermeable **Group 2:** Hydrocolloid dressing (GranuflexE®, Convatec). Dressings were changed when the area discoloured by exudate was less than 1cm from the edge and before exudate had leaked, with a maximum of seven days. GranuflexE®: consists of an outer waterproof polyurethane foam bonded to a matrix of hydrocolloid particles and hydrophobic polymer. **Both groups:** Those patients who were not mobile were given support therapy to prevent additional PU. This included pressure relieving equipment and two to four hour turning schedules.	**Outcome 5:** Percentage of patient reporting the dressing as (very) uncomfortable	**Group 1:** figure unclear **Group 2:** figure unclear **P value:** > 0.05	no report on multiple ulcers; no report in classification of PUs; little information on ulcer assessment and statistical analysis. **Additional outcomes:** time to dressing change, and ease of removal. **Notes:** /

dressing change. Multiple ulcers: **not reported**	moist PU of grade II and III; ulcer could be covered by a single 10x10cm dressing; patients could be managed to prevent further lesions developing. **Exclusion criteria:** lesions that involved tissues other than skin and subcutaneous fat; grade I, IV and V PU; dry and necrotic lesions, patients could be included after debridement; taking systemic corticosteroids; dressed with either study dressing in the two weeks preceding the study; previous sensitivity reaction to either dressings; infected PU; incapable of giving opinion on the dressing; urine or faecal incontinent with PU on sacrum or other sites likely to be soiled.		

Table 57 – BANKS 1994b

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Banks (1994b)** Title: **Comparing two dressings for exuding pressure sores in community patients.** Journal: **Journal of Wound Care, 3 (4); 175-178.** Study type: **randomized controlled trial** Sequence generation: **computer generated random order.** Allocation concealment: **not reported.** Blinding: **not reported.** Addressing incomplete outcome data: **drop-out were excluded.** Statistical analysis: **The Mann-Whitney U test was used to compare ease of dressing removal, pain at removal, and comfort of dressings.** **No Further information.**	**Patient group:** Patients with a grade II or III PU. **All patients** **Randomised N:** 40 **Completed N:** 28 **Drop-outs:** 12 (2 wound deterioration, 2 overgranulation, 2 discomfort, 6 reasons unrelated to wound) **Group 1** **Randomised N:** 20 **Completed N:** 18 **Dropouts:** 2 (1 was admitted to hospital, 1 died) **Age (median years; range):** 71; 40-100 **Gender (m/f):** 9/11 **Ulcer location:** Sacrum: n=4 Buttock: n=10 Other: n=6 **Duration PU (median days; range):** 56; 3-365 **Ulcer area (mean cm² (SD); median; range):** 1.47 (2.26); 0.67; 0.03-9.7 **Group 2**	**Group 1:** Semi-permeable polyurethane dressing (Spyrosorb®, C.V. Laboratories Ltd). Dressings were changed when the area discoloured by exudate was less than 1cm from the edge of the dressing. Spyrosorb®: inner layer consists of non-toxic, pressure sensitive adhesive wound contact surface, the middle layer consists of a microporous polyurethane membrane, and the outer layer is vapourpermeable **Group 2:** Hydrocolloid dressing (GranuflexE®, Convatec). Dressings were changed when the area discoloured by exudate was less than 1cm from the edge of the dressing. GranuflexE®: consists of a thin polyurethane foam sheet bonded onto a semi-permeable polyurethane film. **Both groups:** all patients were provided with standard pressure relieving mattresses and cushions appropriate to their needs.	**Outcome 1:** Proportion of patient completely healed **Outcome 2:** Proportion of patient improved **Outcome 3:** Percentage of patient reporting painful removal of dressing **Outcome 4:** Percentage of patient reporting the dressing as (very) uncomfortable	**Group 1:** 12/18 **Group 2:** 10/10 **Group 1:** 18/18 **Group 2:** 10/10 **Group 1:** figure unclear **Group 2:** figure unclear **P value:** 0.129 **Group 1:** figure unclear **Group 2:** figure unclear **P value:** < 0.097	**Funding:** sponsored by C.V. Laboratories Ltd and Calgon Vestal Laboratories **Limitations:** no report on allocation concealment; no ITT analysis; no a priori sample size calculation; high dropout; no report on blinding; no report on multiple ulcers; no report in classification of PUs; little information on ulcer assessment and statistical analysis. **Additional outcomes:** time to dressing change, and ease of removal. **Notes:** /

Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **community.** Length of study: **6 weeks of treatment or until completely healed.** Assessment of PUs: **PUs classification not reported.** **Wound size were carried out using a structured light method to measure the area of the wound tracing.** Multiple ulcers: **not reported**	**Randomised N:** 20 **Completed N:** 10 **Dropouts:** 10 (2 wound deterioration, 2 overgranulation, 2 discomfort, 2 died, 2 respite care) **Age (median years; range):** 73; 46-93 **Gender (m/f):** 12/8 **Ulcer location:** Sacrum: n=1 Buttock: n=9 Other: n=10 **Duration PU (median days; range):** 21; 5-252 **Ulcer area (mean cm² (SD); median; range):** 1.51 (1.86); 0.74; 0.16-8.19 **Inclusion criteria:** 16 years or older; shallow, moist PU of grade II and III; ulcer could be covered by a single 10x10cm dressing; patients could be managed to prevent further lesions developing. **Exclusion criteria:** lesions that involved tissues other than skin and subcutaneous fat; grade I, IV and V PU; dry and necrotic lesions, patients could be		

	included after debridement; taking systemic corticosteroids; dressed with either study dressing in the two weeks preceding the study; previous sensitivity reaction to either dressings; infected PU; incapable of giving opinion on the dressing; urine or faecal incontinent with PU on sacrum or other sites likely to be soiled.				

Table 58 – BELMIN 2002

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Belmin (2002)** Title: **Sequential treatment with calcium alginate dressings and hydrocolloid dressings accelerates pressure ulcer healing in older subjects: A multicenter randomized trial of sequential versus nonsequential treatment with hydrocolloid**	**Patient group:** Hospitalized patients aged 65 years and older with a grade III or IV PU (according to the Yarkony's classification) **All patients** **Randomised N:** 110 **Completed N:** 72 **Drop-outs:** 38 (29 died, 3 transferred to another unit, 1 worsened in health status, 4 hade local adverse events, 6 had PU impairment)	**Group 1:** Calcium alginate dressing (UrgoSorb®,Urgo, France) for the first four weeks and hydrocolloid dressing (Algoplaque®HP, Urgo, France for the next four weeks. UrgoSorb®: nonwoven dressing composed of calcium alginate (brown seaweeds) fibres and carboxymethylcellulose. Algoplaque®HP: comprised an outer layer of polyurethane and an inner layer formed by an elastomere matric that	**Outcome 1:** proportion of patients reaching a 40% surface area reduction at 4 weeks. **Outcome 2:** proportion of patients reaching a 40% surface area reduction at 8 weeks. **Outcome 3:** mean cm² surface area reduction at	**Group 1:** 39/57 **Group 2:** 12/53 **P value:** <0.0001 **Group 1:** 43/57 **Group 2:** 31/53 **P value:** <0.0001 **Group 1:** 7.0 (5.7) **Group 2:** 1.6 (4.9) **P value:** <0.001	**Funding:** funded by Laboratoires Urgo, Dijon, France **Limitations:** no report on sequence allocation; allocation concealment by block and centre; no blinding of patients and nurses. **Additional**

dressings alone Journal: **Journal of the American Geriatrics Society, 50 (2); 269-274** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **balanced by centre and by blocks of four patients** Blinding: **patients and nurses were not blinded; assessor was blinded.** Addressing incomplete outcome data: **intention-to-treat analysis** Statistical analysis: **A comparison between groups were performed using chi-square test for qualitative parameters and the Mann-Whitney U test for quantitative variable. The percentage of patients reaching SAR40 was analysed by the Kaplan-Meier**	**Group 1** **Randomised N:** 57 **Completed N:** 40 **Dropouts:** 17 (11 died, 1 transferred to another unit, 1 worsened in health status, 1 hade local adverse events, 3 had PU impairment) **Age (mean years (SD)):** 84.8 (7.1) **Gender (m/f):** 15/42 **Norton score (mean (SD)):** 13.2 (3.4) **Number of incontinent patients:** n=27 **Ulcer grade:** Grade III: n=40 Grade IV: n=16 **Ulcer location:** Heel: n=34 Sacrum: n=14 Pelvic: n=5 Other: n=4 **Duration (mean weeks (SD)):** 7.2 (6.8) **Surface area (mean cm² (SD)):** 14.7 (10.4) **Group 2** **Randomised N:** 53 **Completed N:** 37 **Dropouts:** 16 **Age (mean years (SD)):** 82.2 (7.9) **Gender (m/f):** 17/36 **Norton score (mean (SD)):** 12.6 (3.1)	included hydrocolloid molecules. In patients with deep PUs a hydrocolloid paste (Algoplaque Pâte) was added to the hydrocolloid dressing, but not to the calcium alginate dressing. **Group 2:** Hydrocolloid dressing (DuodermE®, Convatec-Bristol Myers Squibb, France) for eight weeks. DuodermE®: comprised an outer layer of polyurethane and an inner layer formed by an elastomere matric that included hydrocolloid molecules. In patients with deep PUs a hydrocolloid paste (DuodermE Pâte) was added to the hydrocolloid dressing, but not to the calcium alginate dressing. **Both groups:** all ulcers were cleaned with a sterile saline, and the surrounding skin was dried before applying the dressings. General treatment (nutrition, medication, use of mattress and cushion) was decided by each investigator according to their usual procedure of care and the patients' health.	4 weeks. **Outcome 4:** mean cm² surface area reduction at 8 weeks. **Outcome 5:** percentage surface area reduction at 4 weeks. **Outcome 6:** percentage surface area reduction at 8 weeks. **Outcome 7:** proportion of patients with an infection **Outcome 8:** proportion of patients with erythema of the surrounding skin **Outcome 9:** proportion of patients with hypergranulation **Outcome 10:** proportion of patients with	**Group 1:** 9.7 (7.1) **Group 2:** 5.2 (7.2) **P value:** <0.001 **Group 1:** 47.3 (30.0) **Group 2:** 14.6 (39.7) **P value:** <0.001 **Group 1:** 69.1 (33.9) **Group 2:** 42.6 (49.1) **P value:** <0.001 **Group 1:** 1/57 **Group 2:** 0/53 **Group 1:** 2/57 **Group 2:** 0/53 **Group 1:** 1/57 **Group 2:** 5/53 **Group 1:** 1/57 **Group 2:** 0/53	**outcomes:** / **Notes:** DuodermE® is the same product as DuodermCGF® in the United Stades, Granulflex® in the United Kingdom, and Varihesive® in Germany. Algoplaque® is the same product as Sorbex® in the United Stades.

method, and treatment groups were compared using the logrank test. The evolution of SAR during the trial was analysed by repeated-measurement analysis of variance, to investigate the effect of time and treatment. Tests were bilateral, and the significance threshold was fixed at .05 Baseline differences: **no statistical difference between groups except for concomitant diseases (diabetes and hypertension)** Study power/sample size: **The size of the study was designed to allow the detection of 35% difference between the groups, with a 5% alpha risk and an 80% power** Setting: **20 French geriatric hospital wards** Length of study: **eight weeks** Assessment of PUs:	**Number of incontinent patients:** n=26 **Ulcer grade:** Grade III: n=43 Grade IV: n=9 **Ulcer location:** Heel: n=37 Sacrum: n=11 Pelvic: n=2 Other: n=3 **Duration (mean weeks (SD)):** 7.7 (6.6) **Surface area (mean cm² (SD)):** 12.6 (8.0) **Inclusion criteria:** 65 years and older; PU that passed the subcutaneous tissue (grade III or IV); PU located on the sacrum, elsewhere on the pelvic girdle, or on the heel; surface area < 50cm²; granulation tissue area not covered > 50% of the ulcer surface; no clinical evidence of active local infection. **Exclusion criteria:** serum albumin < 25g/L; treated with radiotherapy, cytotoxic drugs or corticosteroids; surgical or palliative care needed.	maceration **Outcome 11:** proportion of patients with bleeding	**Group 1:** 1/57 **Group 2:** 0/53

PUs were classified according to the Yarkony's classification. Ulcer surface area was measured by planimetry after cleansing and drying. A sterile transparent polyurethane film was applied to the target ulcer, and the investigator traced its perimeter with a permanent ultra-fine-tipped marker. A photography of the ulcer was taken. Surface area was measured un triplicate, using a digitalization table and computer program, and the mean value was used in the analysis. Multiple ulcers: **Only one ulcer was selected for the study**	

Table 59 – BITO 2012

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Bito (2012)** Title: **Randomised controlled trial evaluating the efficacy of wrap therapy for wound healing acceleration in patients with NPUAP stage II and III pressure ulcer.** Journal: **BMJ, 2; 1-8** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **an allocation centre located received a fax from the health staff with basic information on the patient. A fax with the allocation result was send back to the facility within 48h.** Blinding: **patients and nurses were not blinded; assessor was blinded.**	**Patient group:** Hospitalized patients aged 50 years and older with a stage II or III PU (according to the NPUAP classification) **All patients** **Randomised N:** 66 **Completed N:** 39 **Drop-outs:** 27 (5 died, 20 withdrew, and two were transferred or discharged; the last two were not included in the analysis) **Group 1** **Randomised N:** 35 **Completed N:** 23 **Dropouts:** 12 (2 died and 10 withdrew) **Age (mean years (SD)):** 81 (12) **Gender (m/f):** 16/19 **Braden score (mean (SD)):** 12.7 (2.8) **Number of patients using a pressure relieving mattress:** 35 **Ulcer stage:** Stage II: n=4 Stage III: n=31	**Group 1:** Wrap therapy (food wraps and perforated polyethylene) was used as dressing. The irrigation and covering process was performed every day. **Group 2:** treated with methods conform the 'Evidence-based localized pressure ulcer treatment guidelines' issued by the JSPU in 2005 **Both groups:** /	**Outcome 1:** mean time (days) until complete healing (all stages) **Outcome 2:** mean time (days) until complete healing (stage II PUs) **Outcome 3:** mean time (days) until complete healing (stage III PUs) **Outcome 4:** mean difference in PUSH score (points) **Outcome 7:** proportion of patients who died **Outcome 8:** proportion of patients with systemic worsening	**Group 1:** 59.8 (95% CI: 49.7-69.9) **Group 2:** 57.5 (95% CI: 45.2-69.8) **P value:** 0.75 **Group 1:** 18.8 (95% CI: 10.3-27.2) **Group 2:** 16.0 (95% CI: 8.1-23.9) **P value:** 0.42 **Group 1:** 63.2 (95% CI: 53.0-73.4) **Group 2:** 71.8 (95% CI: 61.4-82.3) **P value:** 0.42 **Group 1:** 0.9 (1.3) **Group 2:** 1.1 (2.1) **P value:** 0.73 **Group 1:** 2/35 **Group 2:** 3/29 **Group 1:** 4/35 **Group 2:** 3/29	**Funding:** This study was supported by Division of the Health for the Elderly at Japanese Ministry of Health, Labour and Welfare. Grant name 'Examination and Research Work into New Pressure Ulcer Treatments for the Care of the Elderly'. **Limitations:** no report on sequence allocation; allocation concealment questionable; no blinding of patients and nurses; sample size lower than calculated sample size; complete healing assessed by clinical, no

Addressing incomplete outcome data: **intention-to-treat analysis. Two patients were excluded from the analysis after randomization because of early transfer or discharge.** Statistical analysis: **For the main endpoint comparisons, Kaplan Meier plots were created, and the estimated mean value until the endpoint occurrence and its 95% CI were calculated. The differences in the PUSH scores were calculated from 2 weeks immediately after the start of observations, between 2-4 weeks, 4-6 weeks, 6-8 weeks, 8-10 weeks and 10-12 weeks and described the speed of pressure ulcer healing over time for both groups. We used PASW Statistics V.18 (SPSS, Inc) for the statistical**	**PUSH score (mean (SD)):** 10.7 (2.7) **Surface area (mean cm² (SD)):** 15 (25) **Group 2** **Randomised N:** 31 **Completed N:** 16 **Dropouts:** 15 (3 died, 10 withdrew and 2 transferred or were discharged; the last 2 were not included in the analysis) **Age (mean years (SD)):** 82 (10) **Gender (m/f):** 15/14 **Braden score (mean (SD)):** 12.8 (3.5) **Number of patients using a pressure relieving mattress:** 27 **Ulcer stage:** Stage II: n=8 Stage III: n=21 **PUSH score (mean (SD)):** 10.8 (2.6) **Surface area (mean cm² (SD)):** 14 (21) **Inclusion criteria:** 50 years and older; NPUAP stage II or III PU on either their torso or trochanter; body temperature of 35.5°C minimum to 37.5°C maximum; 600		**Outcome 9:** proportion of patients with localised adverse events **Outcome 10:** pain during dressing removal assessed by nurses **Outcome 11:** strong odor during dressing removal assessed by nurses **Outcome 12:** mild odor during dressing removal assessed by nurses	**Group 1:** 6/35 **Group 2:** 7/29 **Group 1:** 411/1314 **Group 2:** 316/887 **Group 1:** 173/1314 **Group 2:** 178/887 **Group 1:** 382/1314 **Group 2:** 361/887	further information; no report on multiple ulcers **Additional outcomes:** ease od removal of dressing as assessed by nurses (G1: 1214/1314; G2: 802/887) **Notes:** /

analysis. Baseline differences: **no statistical difference between groups except for use of ointments or sprays and used dressings at baseline.** Study power/sample size: **A sample size of 80 patients per group was required at a tolerable threshold difference of 7 days, a 5% significance level and a power of 90%. The final sample size was lower than the calculated sample size.** Setting: **15 hospitals in Japan related to the Japanese Society of Pressure Ulcers (JSPU)** Length of study: **12 weeks or until PU healed** Assessment of PUs: **PUs were classified according to the NPUAP classification. Every ulcer heal was confirmed by supervising physicians using photographs.**	kcal or over daily intake; no critical nutritional impairment, renal failure, cirrhosis, immunosuppression, uncontrollable diabetes or malignant tumours according to an examination performed within past 4 weeks. **Exclusion criteria:** Patients with an estimated life expectancy < 3 months	

The PUSH score for the localised status of the PU was measured by using photographs. Multiple ulcers: **not reported**					

Table 60 – Brod 1990

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Brod (1994a)** Title: **A randomized comparison of poly-hema and hydrocolloid dressings for treatment of pressure sores.** Journal: **Archives of Dermatology, 126 (7); 969-970.** Study type: **randomized controlled trial** Sequence generation: **60:40 to G1 and G2.** Allocation concealment: **stratified by lesion stage.** Blinding: **blinding of outcome assessor.** Addressing incomplete	**Patient group:** Elderly patients with a grade II or III PU. **All patients** **Randomised N:** 43 **Completed N:** 38 **Drop-outs:** 5 (3 died, 1 poor response, 1 adverse effect) **Group 1** **Randomised N:** 27 **Completed N:** 25 **Dropouts:** 2 (2 died) **Age (median years):** 86 **Ulcer area (median cm²):** 2.5 **Group 2** **Randomised N:** 16 **Completed N:** 13 **Dropouts:** 3 (1 died, 1 poor response, 1 adverse effect)	**Group 1:** Polyhydroxyethyl methacrylate (poly-hema) dissolved in polyethylene glycol (Hydron®, Acme/Chaston Division, National Patient Development Corp, Dayville, Conn). Dressing was applied as a paste, which solidified to a flexible dressing countered to the ulcer. Dressings were changed twice weekly. **Group 2:** Hydrocolloid dressing (DuoDerm®, Convatec, ER Squibb & Sons, Princeton, NJ). Dressing was applied as a sheet with an adhesive backing. Dressings were changed twice weekly. **Both groups:** Surgical debridement was performed before randomization.	**Outcome 1:** Proprotion of patient completely healed **Outcome 2:** Median time (days) to complete healing **Outcome 3:** Absolute rate of healing (cm²/week) **Outcome 4:** Proportion of patients with an adverse effect (unknown if dressing related)	**Group 1:** 14/27 **Group 2:** 10/16 **P-value:** 0.54 **Group 1:** 32 **Group 2:** 42 **P-value:** 0.56 **Group 1:** 0.18 **Group 2:** 0.10 **P value:** 0.005 **Group 1:** 0/27 **Group 2:** 1/16 **P value:** < 0.005	**Funding:** supported in part by a grant from Acme/Chaston Division, National Patient Development Corp, Dayville, Conn **Limitations:** insufficient information on sequence generation; insufficient information on allocation concealment; no a priory sample size calculation; small sample size; no blinding of nurses and patients; no report on multiple

outcome data: **intention-to-treat analysis*** Statistical analysis: **Not reported.** Baseline differences: **Difference between groups was measured statistically for ulcer area (not significant) only. Groups were balanced.** Study power/sample size: **No a priori sample size calculation.** Setting: **academic skilled nursing facility, the Parker Jewish Geriatric Institute, New Hyde Park, NY.** Length of study: **6 weeks of treatment.** Assessment of PUs: **PU classification not reported. Stage II/III PU were seen as inflammatory reaction extending through the dermis or into the subcutaneous fate. Ulcers size and condition were evaluated weekly.** Multiple ulcers: **not**	**Age (median years):** 82 **Ulcer area (median cm²):** 1.9 **Inclusion criteria:** stage II or III PU; life expectancy > 6 months; normal marrow, hepatic, and renal function. **Exclusion criteria:** /		ulcers; little information on ulcer assessment; no information on statistical analysis; unclear if ITT or PP analysis was used; no information on use of preventive measures **Additional outcomes:** / **Notes:** /

reported

** unclearly stated in the article, the primary author was contacted.*

Table 61 – BROWN-ETRIS 2008

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Brown-Etris (2008)** Title: **A prospective, randomized, multisite clinical evaluation of a transparent absorbent acrylic dressing and a hydrocolloid dressing in the management of Stage II and shallow Stage III pressure ulcers.** Journal: **Advances in skin & wound care, 21 (4); 169-174** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported.** Blinding: **no blinding.** Addressing incomplete	**Patient group:** Patients aged 18 years and older with a stage II or shallow III PU. **All patients** **Randomised N:** 72 **Completed N:** not reported **Drop-outs:** not reported **Group 1** **Randomised N:** 35 **Completed N:** not reported **Dropouts:** not reported **Age (mean years (SD)):** 78.3 (14.7) **Gender (m/f):** 13/22 **Braden score (mean (SD)):** 14.9 (3.38) **History of incontinence:** n=23 **Ulcer stage:** Stage II: n=23 Stage III: n=12 **Duration of PU (median; range):** 21.0; 1-291	**Group 1:** Transparent absorbent acrylic dressing (3M Tegaderm® Absorbant Clear Acrylic Dressing, 3M Company, St Paul, MN) was used and changed on an as-needed basis by the facility staff and once a week by the investigator. **Group 2:** Hydrocolloid dressing (DuoDermCGF®, ConvaTec, ER Squibb & Sons, Princeton, NJ) was used and changed on an as-needed basis by the facility staff and once a week by the investigator. **Both groups:** /	**Outcome 1:** percentage difference in ulcer area **Outcome 2:** proportion of patients completely healed **Outcome 3:** linear healing rate (cm/week) **Outcome 4:** adverse events (unrelated to dressing) **Outcome 5:** overall patient comfort assessed by investigator (points: 1 very poor – 5 very good) **Outcome 6:** odor assessed by	**Group 1:** 26.7 **Group 2:** 23.8 **Group 1:** 21/35 **Group 2:** 22/37 **P value:** 0.963 **Group 1:** 0.10 (0.205) **Group 2:** 0.12 (0.136) **P value:** 0.652 **Group 1:** 10/35 **Group 2:** 8/37 **Group 1:** 4.8 (0.34) **Group 2:** 4.4 (0.66) **P value:** 0.048 **Group 1:** 5.0 (0.14) **Group 2:** 4.8 (0.39)	**Funding:** funded by a grand from 3M company **Limitations:** no report on sequence allocation; no report on allocation concealment; no blinding; no ITT analysis; no a priori sample size calculation; difference between groups concerning PU location at baseline; no report on drop-out and number of patient completing the study **Additional outcomes:** ease of application (G1: 4.7 (0.57); G2: 4.5

outcome data: **not reported.** Statistical analysis: **Descriptive statistics were calculated for all variables. The Wilcoxon rank-sum test (a nonparametric equivalent to the t test) was used to test for differences between the treatment groups. Significance was assessed at P≤05, and trends toward significance were assessed at P≤10** Baseline differences: **no statistical difference between groups except ulcer location.** Study power/sample size: **No a priori sample size calculation.** Setting: **five study sites across extended care facilities, out-patient wound care clinics, and home agencies** Length of study: **56 days or until PU healed** Assessment of PUs: **PU classification not**	**Ulcer location:** Sacrum: n=15 Buttock: n=2 Ischium: n=5 Heel: n=4 Other: n=9 **Surface area (mean cm² (SD)):** 1.5 (1.69) **Group 2** **Randomised N:** 37 **Completed N:** not reported **Dropouts:** not reported **Age (mean years (SD)):** 72.7 (18.61) **Gender (m/f):** 19/18 **Braden score (mean (SD)):** 15.0 (3.42) **History of incontinence:** n=24 **Ulcer stage:** Stage II: n=22 Stage III: n=15 **Duration of PU (median; range):** 32.0; 2-635 **Ulcer location:** Sacrum: n=7 Buttock: n=12 Ischium: n=7 Heel: n=4 Other: n=7 **Surface area (mean cm² (SD)):** 2.5 (4.86) **Inclusion criteria:** Stage II or shallow	investigator (points: 1 very poor – 5 very good)	**P value:** 0.016	(0.51); p=0.122) **Notes:** /

reported. **Ulcers and periwound assessments were performed by the investigator at enrolment and nearly weekly. Photographs and ulcer tracings were obtained at time of enrolment and at dressings changes completed by the investigator.** Multiple ulcers: **only one ulcer (the ulcer with the highest PU stage or if same stage, the ulcer with the largest surface area) was considered in the study.**	Stage III, minimally to moderately draining pressure ulcer on any anatomical location that, in the investigator's opinion, could have been treated with an HD; patients with ulcers that could be paired with a size/configuration of study dressings to have a periwound skin margin consistent with the manufacturer's package insert instructions; patients with pressure relief needs that were properly assessed and addressed **Exclusion criteria:** Patients with skin disease or abnormal conditions on or near the product application site; patients with insulin-dependent diabetes that, in the investigator's opinion, had inadequately controlled blood sugar; patients who were receiving steroid, immunosuppressive therapy, or radiation to the area where the pressure ulcer was located; patients with a	

	history of hypersensitivity to adhesive tapes or adhesive wound dressings; patients who were participating in another clinical research study; wounds with more than 50% necrotic tissue or, in the opinion of the investigator, should have undergone debridement before application of an occlusive or semiocclusive dressing; wounds with greater than 1-cm undermining or tunneling; wounds that required use of a filling or packing material; wounds that required the dressing to be cut to a smaller size or to a specialty shape; wounds that exhibited clinical infection as evidenced by purulent, malodorous, or recent increase in drainage and/or periwound erythema, or elevated temperature, or required treatment with a concomitant medication or product	

Table 62 – BURGOS 2000

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Burgos, (2000)** Title: **Cost, Efficacy, Efficiency and Tolerability of Collagenase Ointment versus Hydrocolloid Occlusive Dressing in the Treatment of Pressure Ulcers** Journal: **Clin Drug Invest, 2000; 19 (5): 357-365** Study type: **randomized non-blinded parallel group study** Sequence generation: **Computer generated randomization list into blocks of 4 patients** Allocation concealment: **no details** Blinding: **Blinding of assessor** Addressing incomplete outcome data: **intention-to –treat analysis a per**	**Patient group:** Patients ≥ 5 years presenting with stage III pressure ulcers (skin disruption, tissue damage and exudate, and subcutaneous tissue involvement) **All patients** **Randomised N:** 37 **Completed N:** 23 **Drop-outs:** 14 Reasons in group 1: unrelated death (N=3); discharge from hospital (N=3); transfer to other centre (N=3); Reasons in group 2: unrelated death (N=1); deterioration of general condition (N=1); discharge from hospital (N=1); protocol violation (N=2); ack of efficacy (N=1) **Group 1** **Randomised N:** 18 **Completed N:** 9 **Dropouts:** 9 **Age (mean years (SD)):** 81.9 ± 12.7	**Group 1:** Collagenase ointment (Iruxol® Mono, Laboratorios Knoll, SA) applied once daily in a 1 to 2 mm thick layer to the ulcer bed **Group 2:** Hydrocolloid dressing (Varihesive®, Convatec, SA) that was changed every 3 days. If hydrocolloid dressings showed leakage due to excessive exudate, dressings were changed more frequently. Varihesive® paste was applied to deep ulcers or ulcers with a large amount of exudate according to the investigator's judgment. **Both groups**: /	**Outcome 1:** Proportion of PU with reduction in pressure ulcer area after 12 weeks of treatment **Outcome 2:** Proportion of PU with complete healing of pressure ulcer after 12 weeks of treatment **Outcome 3:** Mean reduction in ulcer area after 12 weeks of treatment (cm^2) **Outcome 4:** Pain intensity decrease **Outcome 5:** Patients with adverse reactions	**Group 1:** 15/18 (83.3%) **Group 2:** 14/19 (73.7%) **Relative risk:** 1.13 **95% CI:** 0.81-1.59 **P value:**0.754 **Group 1:** 3/18 (16.6%) **Group 2:** 3/19 (15.8%) **Relative risk:** 1.06 **95% CI:** 0.24-4.57 **P value:**0.451 **Group 1:** 9.1 ± 12.7 **Group 2:** 6.2 ± 9.8 **P value:**0.369 **P value:** 0.001 **Group 1:** 1/18 **Group 2:** 2/19 **Relative risk:** 0.53 **95% CI:** 0.05-5.33	**Funding:** this study was supported by Labotorios Knoll, SA, Madrid **Limitations:** Underpowered Unclear allocation concealment Not all outcome assessors were blinded Relatively high drop-out No baseline differences reported. **Additional outcomes:** No significant differences were observed in cost and efficiency between collagenase ointment and hydrocolloid dressing in the treatment of pressure ulcers. Granulation tissue

protocol analysis Statistical analysis: **Efficacy analysis ITT was carried out using Student's t-test and the Mann-Whitney U test. Efficacy analysis PP was carried out using factorial analysis of variance 2X9 with repeated measurements of the last factor. Primary outcome measure, ulcer area decrease in absolute terms expressed in cm^2, was obtained by subtracting ulcer area at the end of the study treatment from baseline ulcer area. Similarly, differences in percentages of mean ulcer areas in both treatment groups were calculated according to the formula $(\sigma_t-\sigma_s/\sigma_t) \times 100$, where σ_t is the mean value obtained from transparent acetate films and σ_s is the mean value obtained from the slides. The statistics used were**	**Gender (m/f):** 8/10 **Amell scale score (range):** 17.7 ± 3.4 **Ulcer age :** 3.2 ± 2.0 months **Previously treated ulcers (No. (%)):** 15 (83.33) **Localisation (no. (%)):** Sacrum: 8 (44.44) Trochanter: 4 (22.22) Heel: 3 (16.66) Other: 3 (16.66) **Group 2** **Randomised N:** 19 **Completed N:** 13 **Dropouts:** 6 **Age (mean years (SD)):** 78.6 ± 10.4 **Gender (m/f):** 9/10 **Amell scale score (range):** 20.2 ± 5.9 **Ulcer age (range):** 2.6 ± 1.9 months **Previously treated ulcers (No. (%)):** 17 (89.47) **Localisation (no. (%)):** Sacrum: 7 (36.84) Trochanter: 4 (21.05) Heel: 6 (31.57) Other: 2 (10.53) **Inclusion criteria:** 55 y; Stage III ulcer for < 1 year **Exclusion criteria:** End-		formulation increased (p>0.0005) and exudate production decreased (p>0.0005) in both treatment groups. Odour was not modified throughout the study period.* *no concrete data provided **Notes:** /

the t-test for mean equality. Analysis of ulcer characteristics was carried out using the Friedman test for longitudinal analysis and the Mann-Whitney U test for cross-sectional analysis. The number and percentage of patients presenting ulcer bacterial colonization and the location of colonized ulcers were analyzed by chi-square test and Fisher's exact test. Analysis of tolerability was carried out by calculating the relative risk of adverse reaction occurrence. Statistical significance was set at p≤0.05. Baseline differences: **Not reported** Study power/sample size: **No a priori sample size calculation** Setting: **7 hospitals in Spain** Length of study: **12 weeks of**	stage organ disease; localized or systemic signs or symptoms of infection; hypersensitivity to collagenase	

treatment or until healing of the ulcer, whichever occurred first Assessment of PUs: ***Indirect procedure:*** **After placing an adhesive identification label at one of its margins, the ulcers were photographed according to a standardized method at 50 cm from the focus. The slide of each ulcer was projected and focused in such a way that the size of the attached label matched the actual label size (2.5 cm x 5 cm), and then the contour of each ulcer was transferred to a transparent acetate film.** ***Direct procedure:*** **Were performed by tracing the outline of each ulcer perimeter onto on adequately labelled transparent acetate film.** **Total surface area of the ulcers was calculated using**		

planimetry (HAFF-Planimeter no. 315, Gebrüder Haff, Germany, calibrated for measurements in cm^2). **Examinations were made at 1-week intervals.** **Ulcer characteristics were measured on a 5-point scale and included:** **Pain (no pain, minimal, bearable, intense, unbearable)** **% granulation tissue (≤ 10%, 11 to 30%, 31 to 60%, 61 to 90%, ≥ 90%)** **Exudate (none, minimal, moderate, intense, excessive)** **Odour (none, minimal, tolerable, intense, repulsive)** Multiple ulcers: **No details** **Unit of analysis = patient. However no patient had more than 1 PU.**	

Table 63 – CHANG 1998

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Chang (1998)** Title: **Pressure ulcers-randomised controlled trial comparing hydrocolloid and saline gauze dressings.** Journal: **The Medical journal of Malaysia, 53 (4); 428-431.** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported.** Blinding: **no blinding.** Addressing incomplete outcome data: **no drop-out.** Statistical analysis: **Overall performance, pain, adherence, comfort, ease of removal was analysed by Wilcoxon Rank Sum Test.**	**Patient group:** Patients aged 18 years and older with a stage II or III PU. **All patients** **Randomised N:** 34 **Completed N:** 34 **Drop-outs:** 0 **Age (mean years; range):** 57.6; 20-85 **Incontinence:** Urine: n=5 Faecal: n=16 Both: n=4 **Ulcer stage:** Stage II: n=23 Stage III: n=12 **Duration of PU (mean days; range):** 33; 4-274 **Ulcer location:** Sacrum: n=30 Ilium: n=3 Greater trochanter: n=1 **Group 1** **Randomised N:** 17 **Completed N:** 17 **Dropouts:** 0 **Ulcer stage:** Stage II: n=11 Stage III: n=6 **Group 2**	**Group 1:** Hydrocolloid dressing (DuoDermCGF®). Dressings were changed every seven days or when leakage occurred. Cavity were filled with hydrocolloid gel (DuoDerm Hydroactive Gel®). DuoDermCGF®: occlusive dressing, which is under the influence of wound exudate and provides a moist wound environment. The outer later is made of polyurethane foam which is impermeable. **Group 2:** Wet soaked saline gauze dressing. The saline dressing was covered with a Gamgee® pack. Dressings were changed once a day or when exudate is visible through the second dressing. **Both groups:** /	**Outcome 1:** Mean reduction (%) in ulcer area **Outcome 2:** percentage of patients reporting a dressing as uncomfortable **Outcome 3:** percentage of patients reporting moderate/severe pain during dressing removal **Outcome 4:** proportion of patients reporting with an infection	**Group 1:** 34 **Group 2:** -9 **P value:** 0.23 **Group 1:** 0 **Group 2:** 50 **P value:** <0.01 **Group 1:** 0 **Group 2:** 44 **P value:** <0.01 **Group 1:** 0/17 **Group 2:** 1/17	**Funding:** funded by a grand from 3M company **Limitations:** no report on sequence allocation; no report on allocation concealment; no blinding; no a priori sample size calculation; difference between groups concerning PU location at baseline; no report on drop-out and number of patient completing the study **Additional outcomes:** Ease of use (G1: 62% vs G2: 19; p<0.01) Cost per subject (mean dressing time and mean nursing cost): G1:

Rates of wound healing was analysed by Analysis of Variance Test. Baseline differences: **No statistical difference between groups except ulcer location.** Study power/sample size: **No a priori sample size calculation.** Setting: **University hospital Kuala Lumpur.** Length of study: **8 weeks of treatment or until complete healing.** Assessment of PUs: **PU classification not reported.** **Wound tracings of ulcer perimeter were made at each dressing change by moulding a piece of clear plastic food wrap over the ulcer and into the ulcer cavity. The tracings were then transferred onto acetate transparencies using an Optomax Image Analyzer.** **Colour photographs**	**Randomised N:** 17 **Completed N:** 17 **Dropouts:** 0 **Ulcer stage:** (3 missings) Stage II: n=7 Stage III: n=7 **Inclusion criteria:** Stage II or III PU; at least 18 years of age; provide written informed consent **Exclusion criteria:** Immunocompromised; infected PU; known sensitivity to the study dressings		RM 45.89 vs G2: RM105.30; p=0.025 Cost per subject (mean dressing time, mean nursing cost, and total cost material): G1: RM 271.45 vs G2: RM 173.05; p=0.12 **Notes:** /

were also taken. Assessments were done weekly. Multiple ulcers: **only one PU per patient was eligible for study entry.**					

Table 64 – CHUANGSUWANICH 2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Chuansuwanich (2011)** Title: **The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers.** Journal: **Journal of the Medical Association of Thailand, 94 (5); 559-565** Study type: **randomized controlled trial** Sequence generation: **randomly by computer** Allocation concealment: **not reported.** Blinding: **no blinding.**	**Patient group:** In- and out-patients with a grade III or IV PU (according to the NPUAP 1989 classification). **All patients** **Randomised N:** 40 **Completed N:** 40 **Drop-outs:** 0 **Group 1** **Randomised N:** 20 **Completed N:** 20 **Dropouts:** 0 **Age (mean years (SD)):** 62.60 (20.59) **Gender (m/f):** 8/12 **Duration of PU (mean days (SD)):** 232.00 (180.52) **Ulcer location:** Sacrum: n=16 Greater trochanter: n=1 Ischium: n=3	**Group 1:** Silver mesh dressing (Tegaderm® Ag Mesh dressing) after wound bed cleansing. Cotton gauze was used as outer dressing. Dressings were changed every three days. **Group 2:** Silver sulfadiazine cream after wound bed cleansing. Cotton gauze was used as outer dressing. Dressings were changed twice a day. **Both groups:** Wounds were debrided as necessary.	**Outcome 1:** mean healing rate (%) at eight weeks **Outcome 2:** percentage reduction in PUSH score at eight weeks **Outcome 3:** complications	**Group 1:** 36.95 **Group 2:** 25.06 **P value:** 0.507 **Group 1:** 28.15 **Group 2:** 34.51 **P value:** 0.473 **Group 1:** 0/20 **Group 2:** 0/20	**Funding:** / **Limitations:** no report on allocation concealment; no blinding; no a priori sample size calculation and small sample size **Additional outcomes:** cost was calculated (drug cost + outer dressing cost x time of dressing change/20). G1: 263 USD per patient; G2: 1812 USD per patient; p=0.00 **Notes:** /

Addressing incomplete outcome data: **no missing reported** Statistical analysis: **All data analysis was performed using SPSS 13.0. Data were expressed as mean ± standard deviation (SD). Comparison of the mean between two groups of all parameters was evaluated for the significance by non-parametric Mann-Whitney U-test before treatment and at eight week of treatment. A p-value of less than 0.05 was considered significant.** Baseline differences: **no statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **Siriraj Hospital** Length of study: **eight weeks** Assessment of PUs: **PU were classified according to the**	**Surface area (mean cm² (SD)):** 12.17 **Group 2** **Randomised N:** 20 **Completed N:** 20 **Dropouts:** 20 **Age (mean years (SD)):** 69.10 (16.02) **Gender (m/f):** 9/11 **Duration of PU (mean days (SD)):** 197.40 (131.65) **Ulcer location:** Sacrum: n=14 Greater trochanter: n=5 Ischium: n=1 **Surface area (mean cm² (SD)):** 22.82 **Inclusion criteria:** Grade III or grade IV **Exclusion criteria:** /

NPUAP classification (1989). **Ulcer size was determined by using VISITRAK^{R} Wound measurement system and wound photography at the beginning en very two weeks.** **The PUSH score was assessed every two weeks.** Multiple ulcers: **not reported**					

Table 65 – COLIN 1996

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Colin (1996)** Title: **Managing sloughy pressure sores.** Journal: **Journal of wound care; 5(10):444-446** Study type: **Open, multicentre, multinational, parallel group, prespective and randomized investigation** Sequence generation: **No details**	**Patient group:** Patients were considered eligible for entry into the study if they met strict inclusion and exclusion criteria. **All patients** **Randomised N:** 135 **Completed N:** 96 **Drop-outs:** 39 (adverse incidents (n=5); patient died (n=4); lost to follow up (n=30)) **Group 1** **Randomised N:** 67	**Group 1:** The hydrogel (Intrasite Gel) contains a high proportion of water that has been formulated to allow donation of water molecules to the wound surface in order to rehydrate non-viable tissue and maintain a moist wound environment **Group 2:** The dextranomer paste product (Debrisan Paste) contains polysaccharide beads that are hydrophilic and draw moisture away from the wound surface by capillary action, and is capable of	**Outcome 1:** Reduction in pressure sore area (median and range) **Outcome 2:** Side effects	**Group 1:** Day 7: 8% (-100 to 75%) Day 14: 23% (-100 to 83%) Day 21: 35% (-185 to 91%) **Group 2:** Day 7: 0% (-340 to 92%) Day 14: 5% (-340 to 98%) Day 21: 7% (-340 to 98%) **P value:** p=0.03 at day 21 **Group 1:** 1/67 **Group 2:** 4/68 **Relative risk:** 3.94 **95% CI:**0.45-34.35 There were a total of five	**Funding:** / **Limitations:** No inclusion or exclusion criteria formulated; no blinding or randomization method reported **Additional outcomes:** The median percentage reduction in non-viable tissue was 74% in the

Allocation concealment: **No details** Blinding: **no blinding** Addressing incomplete outcome data: **Intention to treat analysis** Statistical analysis: **Wound area (cm²)= maximum length (cm) * maximum width (cm) * π/4; area of non-viable tissue (cm²) = wound area*(% yellow + % black)*1/100. The difference in treatments with respect to the percentage reduction in slough from day zero to day 21 was assessed using the Wilcoxon Rank Sum Test.** **Baseline differences:** **The two treatment groups were well matched for age, the median being 79 years. In three of the centres several young patients with spinal injuries were included, resulting in a lower median age**	**Completed N:** 53 **Dropouts:** 14 (adverse incidents (n=1); patient died (n=2); lost to follow up (n=11)) **Age:** 79 (25-97) **Gender (m/f):** (28/39) **Other relevant patient characteristics:** Duration <1 month (n=24); 1-3 months (n=28); >3 months (n=15) Area <4cm² (n=15); 4-13 cm² (n=25); >13cm² (n=27) Grade 1 (n=0); grade 2 (n=16); grade 3 (n=38); grade 4 (n=13) Non-viable tissue area <3cm² (n=15); 3-9cm² (n=24); <9cm² (n=28) **Group 2** **Randomised N:** 68 **Completed N:** 43 **Dropouts:** 25 (adverse incidents (n=4); patient died (n=2); lost to follow up (n=19)) **Age:** 81 (25-98) **Gender (m/f):** (34-34) **Other relevant patient characteristics**: Duration <1 month (n=22); 1-3 months (n=35); >3 months	drawing non-viable debris from the wound bed. **Both groups:** Both types of dressings were applied and changed according to manufacturers' instructions. The secondary dressing used for both treatment groups was a non-occlusive absorbent dressing (melolin).	adverse events reported during the clinical investigation, one in the amorphous hydrogel group and four in the dextranomer paste group. The only one that was considered to be dressing-related was pain when the dressing was applied reported by a patient in the dextranomer paste group.	amorphous hydrogel group compared with 62% in the dextranomer paste group. The difference of 12% between the two median values at day 21 was not statistically significant. In the hydrogel group 19% was fully debrided, 30% between 75 and 99% debrided; 18% between 50 and 74% debrided; 13% between 15-49% debrided; 7% between 0-25% debrided (considered as non-responders) and 12% deteriorated. In the dextranomer paste group 21% was fully debrided, 22% between 75 and 99% debrided; 19% between 50 and 74% debrided; 9%

for these centres. Patients numbers were approximately equal in all six trial centres. There were slightly more women (54%) then men (46%) treated in the study. Study power/sample size: **The sample size was set at 120 patients, based on a requirement to be sensitive to a difference of 25% in absolute two treatment groups.** Setting: **Six centres** Length of study: **Patients were treated in the study until the wound was fully cleansed or on completion of 21 days' treatment. Patients could be withdrawn from the study for other reasons, for example, patient choice, investigator's discretion, lost to follow-up, adverse events.** Assessment of PUs: **A formal wound**	(n=11) Area <4cm² (n=18); 4-13 cm² (n=25); >13cm² (n=25) Grade 1 (n=1); grade 2 (n=10); grade 3 (n=45); grade 4 (n=12) Non-viable tissue area <3cm² (n=18); 3-9cm² (n=27);<9cm² (n=23) **Inclusion criteria:** Not reported **Exclusion criteria:** Not reported		between 15-49% debrided; 10% between 0-25% debrided (considered as non-responders) and 19% deteriorated. Assessments were made at day seven, 14 and 21. At each assessment the amorphous hydrogel was found to be easier to apply and remove than the dextranomer paste and was also found to be associated with less pain. **Notes:** /

assessment and an evaluation of dressing characteristics was performed every 7 days. Photographs of each sore were taken at the initial and final assessment. **Pressure sore grading was on a four point scale (Agency for Healthcare Policy and Research (1992) and International Association of Exterostomal Therapy (1987)). Data on patient comfort were assessed subjectively; data on ease of application were assessed subjectively on a four-point scale from "very easy" to "very difficult".** Multiple ulcers: **Where patient presented more than one pressure sore, only the largest sore was assessed as part of this study.**	

Table 66 – COLWELL 1993

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Colwell (1993)** Title: **A comparison of the efficacy and cost-effectiveness of two methods of managing pressure ulcers.** Journal: **Decubitus, 6 (4); 28-36** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported.** Blinding: **no blinding.** Addressing incomplete outcome data: **missing were removed from analysis.** Statistical analysis: **t-test, chi-square and repeated measure ancova were used.** Baseline differences: **Statistical difference between groups for ulcer stage.**	**Patient group:** Hospitalized patients aged 18 years and older with a stage II and/or III PU. **All patients** **Randomised N:** 94 **Completed N:** 70 **Drop-outs:** 24 (12 died, 5 were discharged, 5 were lost to the study, 2 were dropped as they had MRSA, 1 progressed to stage IV PU) **Group 1** **Randomised N:** not reported **Completed N:** 33 with 48 ulcers **Dropouts:** not reported; an equivalent number of patients dropped in both groups **Age (mean years (SD); range):** 68; 18-100 **Gender (m/f):** 18/15 **Number of incontinent patients:** Faeces: n=16 Urine/faeces: n=6	**Group 1:** Hydrocolloid wafer dressing (DuoDerm®CGF™) was used and changed every four days or as needed. DuoDerm®CGF™: occlusive, sterile, control gel formula that consists of an outer layer of polyurethane foam and an adhesive inner layer of a hydrocolloid polymer complex. **Group 2:** moist gauze dressing was used and changed every 6 hours or as needed. Moist gauze dressing: sterile dressing consisting of a layer of fluffed, sterile gauze bandages moistened with 0.9% sodium chloride solution. The dressing was secured with hypoallergenic paper tape. **Both groups:** Cleansing procedure was the same for both groups and was used at each dressing change. All patients were positioned on a pressure-reducing or -relieving surface (e.g. 4" foam overlay or a low air-loss bed)	**Outcome 1:** mean difference (cm^2) in ulcer area **Outcome 2:** proportion of ulcers completely healed	**Group 1:** 0.73 **Group 2:** -0.67 **Group 1:** 11/48 **Group 2:** 1/49 **P value:** 0.963	**Funding:** funded by a grand from 3M company **Limitations:** no report on sequence allocation; no report on allocation concealment; no blinding; no ITT analysis; no a priori sample size calculation; difference between groups concerning PU stage at baseline; high drop-out; no information on randomized patients and ulcers to the intervention groups **Additional outcomes:** average cost (supply cost + labour associated with time

Study power/sample size: **No a priori sample size calculation.** Setting: **a university-affiliated tertiary care centre** Length of study: **minimum eight days of treatment. Range: 6-56 days.** Assessment of PUs: **PU classification not reported.** **Total healing was assessed as complete covering with epithelial tissue.** **The size of the ulcer was determined by tracing the outline of the wound perimeter on a transparent acetate film placed over the ulcer perimeter. Wound perimeters were traced every fourth day.** **The total surface area of the ulcer was calculated using an electronic planimeter, which provided a digital readout.** **Physical measurements of the**	**Ulcer stage:** Stage II: n=33 Stage III: n=15 **Duration of PU (of 46 ulcers; 2 missings):** < 1 month: n=25 1-3 months: n=21 **Ulcer location:** Sacrum/coccyx: n=29 Other: n=19 **Surface area (mean cm²):** 2.29 **Ulcer length (range cm):** 1.0-20.6 **Ulcer width (range cm):** 0.4-9.5 **Group 2** **Randomised N:** not reported **Completed N:** 37 with 49 ulcers **Dropouts:** not reported; an equivalent number of patients dropped in both groups **Age (mean years (SD); range):** 68; 29-92 **Gender (m/f):** 19/18 **Number of incontinent patients:** Faeces: n=23 Urine/faeces: n=6 **Ulcer stage:** Stage II: n=21 Stage III: n=28 **Duration of PU (of 46 ulcers; 3 missings):**		difference): G1: $53.68 per case versus G2: $176.90 per case **Notes:** /

width and length of the PU using a centimetre guide were also obtained every fourth day Multiple ulcers: **70 patients had 97 wounds**	< 1 month: n=27 1-3 months: n=19 **Ulcer location:** Sacrum/coccyx: n=27 Other: n=22 **Surface area (mean cm²):** 2.37 **Ulcer length (range cm):** 1.4-12.1 **Ulcer width (range cm):** 0.6-10.0 **Inclusion criteria:** non-infected stage II and/or III PU **Exclusion criteria:** presence of any factor that adversely influence wound healing such as uncontrolled diabetes or radiation therapy; presence of clinical signs and symptoms indicating the PU was clinically infected; stage I or IV PU; PU that could not be accurately staged; minimum of eight days in the study				

Table 67 – DARKOVICH 1990

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Darkovic (1990)** Title: **Biofilm hydrogel**	**Patient group:** Patients with a stage I or II PUs (according to the Ebis	**Group 1:** Hydrogel (BioFilm™, BF Goodrich Company). The ulcers were	**Outcome 1:** Proportion of ulcers completely	**Group 1:** 24/62 **Group 2:** 12/67	**Funding:** / **Limitations:** no

dressing: a clinical evaluation in the treatment of pressure sores. Journal: **Ostomy/wound management, 29; 47-60.** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **No report on intention to treat analysis. Wounds were treated for a maximum of 60 days, complete healing, discharge or judgement of the clinical to change treatment. No information on the number of patients and wound for the two latter situations. Six patients were eliminated from the analysis, unclear how many wounds this included.**	and Sarmienti 1973 classification). **All patients** **Randomised N:** 90 patients and 129 ulcers **Completed N:** not reported **Drop-outs:** not reported **Age (mean years; range):** 75; 30-98 **Gender (m/f):** 35/55 **Group 1** **Randomised N:** 41 patients and 62 ulcers **Completed N:** not reported **Drop-outs:** not reported **Ulcer stage:** Stage I: n=27 Stage II: n=35 **Surface area (mean cm²):** 11.0 **Group 2** **Randomised N:** 49patients and 67 ulcers **Completed N:** not reported **Drop-outs:** not reported **Ulcer stage:** Stage I: n=31 Stage II: n=36 **Surface area (mean cm²):** 9.2 **Inclusion criteria:**	cleaned with normal saline, the surrounding skin was dried, and the dressing was applied. Dressing were changed based on clinical judgement with an average of every three to four days. **Group 2:** Hydrocolloid (DuoDerm®, ConvaTec, Division of Bristol-Myers Squibb). The ulcers were cleaned with normal saline, the surrounding skin was dried, and the dressing was applied. Dressing were changed based on clinical judgement with an average of every three to four days. **Both groups:** All patients were placed on a pressure reducing air mattress (Gaymar SofCare®)	healed **Outcome 2:** Proportion of ulcers improved **Outcome 3:** Proportion of ulcers with no change **Outcome 4:** Proportion of ulcers worsened **Outcome 5:** Mean percentage ulcer area reduction in stage I ulcers **Outcome 6:** Mean percentage ulcer area reduction in stage II ulcers **Outcome 7:** Mean percentage ulcer area reduction in stage II ulcers and size between 2cm² and 20cm² **Outcome 8:** Healing rate (percentage/day)	**Group 1:** 56/62 **Group 2:** 52/67 **Group 1:** 5/62 **Group 2:** 8/67 **Group 1:** 1/62 **Group 2:** 7/67 **Group 1:** 72 **Group 2:** 44 **P value:** > 0.05 **Group 1:** 64 **Group 2:** 34 **P value:** <0.01 **Group 1:** 72.3 **Group 2:** 38.1 **P value:** <0.01 **Group 1:** 8.1 **Group 2:** 3.1 **P value:** <0.01	report on sequence allocation; no report on allocation concealment; no blinding; no a priori sample size calculation; difference between groups not statistically measured; drop-outs and use of ITT unclear; little information on patient characteristics; no report on debridement of ulcers. **Additional outcomes:** / **Notes:** /

Statistical analysis: **Two methods of analysis were utilized: student t-test and multiple regression. The student –t-test was used to compare average and standard deviations between groups and considers variation within groups. A t exceeding 2.0 approximates a significant difference at 95% confidence. With multiple regression, algebraic mathematical models are fitted to the results and the coefficients of the models were estimated by least squares.** Baseline differences: **Difference was not statistically measured.** Study power/sample size: **No a priori sample size calculation.** Setting: **two acute care facilities and several nursing homes.**	Stage I or II PU; no venous stasis ulcers or diabetic ulcers; lesions ranging in size from at least 0.2 to 100cm²; PU on sacrum, trochanter, lower extremities, buttocks, scapula, and heels; no radiotherapy; blood sugar level <180mg/dl; improved nutritional status (receiving oral supplement, enteral feedings, TPN, PPN); no infection, sinus tracts or fistulae in the ulcer **Exclusion criteria:** /	in stage II ulcers and size between 2cm² and 20cm² **Outcome 9:** Mean percentage ulcer area reduction in stage II ulcers and size between 2cm² and 20cm² (acute care setting) **Outcome 10:** Healing rate (percentage/day) in stage II ulcers and size between 2cm² and 20cm² (acute care setting)	**Group 1:** 80.0 **Group 2:** 15.1 **P value:** <0.0001 **Group 1:** 10.6 **Group 2:** 1.3 **P value:** <0.001

Length of study: **maximum of 60 days, complete healing, discharge or judgement of the clinical to change treatment.** Assessment of PUs: **PU were classified according to Enis and Sarmienti's classification (1973). Ulcer tracings were taken and, in some cases, photography was used to supplement the tracing to determine the size of the ulcer. A Kundin gauge or metric ruler was used to measure the depth of the ulcer. Assessment was performed at each dressing change or at least weekly..** Multiple ulcers: **129 ulcers in 90 patients. Ulcers were unit of analysis.**		

Table 68 – DAY 1995

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Day (1995)** Title: **Managing sacral pressure ulcers with hydrocolloid dressings: results of a controlled, clinical study.** Journal: **Ostomy/wound management, 41 (2); 52-65.** Study type: **randomized controlled trial** Sequence generation: **randomized schedule** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **Intention to treat analysis except patients who didn't completed a minimum of two dressings change (n=7; G1: 5 and G2: 2).** Statistical analysis:	**Patient group:** Patients with a stage II or III PU to the sacral area (according to the NPUAP 1989 classification). **All patients** **Randomised N:** 103 **Completed N:** 96 **Drop-outs:** 7 (lost to follow up shortly after study enrolment) **Group 1** **Randomised N:** 52 **Completed N:** 47 **Dropouts:** 5 **Age (mean years (SD)):** 72 (16) **Gender (m/f):** 27/20 **Diabetes:** 10 **Activity level:** Ambulant: n=0 Some ambulant: n=8 Mainly sitting: n=19 Recumbent: n=20 **Incontinence:** Urine: n=3 Faecal: n=9 Both: n=12 **Ulcer stage:** Stage II: n=38	**Group 1:** Hydrocolloid triangular shape (DuoDerm® or DuoDermCGF® for US Varihesive™ for Canada or Granuflex™ for UK, Bristol-Myers Squibb Company). Ulcers were cleaned with saline and the skin needed to be completely dried prior to application of the dressing. The dressing was applied in rolling motion and had to extend at least 1 inch beyond the wound edge. **Group 2:** Hydrocolloid oval shape (Tegasorb™, 3M Medical-Surgical Division, St Paul, MN). Ulcers were cleaned with saline and the skin needed to be completely dried prior to application of the dressing. The dressing was applied in rolling motion and had to extend at least 1 inch beyond the wound edge. **Both groups:** Pressure reducing mattress or bed were provided if necessary (70% G1 and 73% G2)	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Proportion of patients improved **Outcome 3:** Proportion of patients with no change **Outcome 4:** Proportion of patients worsened **Outcome 5:** Mean percentage ulcer length reduction **Outcome 6:** Mean percentage ulcer width reduction **Outcome 7:** Mean pain at dressing change	**Group 1:** 17/47 **Group 2:** 11/49 **Group 1:** 41/47 **Group 2:** 31/49 **Group 1:** 4/47 **Group 2:** 3/49 **Group 1:** 2/47 **Group 2:** 15/49 **Group 1:** 32 **Group 2:** 17 **P value:** 0.034 **Group 1:** 28 **Group 2:** 24 **P value:** >0.05 **Group 1:** 2.1 (2.1); range: 1-10 **Group 2:** 4.3 (1.75); range: 2-9	**Funding:** / **Limitations:** insufficient information on sequence allocation; no report on allocation concealment; no blinding; no a priori sample size calculation; difference between groups not statistically measured except for two variables; no report on debridement of ulcers; no report on multiple ulcers **Additional outcomes:** Number of dressing changes: G1: 197 vs G2: 201 Average wear time in continent and incontinent patients

Analysis of variance was utilized to assess variables when responses were normally distributed. Categorical and ordinal data were analyzed using Fischer's exact test respectively and the Wilcoxon Rank Sum test respectively. A aired t-test was utilized to compare change from baseline for ulcer length and width. All tests were performed at the 0.05 level of significance utilizing the Statistical Analysis System (SAS). Baseline differences: **Difference was statistically measured for age and height (not significantly different).** Study power/sample size: **No a priori sample size calculation.** Setting: **eight different acute care hospitals in the United States, United Kingdom and**	Stage III: n=9 **Duration of PU:** < 1 month: n=43 1-3months: n=4 3-6 months: n=0 > 6 months: n=0 **Ulcer length (mean cm (SD)):** 2.93 (1.96) **Ulcer width (mean cm (SD)):** 2.24 (1.89) **Group 2** **Randomised N:** 51 **Completed N:** 49 **Dropouts:** 2 **Age (mean years (SD)):** 78 (13) **Gender (m/f):** 64 (3.7) **Diabetes:** 11 **Activity level:** Ambulant: n=4 Some ambulant: n=3 Mainly sitting: n=19 Recumbent: n=23 **Incontinence:** Urine: n=3 Faecal: n=11 Both: n=15 **Ulcer stage:** Stage II: n=41 Stage III: n=8 **Duration of PU:** < 1 month: n=39 1-3months: n=7 3-7 months: n=2 > 6 months: n=1 **Ulcer length (mean cm (SD)):** 2.97 (1.68)	**Outcome 8:** Proportion of patients reporting ulcer pain at and of the study	**Group 1:** 8/47 **Group 2:** 15/49 **P value:** <0.05	**Notes:** /
		Outcome 9: Proportion of patients with adverse events (dressing related)	**Group 1:** 0/47 **Group 2:** 4/49 (increase in necrotic tissue, wound size and depth, inflammation of surrounding skin, severe pain upon dressing removal, and bleeding **P value:** 0.012	

Canada. Length of study: **six dressings or until complete healing.** Assessment of PUs: **PU were classified according to NPUAP classification (1989). The ulcer was assessed and measured utilizing a centimeter ruler prior to the first application and every subsequent dressing change. Photographs were taken at every dressing change.** Multiple ulcers: **not reported.**	**Ulcer width (mean cm (SD)):** 1.73 (1.19) **Inclusion criteria:** Stage II or III PU; legally consenting; PU at sacral area **Exclusion criteria:** signs and symptoms of wound infection; treated with systematic steroid; condition that impairs healing (e.g. AIDS); receiving concomitant topical or local treatment that could not be interrupted; chronic skin conditions or hypersensitivity to the skin adhesives; participation in similar study one month prior to this study; previous use of tested dressings.				

Table 69 – FELZANI 2011

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Felzani (2011)** Title: **Effect of lysine hyaluronate on the healing of decubitus ulcers in rehabilitation patients.**	**Patient group:** Hospitalized patients aged 18 years and older with stage I, II or III PUs (according to the NPUAP classification). **All patients**	**Group 1:** Hyaluronic acid, Lys-HA (Lysial®, Fatai-Nyl Srl, Jasper LLC, Lugano, Switzerland). Ulcers were cleansed with saline and the cream was applied as a thin layer across the ulcer surface. The ulcer was	**Outcome 1:** Percentage of ulcer area healed at 15 days in stage I PUs **Outcome 2:** Percentage of	**Group 1:** 90 **Group 2:** 70 **P value:** < 0.05 **Group 1:** 70 **Group 2:** 40	**Funding:** / **Limitations:** no report on sequence allocation; no report on allocation

Journal: **Advances in Therapy, 28 (5); 439-445** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **blinding of nurses, outcome assessor and statistician. Unclear if patients were blind to the allocation but products were provided in identical containers.** Addressing incomplete outcome data: **drop-outs were excluded.** Statistical analysis: **Data are expressed as average ±1 standard deviation or as percentage where appropriate. Data were assessed to evaluate normal distribution according to the Kologorov–Smirnov test. The two-tailed Student *t* test for matched data was**	**Randomised N:** 59 patients and 63 ulcers **Completed N:** 50 patients and 54 ulcers **Drop-outs:** 9 (3 were discharged, 2 worsened and required antibiotics, 2 were suspended from the study treatment) **Characteristics of completed N:** **Age (mean years (SD)):** 56 (7) **Gender (m/f):** 21/29 **Diabetes:** n=9 **Ulcer stage:** Stage I: n=20 Stage II: n=20 Stage III: n=14 (two subjects had two ulcers and one subject had three ulcers) **Group 1** **Randomised N:** not reported **Completed N:** 17 ulcers **Dropouts:** not reported **BMI (mean kg/m² (SD)):** 27.4 (2.8) **Ulcer stage:** Stage I: n=10 Stage II: n=10 Stage III: n=7 **Group 2** **Randomised N:** not reported	covered with a fat gauze and on top of that a sterile gauze. **Group 2:** Sodium hyaluronate. Ulcers were cleansed with saline and the cream was applied as a thin layer across the ulcer surface. The ulcer was covered with a fat gauze and on top of that a sterile gauze. **Both groups:** Necrotic tissue were removed with gauze and macerated skin borders were surgically removed. Dressings were used on top of the standard therapy for cutaneous lesions.	ulcer area healed at 15 days in stage II PUs **Outcome 3:** Percentage of ulcer area healed at 15 days in stage III PUs **Outcome 4:** Time (days) to 50% reduction in ulcer diameter in stage I PUs **Outcome 5:** Time to 50% reduction in ulcer diameter in stage II PUs **Outcome 6:** Time to 50% reduction in ulcer diameter in stage III PUs	**P value:** < 0.02 **Group 1:** not reported **Group 2:** not reported **P value:** <0.01 **Group 1:** 9 **Group 2:** 15 **P value:** < 0.05 **Group 1:** 9.5 **Group 2:** 15 **P value:** < 0.05 **Group 1:** 12.9 **Group 2:** 19.2 **P value:** < 0.05	concealment; no ITT analysis; on report on required sample size, despite calculation; difference between groups not statistically measured; no report on preventive measures of ulcers **Additional outcomes:** / **Notes:** /

used in order to test pretreatment and posttreatment differences in each group. The difference between groups was tested by analysis of covariance (ANCOVA), utilizing basis values as constant covariates. A value of *P*<0.05 was accepted as level of statistical significance. Baseline differences: **Difference was not measured statistically.** Study power/sample size: **Sample size was calculated according to the hypothesis that there should be a 30% difference between the two preparations (the Lys-HA and the SH groups) at the primary endpoint: time taken to reach a 50% reduction of the skin lesion diameter.** Setting: **one hospital** Length of study: **15 days of treatment.** Assessment of PUs: **PU were classified**	**Completed N:** 17 ulcers **Dropouts:** not reported **BMI (mean kg/m² (SD)):** 26.9 (3.1) **Ulcer stage:** Stage I: n=10 Stage II: n=10 Stage III: n=7 **Inclusion criteria:** Older than 18; hospitalized for a period of 15 days or longer; PU grade I, II or III **Exclusion criteria:** patients who could not cooperate with the hygienic measures; patients with a history of intolerance to hyaluronic acid.	

according to the NPUAP classification Ulcer size (length, and width) location, condition, duration and stage were measured. Ulcers were digitally photographed, including a reference ruler was taken before the treatment start, then every 3 days during the study period, and at the end of the study. The picture was taken with an 8-megapixel digital camera with digital zoom. Multiple ulcers: **50 patients and 54 ulcers**					

Table 70 – GRAUMLICH 2003

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Graumlich (2003)** Title: **Healing pressure ulcers with collagen or hydrocolloid: A randomized, controlled trial.** Journal: **Journal of**	**Patient group:** Patients aged 18 years and older with a stage II or III PU (according to the NPUAP 1994 classification). **All patients** **Randomised N:** 65	**Group 1:** Type I collagen dressing (Medifil®, Kollagen, BioCore, Topeka, KS) covered with dry gauze. Changed daily. **Group 2:** Hydrocolloid (DuoDerm®; ConvaTec, ER Squibb & Sons, Inc. Princeton, NJ) and perimeter	**Outcome 1:** proportion of patients completely healed at eight weeks **Outcome 2:** Mean healing time (weeks) (complete	**Group 1:** 18/35 **Group 2:** 15/30 **P value:** 0.893 **Group 1:** 5 (95% CI: 4-6) **Group 2:** 6 (95% CI: 5-7) **P value:** 0.409	**Funding:** BioCore Medical Technologies, Topeka, Kansas, donated the collagen product used in the trial. A grant from the

the American Geriatrics Society, 51 (2); 147-154 Study type: **randomized controlled trial** Sequence generation: **computerized random number generator. Assignment was in a 1:1 ratio** Allocation concealment: **stratified (diabetes) and block (4 and 10) design. Assignment by personnel unassociated with trial.** Blinding: **blinding of outcome assessor.** Addressing incomplete outcome data: **intention to treat analysis.** Statistical analysis: **For categorical variables, comparisons involved chi-square or Fisher exact tests. Comparisons for continuous variables employed *t* tests or Mann-Whitney tests when**	**Completed N:** 54 **Drop-outs:** 11 (5 died, 3 were hospitalized, 1 withdrew, 2 were lost to follow-up) **Ulcer location:** Sacrum/coccyx: n=34 Heel: n=12 Ankle: n=8 **Group 1** **Randomised N:** 35 **Completed N:** 29 **Dropouts:** 6 (3 died, 1 withdrew, and 2 were hospitalized) **Age (mean years (SD)):** 82.0 (9.9) **Gender (m/f):** 13/22 **Braden score (mean (SD)):** 12 (3) **Ulcer stage:** Stage II: n=29 Stage III: n=6 **Duration of PU (median weeks (25%, 75%)):** 3.0 (1.6, 8.0) **Surface area (median mm² (25%, 75%)):** 121 (63, 338) **Ulcer depth (median mm (25%, 75%)):** 1 (0, 2) **Group 2** **Randomised N:** 30 **Completed N:** 25 **Dropouts:** 5 (2 died, 2	was rimmed with tape. Changed every four days **Both groups:** All ulcers were irrigated with sterile saline before applying the dressing. Ancillary wound treatment were prohibited.	healing) **Outcome 3:** Mean area healed per day (mm²/day) **Outcome 4:** Percentage healing rate within eight weeks **Outcome 4:** Adverse events related to study treatment as assessed by physicians	**Adj for depth: P value:** 0.229 **Group 1:** 6 (19) **Group 2:** 6 (16) **P value:** 0.942 **Group 1:** 33% **Group 2:** 9% **P value:** 0.197 **Group 1:** 0/35 **Group 2:** 0/30	Retirement Research Foundation, Chicago, Illinois, paid for other study supplies and paid partial salary support for the investigators. **Limitations:** no blinding of patient and nurses; sample size lower than calculated **Additional outcomes:** The multivariate logistic regression model entered stage, depth, duration, and area. In the model, only ulcer depth remained a significant predictor of complete healing within 8 week. Exploratory analyses related ulcer stage, ulcer duration, ulcer area, and diabetes to healing was

appropriate. Two-sided *P* values less than .05 were considered significant. Adjustment for multiple comparisons involved the Bonferroni inequality. Analysis of time to complete healing used survival methods. Pairwise comparisons between groups employed the log-rank test with event rates calculated by the Kaplan-Meier method. Exploratory logistic regression analyses evaluated the relationship between the primary endpoint and covariates identified by literature review. Covariates included the following variables associated with pressure ulcer development: age, weight, blood pressure, Braden score, dementia, diabetes mellitus, nursing home, and	were lost to follow-up, and 1 was hospitalized) **Age (mean years (SD)):** 80.6 (12.2) **Gender (m/f):** 11/19 **Braden score (mean (SD)):** 13 (3) **Ulcer stage:** Stage II: n=23 Stage III: n=7 **Duration of PU (median weeks (25%, 75%)):** 6.5 (2.0, 12.0) **Surface area (median mm² (25%, 75%)):** 174 (50, 436) **Ulcer depth (median mm (25%, 75%)):** 0 (0, 3) **Inclusion criteria:** Older than 18; at least one pressure ulcer stage II or III **Exclusion criteria:** hypersensitivity to collagen or bovine Products; concomitant investigational therapy; previous enrollment in the trial; osteomyelitis, cellulitis or malnutrition, ulcers covered by eschar or necrotic material (rescreened after successful debridement); ulcers covered by orthopedic casts or		performed. After adjustment for these variables (individually), there was no significant difference in healing time between collagen and hydrocolloid. Average cost was [acquisition cost + (labor cost per hour x hours per dressing change x dressing changes per week x 8 weeks) + (ancillary supplies cost per dressing change x dressing changes per week x 8 weeks)]: G1: $627.56 per patient versus G2: $222.36 per patient. Sensitivity analysis did not reveal likely conditions in which the cost analysis would favor collagen. **Notes:** /

sex. Covariates associated with ulcer healing were area, depth, age, and stage. Covariates chosen from recommendations of expert consensus were serum albumin and ulcer duration before enrollment. Variables significant at the .10 level were examined further in a multivariate model with forward and backward stepwise procedures (SPSS for Windows, Release 9.0.0, SPSS Inc., Chicago, IL). Baseline differences: **No statistical difference between groups.** Study power/sample size: **The sample size estimate assumed that 24% difference in healing rates was clinically important (alpha 0.05 and 80% power). The estimated sample size was 58 patients per group,**	devices; burn ulcers; diabetic foot ulcers distal to tarsals; life expectancy less than 8 week; anticipated transfer to acute care within 8 weeks.	

and estimated dropout rate was 10%. After adjusting sample size for dropouts, the total sample size was 128 patients. The final sample size was lower than calculated. Setting: **11 skilled nursing facilities in central Illinois** Length of study: **eight weeks of treatment, with a median follow-up of 35 days.** Assessment of PUs: **PU were classified according to the NPUAP (1994). Ulcer are and perimeter were assessed by using photography with a computer-aided system with image capture and morphometric software. During each study visit, the observers used validated, standardized techniques to record ulcer length, width, and appearance. The center ulcer depth (in**						

mm) was measured with a sterile probe. Multiple ulcers: **only one ulcer per patient was included in the study.**					

Table 71 – GÜNES 2007

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Günes (2007)** Title: **Effectiveness of a honey dressing for healing pressure ulcers.** Journal: **Journal of Wound, Ostomy and Continence Nursing, 34 (2); 184-190.** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **no blinding.** Addressing incomplete outcome data: **drop-outs were excluded.** Statistical analysis: **Data are analysed using the Statistical**	**Patient group:** Hospitalized patients aged 18 years and older with stage II or III PUs (according to the US Agency for Health Care Research and Quality's PU Guideline Panel classification). **All patients** **Randomised N:** 27 patients **Completed N:** 26 patients and 50 ulcers **Drop-outs:** 1 (died) **Ulcer stage:** Stage II: n=2 Stage III: n=48 **Group 1** **Randomised N:** 15 patients and 25 ulcers **Completed N:** 15 patients and 25 ulcers **Dropouts:** 0	**Group 1:** Honey dressing (3.8% concentration, and sterilized at 25kGy Gamma irradiation). Ulcers were irrigated with NaCl0.9% at each dressing change. A gauze dressing impregnated with honey (20ml) was used as a primary dressing. A semipermeable adhesive dressing was used as secondary dressing to prevent leakage of honey. Dressings were changed once daily or when contaminated with urine or faeces. **Group 2:** Ethoxydiaminoacridine and nitrofurazone dressing. Ulcers were cleaned with ethoxydiaminoacridine solution (0.1%) and a nitrofurazone cream was spread to the surface of the wound. A gauze dressing	**Outcome 1:** Mean percentage decrease in PUSH score **Outcome 2:** Mean percentage reduction in ulcer size **Outcome 3:** Proportion of ulcers completely healed **Outcome 4:** Proportion of patients with adverse events attributed to the treatment	**Group 1:** 12.62 (2.15) **Group 2:** 6.55 (2.14) **P value:** < 0.001 **Group 1:** 56 **Group 2:** 13 **P value:** < 0.001 **Group 1:** 5/25 **Group 2:** 0/25 **P value:** < 0.001 **Group 1:** 0/15 **Group 2:** 0/11	**Funding:** / **Limitations:** no report on sequence allocation; no report on allocation concealment; no blinding; no ITT analysis; no a priori sample size calculation **Additional outcomes:** / **Notes:** /

Package for the Social Sciences (Version 11.0 for Windows). PUSH scores were used to characterize PU healing. Chi-square analysis was conducted to compare wound and patient demographics by groups. Repeated anova were calculated to compare PU healing in both groups. Baseline differences: **No statistical difference between groups..** Study power/sample size: **No a priori sample size calculation.** Setting: **one university hospital in Izmir** Length of study: **maximum five weeks of treatment or until complete healing.** Assessment of PUs: **PU were classified according to the Agency Health Care Research and Quality's Pressure Ulcer Guideline Panel**	**Age (mean years (SD)):** 65.80 (6.30) **Gender (m/f):** 9/6 **BMI (mean kg/m² (SD)):** 27.2 (1.38) **Mobility level (mean score (SD));** score 1 to 4, with 1 greater impairment**:** 1.20 (0.40) **Group 2** **Randomised N:** 12 patients **Completed N:** 11 patients and 25 ulcers **Dropouts:** 1 (died) **Age (mean years (SD)):** 66.56 (5.53) **Gender (m/f):** 8/3 **BMI (mean kg/m² (SD)):** 26.4 (1.40) **Mobility level (mean score (SD));** score 1 to 4, with 1 greater impairment**:** 1.32 (0.47) **Inclusion criteria:** Older than 18; life expectancy > 2 months **Exclusion criteria:** diabetes mellitus	soaked with ethoxydiaminoacridine covered the ulcer. A semipermeable adhesive dressing was used as secondary dressing. Dressings were changed once daily or when contaminated with urine or faeces. **Both groups:** all patients received preventive skin regimen (a turning and repositioning program and a pressure relieving mattress)

classification (1994) Ulcer were made by standard acetate hand tracing. Ulcer characteristics were documented via the PUSH instrument. Measurement were carried out at baseline and on each weekly visit. The total score ranged from 0 to 17, with 0 representing a healed wound. Multiple ulcers: **26 patients with 50 ulcers were included.**					

Table 72 – HOLLISAZ 2004

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Hollisaz (2004)** Title: **A randomized clinical trial comparing hydrocolloid, phenytoin and simple dressings for the treatment of pressure ulcers [ISRCTN33429693].** Journal: **BMC Dermatology, 4 (1); 18-26**	**Patient group:** Patients with a spinal cord injury and a stage I or II PU (according to the NPUAP or Shea classification) **All patients** **Randomised N:** 83 patients with 91 ulcers **Completed N:** 83 patients with 91 ulcers **Drop-outs:** 0	**Group 1:** Hydrocolloid adhesive dressing was used after cleaning and washing (3 times with normal saline) of the ulcer. The adhesive dressing was changed twice a week. **Group 2:** Phenytoin cream was used after cleaning and washing (3 times with normal saline) of the ulcer. A thin layer was applied to the ulcer before the dressing was performed. The dressing was	**Outcome 1:** proportion of ulcers complete healed after eight weeks (all stages; all sites) **Outcome 2:** proportion of ulcers complete healed after eight weeks (stage I; all sites)	**Group 1:** 23/31 **Group 2:** 12/30 **Group 3:** 8/30 **P value G1 vs G2:** <0.01 **P value G1 vs G3:** <0.005 **Group 1:** 11/13 **Group 2:** 2/9 **Group 3:** 5/11 **P value G1 vs G2:** <0.005 **P value G1 vs G3:** <0.05	**Funding:** The study was supported by the Jaonbazan Medical and Engineering Research Center, the medical and research section of the official governmental body responsible for SCI war victims.

Study type: **randomized controlled trial** Sequence generation: **random number table was used. The statistician in the team generated the random allocation sequence.** Allocation concealment: **stratified randomization (ulcers stage and location) was used. The statistician delivered the treatment category in an opaque sealed envelope bearing only the number of the patient.** Blinding: **outcome assessor blinding.** Addressing incomplete outcome data: **no drop-out.** Statistical analysis: **All the data collected from the patients' preliminary and complementary questionnaires were analyzed by SPSS software using ANOVA**	**Group 1** **Randomised N:** 28 patients with 31 ulcers **Completed N:** 28 patients with 31 ulcers **Dropouts:** 0 **Age (mean years (SD)):** 36.81 (6.71) Gender (m/f): 28/0 **Duration of PU (mean weeks (SD)):** 7.63 (5.59) **Ulcer stage:** Stage I: n=13 Stage II: n=18 **Ulcer location:** Gluteal: n=6 Ischial: n=18 Sacral: n=7 **Surface area (mean cm² (SD)):** 7.26 (15.4) **Group 2** **Randomised N:** 28 patients with 30 ulcers **Completed N:** 28 patients with 30 ulcers **Dropouts:** 0 **Age (mean years (SD)):** 36.5 (4.99) **Duration of PU (mean weeks (SD)):** 5.84 (8.04) **Ulcer stage:** Stage I: n=9 Stage II: n=21 **Ulcer location:** Gluteal: n=7 Ischial: n=18 Sacral: n=5	changed daily. **Group 3:** Simple dressing was used after cleaning, washing (3 times with normal saline) and drying of the ulcer with a sterile gauze. The ulcer was covered with wet saline gauze dressing and was changed twice a day. **Both groups:** all ulcers were debrided before treatment. No concomitant topical or systematic antibiotic, glucocorticoid or immunosuppressive agent were allowed during the treatment.	**Outcome 3:** proportion of ulcers complete healed after eight weeks (stage II; all sites) **Group 1:** 12/18 **Group 2:** 10/21 **Group 3:** 3/19 **P value G1 vs G2:** >0.05 **P value G1 vs G3:** <0.005 **Outcome 4:** proportion of ulcers complete healed after eight weeks (all stages; gluteal) **Group 1:** 6/6 **Group 2:** 2/7 **Group 3:** 1/8 **P value G1 vs G2:** <0.005 **P value G1 vs G3:** <0.001 **Outcome 5:** proportion of ulcers complete healed after eight weeks (all stages; ischial) **Group 1:** 13/18 **Group 2:** 8/18 **Group 3:** 3/14 **P value G1 vs G2:** <0.1 **P value G1 vs G3:** <0.005 **Outcome 6:** proportion of ulcers complete healed after eight weeks (all stages; sacral) **Group 1:** 4/7 **Group 2:** 2/5 **Group 3:** 4/8 **P value G1 vs G2:** >0.35 **P value G1 vs G3:** >0.20 **Outcome 7:** proportion of ulcers partially healed after eight weeks **Group 1:** 4/31 **Group 2:** 4/30 **Group 3:** 5/30 **Outcome 8:** proportion of ulcers worsened after eight weeks **Group 1:** 2/31 **Group 2:** 2/30 **Group 3:** 9/30	**Limitations:** no blinding of patients and nurses; sample size lower than calculated sample size **Additional outcomes:** / **Notes:** /

and Chi square tests, and P-values of <0.05 were assumed significant. The 95% confidence intervals were also calculated and reported. For rare events (more than 20 percent of cross tabulation cells had values less than 5), Fisher's exact test **was used. Based on stage and location of ulcers, subgroup analyses were performed using the same statistical tests.** Baseline differences: **no statistical difference between groups.** Study power/sample size: **A response rate of 30%, 40% and 80%w was assumed for SD, PC and HD, respectively. Based on a 40% difference, power of 0.85, 95% confidence level and estimated follow-up loss of 10%, 29 patients were required for each study group. Final**	**Surface area (mean cm² (SD)):** 5.12 (3.63) **Group 3** **Randomised N:** 27 patients with 30 ulcers **Completed N:** 27 patients with 30 ulcers **Dropouts:** 0 **Age (mean years (SD)):** 36.6 (6.17) **Duration of PU (mean weeks (SD)):** 5.25 (5.39) **Ulcer stage:** Stage I: n=11 Stage II: n=19 **Ulcer location:** Gluteal: n=8 Ischial: n=14 Sacral: n=8 **Surface area (mean cm² (SD)):** 10.27 (15.32) **Inclusion criteria:** Paraplegia caused by spinal cord injury; PU stage I or II according to Shea or NPUAP classification; informed consent; smoothness of ulcer area to establish whether adhesive could be used at the site **Exclusion criteria:** Addiction; heavy smoking (more than 20 cigarettes a day or more than 10 packs	**Outcome 9:** proportion of patients completely healed after eight weeks (one ulcer per patient randomly drawn)	**Group 1:** 20/28 **Group 2:** 11/28 **Group 3:** 8/27 **P value G1 vs G2:** <0.01 **P value G1 vs G3:** <0.005

sample size lower than calculated. Setting: **home care and long-term care centres** Length of study: **8 weeks of treatment** Assessment of PUs: **PUs were classified according to the NPUAP (1989) and Shea (1975) classification.** **The general practitioner filled in a questionnaire on ulcer status.** **One of the authors assesses complete/partial/without/worsening healing at the end of the study.** **Ulcer surface area was measured by tracing on an paper overly, which was scanned, redrawn and measured by AutoCAD 2000** Multiple ulcers: **if a patient had more than one ulcer, all ulcers were treated by the same method. Ulcers was unit of analysis.**	per year; concomitant chronic disease (e.g. diabetes mellitus or frank vascular disease such as Buerger's disease).	

Table 73 – HONDÉ 1994

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Hondé (1994)** Title: **Local treatment of pressure sores in the elderly: Amino acid copolymer membrane versus hydrocolloid dressing.** Journal: **Journal of the American Geriatrics Society, 42 (11); 1180-1183.** Study type: **randomized controlled trial** Sequence generation: **randomised list prepared by the Biometry group (using procedure Plan of the SAS package).** Allocation concealment: **not reported.** Blinding: **not reported.** Addressing incomplete outcome data: **all patient with at least one assessment after day 0 were included**	**Patient group:** Hospitalized patients aged 65 years and older with a grade II, III or IV PU (according to the Shea classification) **All patients** **Randomised N:** 168 **Completed N:** 130 **Drop-outs:** 38 (10 local complications, and 28 reasons unrelated to the treatment such as discharge, death, transfer) **Ulcer location:** Foot: n=91 Sacrum: n=61 Trochanter: n=5 Shoulder: n=1 Elbow: n=1 Knee: n=4 Thigh: n=1 Back: n=3 **Group 1** **Randomised N:** 80 **Completed N:** 66 **Dropouts:** 14 (4 local complications, and 10 reasons unrelated to the treatment such as	**Group 1:** Amino acid copolymer membrane (Interpan™, Synthélabo). Ulcers were cleansed with normal saline and dried at each renewal of dressings. **Group 2:** Hydrocolloid dressing (Comfeel™, Coloplast). Ulcers were cleansed with normal saline and dried at each renewal of dressings. **Both groups:** All patients received standardized local care	**Outcome 1:** proportion of patients complete healed **Outcome 2:** Median healing time (days; range) **Outcome 4:** proportion of patient with infection	**Group 1:** 31/80 **Group 2:** 23/88 **P value:** 0.089 **Group 1:** 32; 13-59 **Group 2:** 38; 11-63 **P value adj for wound depth:** 0.044 **Group 1:** 6/80 **Group 2:** 6/88	**Funding:** Funded by Synthélabo Recherche **Limitations:** no report on allocation concealment; no report on blinding; no a priori sample size calculation; statistical difference between groups for age **Additional outcomes:** / **Notes:** /

in the analysis with the last observed carried forward technique. Statistical analysis: **Statistical methods used included Student's t test, Fisher exact test, chi-square test, Wilcoxon test (survival curves), and 2-way anova. Wilcoxon was chosen to compare survival curves. Means throughout the paper are expressed as mean +/- SD.** Baseline differences: **Groups were not statistical different, except for age, which was not a significant factor in the survival curve.** Study power/sample size: **No a priori sample size calculation.** Setting: **multiple French hospitals** Length of study: **8 weeks of treatment or until complete healing, whichever came first** Assessment of PUs: **PUs were classified**	discharge, death, transfer) **Age (mean years (SD); range):** 80.4 (8.2); 63-98 **Gender (m/f):** 26/54 **Norton score (mean (SD)):** 12.5 (3.2) **Ulcer grade:** Grade II: n=51 Grade III: n=24 Grade IV: n=5 **Surface area (mean cm²):** 8.99 **Group 2** **Randomised N:** 88 **Completed N:** 64 **Dropouts:** 24 (6 local complications, and 18 reasons unrelated to the treatment such as discharge, death, transfer) **Age (mean years (SD); range):** 83.5 (7.8); 64-101 **Gender (m/f):** 21/67 **Norton score (mean (SD)):** 12.0 (3.0) **Ulcer grade:** Grade II: n=48 Grade III: n=35 Grade IV: n=5 **Surface area (mean cm²):** 6.85 **Inclusion criteria:** Hospitalized; 65 years or

according to the Shea (1975) classification. Ulcer depth scores, and the area trace were measured. The area was determined rom this tracing by computer planimtery. A color photograph was taken at the initial visit and at each visit thereafter. Multiple ulcers: **only one ulcer per patient was evaluated.**	older; grade II to IV PU; less than 10 cm in diameter **Exclusion criteria:** signs and symptoms of clinical infection; necrotic PU; PU on irritated skin; Pu requiring surgery; PU extending to bone with risk of osteitis; patients on air-fluized beds.				

Table 74 – KAYA 2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Kaya (2005)** Title: **The effectiveness of a hydrogel dressing compared with standard management of pressure ulcers.** Journal: **Journal of Wound Care, 14 (1); 42-44** Study type: **randomized controlled trial**	**Patient group:** Hospitalized patients with a spinal cord injury and with PUs (according to the NPUAP classification) **All patients** **Randomised N:** 27 patients and 49 ulcers **Completed N:** not reported **Drop-outs:** not reported **Group 1** **Randomised N:** 15	**Group 1:** Hydrogel dressing (Elasto-Gel™, South-West Technologies, North Kansas City, Missouri, USA). Dressings were changed every four days, or more if membrane became contaminated or non-occlusive. **Group 2:** Povidone-iodine soaked gauze dressings which were changed every daily. **Both groups:** necrotic areas were mechanically debrided	**Outcome 1:** Mean healing rate (cm²/day; range)	**Group 1:** 0.12 (0.16); 0.02-0.36 **Group 2:** 0.09 (0.05); 0.03-0.23 **P value:** 0.97	**Funding:** / **Limitations:** no report on sequence allocation; no report on allocation concealment; no report on drop-outs; no report on blinding; little information on ulcer assessment and statistical analysis; no

Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **not reported.** Statistical analysis: **The Mann-Whitney U test was used to compare arithmetic means and differences between groups. All statistical analyses were performed using SPSS** Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **Hospital.** Length of study: **Not reported** Assessment of PUs: **PUs were classified according to the NPUAP classification. Ulcers were measured in cm². The surface area was evaluated every four**	patients and 25 ulcers **Completed N:** not reported **Dropouts:** not reported **Age (mean years (SD); range):** 35.27 (14.57) **Ulcer grade:** Grade I: 6 Grade II: 17 Grade III: 2 **Ulcer location:** Sacral: n=7 Ischia: n=6 Heel: n=6 Greater trochanter: n=3 Knee: n=1 Lateral malleolus: n=2 **Ulcer area (mean cm² (SD); range):** 4.13 (2.73) **Group 2** **Randomised N:** 12 patients and 24 ulcers **Completed N:** not reported **Dropouts:** not reported **Age (mean years (SD); range):** 29.67 (6.41); 17-39 **Ulcer grade:** Grade I: 6 Grade II: 17 Grade III: 1 **Ulcer location:** Sacral: n=6 Ischia: n=3 Heel: n=2	information on preventive measures. **Additional outcomes:** / **Notes:** /

days until epithelisation was complete. Multiple ulcers: **27 patients with 49 ulcers.**	Greater trochanter: n=4 Iliac cest: n=4 Knee: n=2 Fibula: n=2 Foot: n=1 **Ulcer area (mean cm² (SD); range):** 6.45 (6.88); 2-35 **Inclusion criteria:** SCI patient; PU **Exclusion criteria:** /

Table 75 – KERIHUEL 2010

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Kerihuel (2010)** Title: **Effect of activated charcoal dressings on healing outcomes of chronic wounds.** Journal: **Journal of Wound Care, 19 (5); 208-215** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **Randomisation was by blocks of four.**	**Patient group:** Hospitalized patients with a stage III or IV PU (according to the Yarkoni classification). **All patients** **Randomised N:** 60 **Completed N:** 46 **Drop-outs:** 15 (5 had wound stagnation, 1 had septicaemia, 3 died, 2 were discharged, 1 had a wound infection, 1 had a hip fracture, 1 had a wound graft, 1 withdrew) One patient was not included in the analysis despite ITT because no information was	**Group 1:** Charcoal dressing (Actisorb® without silver). The wounds were cleansed with sterile saline only and dressings were changed two or three times a week or when needed. **Group 2:** Hydrocolloid (DuoDerm®, ConvaTec). The wounds were cleansed with sterile saline only and dressings were changed two or three times a week or when needed. **Both groups:** Standardized PU management strategies (regular repositioning and use of pressure-redistributing surfaces) were applied to all	**Outcome 1:** Median reduction in ulcer area (cm²; range) at 4 weeks **Outcome 2:** Median percentage reduction (%; range) in ulcer size at 4 weeks **Outcome 3:** Proportion of patients with maceration **Outcome 4:** Proportion of patients with ulcer	**Group 1:** -4.3 (-31.2-13.8) **Group 2:** -3.1 (-24.1-46.0) **Group 1:** -26.9 (-82-97.9) **Group 2:** -18.5 (-100-260.9) **Group 1:** 0/29 **Group 2:** 2/30 **Group 1:** 1/29 **Group 2:** 2/30	**Funding:** / **Limitations:** no report on sequence allocation; no blinding of patient and nurses; no a priori sample size calculation; no statistical calculation of difference between groups at baseline; high drop-out (ITT); small sample size **Additional outcomes:** /

Identical sealed boxes containing the allocated dressings were randomly allocated to each patient. Blinding: **outcome assessor blinding.** Addressing incomplete outcome data: **intention-to-treat analysis** Statistical analysis: **Scale variables are presented as mean ± standard deviation or as median (range). Absolute and relative changes in ulcer area were compared between groups at weeks 1, 2, 3 and 4 using the non-parametric Mann-Whitney U test. No adaptation of the alpha risk for repeated testing was used. Ordinal and nominal variables were compared using either the chi-square test or Fisher's exact test. SPS software was used. A p value of less than 5% (<0.05) was considered as**	available on wound tracing (died two days after randomisation) **Group 1** **Randomised N:** 29 **Completed N:** 22 **Dropouts:** 7 (3 had wound stagnation, 1 had septicaemia, 1 died, 2 were discharged) **Age (mean years (SD)):** 83.2 (13.2) **Gender (m/f):** 5/24 **BMI:** > 30: n=1 20-29: n=26 < 19: n=2 **Duration of PU:** > 1 month: n=15 > 3 months: n=3 **Ulcer location:** Sacrum: n=4 Heel: n=22 Other: n=3 **Surface area (mean cm²; median):** 25.3 (24.6); 17.5 **Group 2** **Randomised N:** 31 **Completed N:** 23 **Dropouts:** 8 (2 had wound stagnation, 2 died, 1 had a wound infection, 1 had a hip fracture, 1 had a wound graft, 1 withdrew)	patients.	infection **Outcome 5:** Proportion of patients with ulcer aggravation **Outcome 6:** Proportion of patients with overgranulation **Outcome 7:** Proportion of patients with eczema **Outcome 8:** Proportion of patients with pruritus **Outcome 9:** Proportion of patients with wound pain **Outcome 10:** Proportion of patients with skin irritation **Outcome 11:** Proportion of patients with bleeding at dressing removal	**Group 1:** 0/29 **Group 2:** 1/30 **Group 1:** 0/29 **Group 2:** 1/30 **Group 1:** 0/29 **Group 2:** 1/30 **Group 1:** 1/29 **Group 2:** 0/30 **Group 1:** 0/29 **Group 2:** 0/30 **Group 1:** 0/29 **Group 2:** 0/30 **Group 1:** 0/29 **Group 2:** 0/30	**Notes:** /

indicating statistical significance. Baseline differences: **Difference not statistically measured. Groups were comparable** Study power/sample size: **No a priori sample size calculation.** Setting: **six hospitals** Length of study: **four weeks of treatment.** Assessment of PUs: **PU were classified according to the Yarkoni classification (1994).** **Ulcer was traced and photographed, and the exudate level and ulcer bed characteristics were assessed.** Multiple ulcers: **only one ulcer was included per patient.**	**Age (mean years (SD)):** 78.5 (16.5) **Gender (m/f):** 9/21 **BMI:** > 30: n=3 20-29: n=19 < 19: n=8 **Duration of PU:** > 1 month: n=15 > 3 months: n=1 **Ulcer location:** Sacrum: n=6 Heel: n=20 Other: n=4 **Surface area (mean cm²; median):** 22.6 (18.4); 16.0 **Inclusion criteria:** PUs with an area ranging from 5 to 100cm²; PUs of less than three months' duration; PUs graded IIc or IV on the Yarkoni classification; PUs considered by investigators to have abundant necrotic tissue and slough (covering >50% of the wound surface) **Exclusion criteria:** Inability to give written consent to participate; severe illness; Pus totally covered with necrotic tissue or	**Outcome 12:** Proportion of patients with pain at dressing change	**Group 1:** 19/29 **Group 2:** 19/30

	requiring surgical debridement; infected ulcers requiring systemic antibiotics; known allergy to the study dressing; previous use of Actisorb				

Table 76 – KIM 1996

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Kim (1996)** Title: **Efficacy of hydrocolloid occlusive dressing technique in decubitus ulcer treatment: a comparative study.** Journal: **Yonsei Medical Journal, 37 (3); 181-185** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **no missings reported** Statistical analysis:	**Patient group:** Patients with a stage I or II PU (according to the NPUAP classification). **All patients** **Randomised N:** 44 **Completed N:** 44 **Drop-outs:** 0 **Group 1** **Randomised N:** 26 **Completed N:** 26 **Dropouts:** 0 **Age (mean years (SD)):** 50.5 (18.3) **Gender (m/f):** 23/3 **Incontinence:** Urine: n=19 Faecal: n=10 **Ulcer stage:** Stage I: n=6 Stage II: n=20 **Ulcer location:** Sacrum: n=7 Pelvic girdle: n=7	**Group 1:** Hydrocolloid occlusive dressing (DuoDerm®, Squib, Princeton, NJ). Ulcers were cleaned with saline irrigation and boric solution prior to application of the dressing. Dressings were changed every 4-5 days. **Group 2:** Wet-to-dry dressing. Ulcers were cleaned with saline irrigation and boric solution prior to application of the povidine soaked wet gauze. Dressings were changed three times a day. **Both groups:** All ulcers were debrided prior to application of the dressing. All patients received position change to relieve the pressure to the ulcer site.	**Outcome 1:** Healing rate (%) **Outcome 2:** Mean healing speed (mm²/day) **Outcome 3:** Proportion of patients with complete healing **Outcome 4:** Proportion of patients with hypergranulation	**Group 1:** 80.8 **Group 2:** 77.8 **P value:** > 0.05 **Group 1:** 9.1 (5.4) **Group 2:** 7.9 (4.7) **P value:** > 0.05 **Group 1:** 21/26 **Group 2:** 14/18 **Group 1:** 3/26 **Group 2:** 0/18	**Funding:** / **Limitations:** no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; no report on multiple ulcers **Additional outcomes:** cost (won): G1: 8204 (2664) versus G2: 14571 (6700) **Notes:** /

The chi-square and t-test were used for the statistical analysis. Baseline differences: **No statistical difference between groups** Study power/sample size: **No a priori sample size calculation.** Setting: **department of rehabilitation medicine** Length of study: **mean treatment duration was 18.9 (8.2) days in G1 and 24.3 (11.2) days in G2** Assessment of PUs: **PU were classified according to the NPUAP classification (1989).** **Ulcer size was estimated by measuring the longest diameters and the longest diameter perpendicular to it. Other measured variables were ulcer site, size and degree, presence of necrotic tissue, exudate, serum albumin level, hemoglobin level and**	Other: n=12 **Surface area (mean cm²):** unclear **Group 2** **Randomised N:** 18 **Completed N:** 18 **Dropouts:** 0 **Age (mean years (SD)):** 46.9 (16.8) **Gender (m/f):** 13/5 **Incontinence:** Urine: n=12 Faecal: n=7 **Ulcer stage:** Stage I: n=6 Stage II: n=12 **Ulcer location:** Sacrum: n=4 Pelvic girdle: n=7 Other: n=7 **Surface area (mean cm²):** unclear **Inclusion criteria:** PUs stage I or II **Exclusion criteria:** PU stage III or IV; systemic infection, endocrinological disorder, difficulty keeping pressure relieving positions; aggravated general condition due to other factors

urinary and fecal incontinence. Multiple ulcers: **not reported.**					

Table 77 – KORDESTANI 2008

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Kordestani (2008)** Title: **A randomised controlled trial on the effectiveness of an advanced wound dressing used in Iran.** Journal: **Journal of Wound Care, 17 (7); 323-327** Study type: **randomized controlled trial** Sequence generation: **alternating sequence randomization; no further information** Allocation concealment: **concealed; no further information** Blinding: **blinding; no further information** Addressing incomplete outcome data: **no drop-out** Statistical analysis:	**Patient group:** Hospitalized patients with a PU (according to the NPUAP classification). Also patients with diabetic foot ulcers and leg ulcers were included (separate analysis) **All patients** **Randomised N:** 85 patients and 98 wounds **Completed N:** 54 patients and 60 wounds (28 PUs) **Drop-outs:** 31 patients and 38 wounds (10 patient died, 21 patient withdrew) **Age (mean years (SD)):** 43.42 (5.08) **Gender (m/f):** 25/29 **Ulcer width (mean cm (SD)):** 14.13 (2.3) **Ulcer length (mean cm (SD)):** 8.24 (1.92) **Ulcer duration (mean**	**Group 1:** Bioactive dressing (containing hydrophilic mucopolysaccharide, chitosan). The wound was then covered with a non-adherent pad and fixed with a polyurethane adhesive. Ulcers were irrigated with normal saline prior to application of the dressing. Dressings were changed every other day or every four days (exudate) **Group 2:** Gauze. Wet-to-dry dressing. Ulcers were irrigated with normal saline and covered with gauze secured with a bandage and adhesive tape. **Both groups:** All ulcers were debrided as required. None of the patients received pressure relief of offloading.	**Outcome 1:** Proportion of ulcers completely healed **Outcome 2:** Proportion of infected ulcers	**Group 1:** 14/16 **Group 2:** 4/12 **Group 1:** 0/16 **Group 2:** 0/12	**Funding:** Sponsored by Chito Tech **Limitations:** little information on sequence allocation; little information on allocation concealment; no report on blinding; no a priori sample size calculation; no measurement of statistical difference between groups at baseline; high drop-out; no-intention-to treat analysis **Additional outcomes:** / **Notes:** Patient characteristics are

Data were analyzed using analysis of variance (ANIOVA) and chi-square test, using SPSS software. A p value of <0.05 was considered significant. Baseline differences: **Difference was not statistically measured. Groups were comparable.** Study power/sample size: **The power is between 1.5 and 2 for a sample size (wounds) of 65.** Setting: **five major teaching hospitals in Tehran** Length of study: **21 days of treatment and three months follow-up** Assessment of PUs: **PU were classified according to the NPUAP classification. Wound size was estimated by photographs, which were scanned. The exact length and width were calculated using AutoCAD 2000. All wound were swabbed if signs of**	**days (SD)):** 21.5 (6.2) **Group 1** **Randomised N:** 33 patients and 45 wounds **Completed N:** 32 patients and 34 wounds (16 PUs) **Dropouts:** 1 patient and 11 wounds (died) **Age (mean years):** 45.8 **Group 2** **Randomised N:** 52 patients and 53 wounds **Completed N:** 22 patients and 26 wounds (12 PUs) **Dropouts:** 30 patient and 27 wounds (9 patient died, 21 patient withdrew) **Age (mean years):** 41.2 **Inclusion criteria:** PU, diabetic foot ulcer or leg ulcer **Exclusion criteria:** PU pregnancy; addiction to alcohol, cigarettes or narcotics; immunocompromising condition		for all patients. The outcome are for PU patients only.

wound infection Multiple ulcers: **multiple ulcers included. Ulcers unit of analysis**					

Table 78 – KRAFT 1993

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Kraft (1993)** Title: **A comparison of Epi-Lock and saline dressings in the treatment of pressure ulcers.** Journal: **Decubitus, 6 (6); 42-48** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **intention-to-treat analysis** Statistical analysis: **Not reported except for correlation between determined**	**Patient group:** Male veterans with a stage II or III PU (according to the Enterstomal Therapy definition). **All patients** **Randomised N:** 34 **Completed N:** 17 **Drop-outs:** 17 (2 died, 2 withdrew, staff requested withdrawal for 6 patients, 1 had surgery, 1 had special bed treatment, 5 had a reaction to RX) **Age (mean years; range):** 56; 28-78 **Gender (m/f):** 38/0 **Spinal cord injury:** 33 **Ulcer stage:** Stage II: n=22 Stage III: n=16 **Ulcer duration:** range: new to five years ≤ 2 months: n=20 > 2 months: n=14	**Group 1:** foam dressing (Epi-Lock™). Epi-Lock™: a sterile, non-adherent, semi-occlusive polyurethane foam wound dressing with an adhesive cover. **Group 2:** saline moistened gauze dressing. **Both groups:** Standardized dressing procedures were performed in all patients.	**Outcome 1:** Proportion of patients/ulcers completely healed	**Group 1:** 10/24 **Group 2:** 3/14	**Funding:** funding by Calgon Vestal Labaratories **Limitations:** no report on sequence allocation; no report on allocation concealment; no report on blinding; a priori sample size calculation unclear; small sample size and high drop-out (ITT); no measurement of statistical difference between groups at baseline; no information on statistical analysis; no information on

variables and ulcer healing. Data were analyzed using regression analysis. Baseline differences: **Difference was not statistically measured.** Study power/sample size: **Unclear if a priori sample size calculation was performed. Sample size was targeted to allow for drop-outs. The sample size was adequate to permit statistical analysis to detect difference in healing between groups, stages and over time.** Setting: **tertiary care veteran's hospital in the Midwest consisting of a spinal cord injury centre and an extended care centre.** Length of study: **24 days of treatment** Assessment of PUs: **PU were classified according to the Enterstomal Therapy definition (1987).** **All subjects were assessed by the**	**Group 1** **Randomised N:** 24 **Completed N:** 11 **Dropouts:** 13 (1 withdrew, staff requested withdrawal for 5 patients, 1 had special bed treatment, 4 had a reaction to RX) **Group 2** **Randomised N:** 14 **Completed N:** 6 **Dropouts:** 8 (2 died, 1 withdrew, staff requested withdrawal for 1 patients, 1 had surgery, 1 had a reaction to RX) **Inclusion criteria:** / **Exclusion criteria:** PU stage I or IV; clinically infected ulcer; patient on special bed; unstable insulin-dependent diabetes; serum albumin < 2gm; hemoglobin < 12gm; class IV congestive heart failure; chronic renal insufficiency; documented severe peripheral vascular disease; documented COPD		ulcer assessment; little information on dressing and standardized procedure. **Additional outcomes:** Cost (nursing time and dressing cost): G1: $20.48 versus G2: $74.97 Correlation (variables: medication, cultures, age, smoking, serum albumin, TIBC, CBC, fasting blood sugar, electrolytes, CO_2 levels): serum albumin was inversely related to patients age **Notes:** /

same rater who noted stage, tissue color, drainage, odor and condition of the skin surrounding the ulcer. Multiple ulcers: **Indirect: one ulcer per patient.**					

Table 79 – LJUNGBERG 2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Ljungberg (1998)** Title: **Comparison of dextranomer paste and saline dressings for management of decubital ulcers.** Journal: **Clinical Therapeutics, 20 (4); 737-743.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **intention to treat**	**Patient group:** Male patients with a spinal cord injury, aged 18 years and older, and with exudative PUs (according to the Eltorai classification). **All patients** **Randomised N:** 23 patients with 30 ulcers **Completed N:** not reported **Drop-outs:** not reported **Age (range years):** 23-73 **Gender (m/f):** 23/0 **Group 1** **Randomised N:** 15 ulcers **Completed N:** not reported	**Group 1:** Dextranomer paste (Debrisan®, Pharmacia Pharmaceuticals, AB, Uppsala, Sweden). Ulcers were cleaned with mild soap and water and rinsed with saline solution. Paste was applied on the wet ulcer and was covered with a dry sterile dressing. Debrisan®: contained 64% dextranomer, 30.5% polyethylene glycol 600 and 5.5% distilled water **Group 2:** Saline dressing. Ulcers were cleaned with mild soap and water and rinsed with saline solution. The saline soaked dressing was applied on the wet ulcer and was covered with a dry sterile dressing.	**Outcome 1:** Proportion of ulcer improved with 25% **Outcome 2:** Proportion of ulcers with granulation after 15 days **Outcome 3:** Proportion of ulcers with epithelialization after 15 days **Outcome 4:** Proportion of patients with adverse events	**Group 1:** 11/15 **Group 2:** 2/15 **P value:** < 0.01 **Group 1:** 10/15 **Group 2:** 8/15 **P value:** > 0.05 **Group 1:** 7/15 **Group 2:** 4/15 **P value:** > 0.05 **Group 1 and 2:** 0/23	**Funding:** Grant from Pharmacia Pharmaceuticals AB, Sweden. **Limitations:**; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; no measurement of statistical difference between groups; little information on ulcer assessment; no information on

analysis Statistical analysis: **Treatment comparisons were based on the change from study entry to day 15 or the end of the study (end point) and using the chi-square test. The level of significance for all tests was *p* < 0.05.** Baseline differences: **Difference not statistically measured. Groups were comparable.** Study power/sample size: **No a priori sample size calculation.** Setting: **Spinal cord injury service, Long Beach Veterans Administration Hospital, Long Beach, California.** Length of study: **15 days of treatment.** Assessment of PUs: **PU were classified according to the Eltorai classification. Qualitative assessment of the ulcers was conducted with the**	**Dropouts:** not reported **Duration of PU (mean months; median months; range):** 4.2; 4; 0.5-12 **Ulcer stage:** Stage II: n=10 Stage III: n=4 Stage IV: n=1 **Ulcer location:** Ischium: n=6 Sacrum: n=3 Hips: n=4 Ankle: n=2 Other: n=0 **Infected ulcers:** 6 **Group 2** **Randomised N:** 15 ulcers **Completed N:** not reported **Dropouts:** not reported **Duration of PU (mean months; median months; range):** 4.3; 4; 0.5-10 **Ulcer stage:** Stage II: n=12 Stage III: n=3 Stage IV: n=0 **Ulcer location:** Ischium: n=5 Sacrum: n=3 Hips: n=3 Ankle: n=1 Other: n=3 **Infected ulcers:** 9	**Both groups:** All ulcers were surgically debrided before application of the dressing.		number of patients per group. **Additional outcomes:** / **Notes:** /

aid of photographs. The extent of granulation was measured on a six-point scale. Ulcers were assessed each time the nurse changed the dressing. Multiple ulcers: **30 ulcers in 23 patients. Ulcers was unit of analysis.**	**Inclusion criteria:** Aged 18 years and older; exudative PU **Exclusion criteria:** PU involving the bone				

Table 80 – MATZEN 1999

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Matzen (1999)** Title: **A new amorphous hydrocolloid for the treatment of pressure sores: A randomised controlled study.** Journal: **Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery, 33 (1); 13-15.** Study type: **randomized controlled trial** Sequence generation: **not reported.**	**Patient group:** Patients older than 18 years with a stage III or IV PU (according to the Lowthian classification). **All patients** **Randomised N:** 32 **Completed N:** 6 **Drop-outs:** 20 (8 had other illnesses, 3 died, 1 had a missing schedule, 2 withdrew, 6 had insufficient effect of the treatment). **Ulcer location:** Sacrum: n=21 Trochanter: n=11	**Group 1:** Hydrocolloid dressing (Hydrogel®, Coloplast A/S, Denmark). The dressing was covered with a transparent hydrocolloid dressing (Comfeel®, Coloplast A/S, Denmark). The ulcers were cleaned and changed daily. **Group 2:** Saline gauze compresses. The dressing was covered with a transparent hydrocolloid dressing (Comfeel®, Coloplast A/S, Denmark). The ulcers were cleaned and changed daily. **Both groups:** All ulcers	**Outcome 1:** Mean relative volume reduction (%) **Outcome 2:** Proportion of patients completely healed **Outcome 3:** Median pain during treatment **Outcome 4:** Median smell during treatment **Outcome 5:**	**Group 1:** 26 (20) **Group 2:** 64 (16) **P value:** < 0.02 **Group 1:** 5/17 **Group 2:** 0/15 **Group 1:** 2 (1-4) **Group 2:** 2 (1-3) **Group 1:** 2 (1-4) **Group 2:** 2 (1-3) **Group 1:** 4 (3-4)	**Funding:** /. **Limitations:**; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; no measurement of statistical difference between groups; setting not reported; little information on

Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **intention to treat analysis.** Statistical analysis: **The data were skewed and therefore assessed by the nonparametric Mann-Whitney test. Differences were accepted as significant if the probability was less than 0.05.** Baseline differences: **Difference not statistically measured.** Study power/sample size: **No a priori sample size calculation.** Setting: **not reported.** Length of study: **12 weeks of treatment or until complete healing.** Assessment of PUs: **PU were classified according to the Lowthian classification (1994). Healing of ulcers was**	**Group 1** **Randomised N:** 17 **Completed N:** 8 **Dropouts:** 9 (5 had other illnesses, 2 died, 1 had a missing schedule, 1 withdrew) **Age (mean years range):** 82; 32-97 **Gender (m/f):** 2/15 **Group 2** **Randomised N:** 15 **Completed N:** 4 **Dropouts:** 11 (3 had other illnesses, 1 died, 1 had a missing schedule, 1 withdrew, 6 had insufficient effect of the treatment) **Age (mean years range):** 84; 46-89 **Gender (m/f):** 3/12 **Inclusion criteria:** Stage III or IV PU; non-infected PU **Exclusion criteria:** diseases or taking drugs known to impair healing	were debrided before application of the dressing as necessary.	Median comfort during treatment	**Group 2:** 3 (2-4)	ulcer assessment, pain, smell, comfort **Additional outcomes:** / **Notes:** /

estimated by measuring the amount of water needed to fill the cavity. Multiple ulcers: **not reported**					

Table 81 – MEAUME 2003

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Meaume (2003)** Title: **A study to compare a new self-adherent soft silicone dressing with a self-adherent polymer dressing in stage II pressure ulcers.** Journal: **Ostomy/wound management, 49 (9); 44-51.** Study type: **randomized controlled trial** Sequence generation: **predetermined computer-generated randomized list.** Allocation concealment: **stratified according to study centre.**	**Patient group:** Patients aged 65 years or older with a stage II PU (according to the NPUAP classification). **All patients** **Randomised N:** 38 **Completed N:** 36 **Drop-outs:** 2 (died) – unclear if other also dropped **Group 1** **Randomised N:** 18 **Completed N:** 17 **Dropouts:** 1 (died) – unclear if other also dropped **Age (mean years; range):** 83.8; 74.9-95.1 **Gender (m/f):** 2/16 **Duration of PU (mean weeks; range):** 8.3; 1-24	**Group 1:** Self-adherent soft silicone dressing (Mepilex®, Mölnlycke Health Care AB, Sweden). The dressing was changed at least once a week or more frequently as needed. If necessary, extra fixation (Mefix®/Mefilm®) and hydrating gel (Normlgel®) could be used. Mepilex®: Silicone, polyurethane foam, and polyacrylate fibers. **Group 2:** Self-adherent hydropolymer dressing (Tielle®, Johnson & Johnson Mecial, England). The dressing was changed at least once a week or more frequently as needed. If necessary, extra fixation (Mefix®/Mefilm®) and hydrating gel (Normlgel®) could be used. Tielle®: hydropolymer	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Proportion of patients improved **Outcome 3:** Proportion of patients worsened **Outcome 4:** Proportion of patients with maceration **Outcome 5:** Proportion of patients reporting odour **Outcome 6:** Proportion of	**Group 1:** 8/18 **Group 2:** 10/20 **Group 1:** 15/18 **Group 2:** 19/20 **Group 1:** 2/18 **Group 2:** 1/20 **Group 1:** 0/18 **Group 2:** 3/20 **Group 1:** 0/18 **Group 2:** 3/20 **Group 1:** 1/18 **Group 2:** 3/20	**Funding:** / **Limitations:** no blinding; no a priori sample size calculation; small sample size; no report on multiple ulcers **Additional outcomes:** / **Notes:** /

Numbered, sealed envelopes Blinding: **no blinding** Addressing incomplete outcome data: **intention to treat analysis.** Statistical analysis: **Descriptive statistics were used to describe the study population and results. A post-hoc significance test using the Fischer exact test was performed for the damage to tissue variable.** Baseline differences: **No measurement of statistical difference between groups. Groups were similar in distribution.** Study power/sample size: **No a priori sample size calculation.** Setting: **three nursing homes (Paris, Antwerp and Pisa).** Length of study: **eight weeks of treatment or until complete healing.** Assessment of PUs: **PU were classified**	**Ulcer area (mean cm²; range):** 4.9; 0.7-25.3 **Ulcer location:** Heel: 7 Foot: 2 Leg: 1 Sacrum: 3 Back: 3 Ischiatic: 2 Elbow: 0 **Group 2** **Randomised N:** 20 **Completed N:** 19 **Dropouts:** 1 (died) – unclear if other also dropped **Age (mean years; range):** 82.5; 66.4-91.9 **Gender (m/f):** 4/16 **Duration of PU (mean weeks; range):** 13.0; 1-52 **Ulcer area (mean cm²; range):** 5.4; 0.2-26.0 **Ulcer location:** Heel: 4 Foot: 2 Leg: 4 Sacrum: 6 Back: 2 Ischiatic: 1 Elbow: 1 **Inclusion criteria:** Aged 65 years or older; stage II PU; Modified Norton score ≥ 11;	dressing that contains polyurethane foams, a non-woven layer, and polyurethane backing. **Both groups:** Most patient received pressure relieving mattresses (78.9% baseline and 71.1% at final); few patients received position changes and/or use of heel boots (7.9% baseline and 5.3% at final).	patients with dressing related adverse events	(hypergranulation, new ulcer, and redness and irritation)	

according to the NPUAP classification. Ulcers were traced to determine size. Multiple ulcers: **not reported**	red/yellow wound according to the Red-Yellow-Black systel. **Exclusion criteria:** underlying disease, that might interfere with the treatment of PU; food and/or liquid intake score ≤ 2 on modified Norton scale; allergic/hypersensitivity to either dressing; wound larger than 11cm x 11cm; necrotic ulcer; clinical signs of local infection				

Table 82 – MEAUME 2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Meaume (2005)** Title: **Evaluation of a silver-releasing hydroalginate dressing in chronic wounds with signs of local infection.** Journal: **Journal of Wound Care, 14 (9); 411-419.** Study type: **randomized controlled trial** Sequence generation:	**Patient group:** Patients aged 65 years or older with a stage III or IV PU (according to the NPUAP classification). Also patients with leg ulcers were included. **All patients** **Randomised N:** 99 (28 with PU) **Completed N:** 80 (24 with PU) **Drop-outs:** 19 (2 alginate dressing no longer indicated, 1	**Group 1:** Silver hydroalginate dressing (Silvercel®, Johnson & Johnson). Ulcers were cleansed with sterile saline. The dressing was applied and covered with a sterile pad and a hypoallergenic adhesive was used to secure these. The dressing was changed every two to three days as needed. Silvercel®: a sterile, non-woven pad composed of a high-G (guluronic acid) alginate, carboxymethylcellulose	**Outcome 1:** Absolute decrease in ulcer area (cm²) **Outcome 2:** Percentage reduction in ulcer area **Outcome 3:** Healing rate (cm²/day) **Outcome 4:** Mean mASEPSIS	**Group 1:** -7.2 (9.0) **Group 2:** -0.8 (10.0) **Group 1:** 31.6 (38.1) **Group 2:** 13.9 (50.3) **Group 1:** 0.26 (0.32) **Group 2:** 0.03 (0.36) **ITT analysis** **Group 1:** 81.8 (45.1)	**Funding:** funded by a grant from Johnson & Johnson Wound Management. **Limitations:** inadequate allocation concealment; no blinding; sample size calculation based on non-critical outcome; few patients with PU; setting

an a priori randomisation list was prepared by block of six. Allocation concealment: **stratified according to wound type** Blinding: **no blinding** Addressing incomplete outcome data: **intention to treat analysis, after exclusion of two cases (incorrectly included and died three days after randomisation) and per protocol analysis.** Statistical analysis: **Data analysis was conducted using SPSS. Comparability of groups was verified using univariate anova for continuous variables and chi-square test for categorical variables. Group comparisons used an univariate general linear model procedure (Type III) with dressing and wound as fixed factors. For variables evaluated at weekly**	withdrawal of consent, 5 intercurrent event, 3 wound grafting, 3 wound infection, 6 wound aggravation) **Group 1** **Randomised N:** 51 (13 with PU) **Completed N:** 41 (12 with PU) **Dropouts:** 10 (1 alginate dressing no longer indicated, 1 withdrawal of consent, 4 intercurrent event, 1 wound grafting, 1 wound infection, 2 wound aggravation) **Age (mean years (SD)):** 74.9 (9.0) **Gender (m/f):** 30/21 **BMI (mean kg/m² (SD)):** 28.6 (8.7) **Diabetes:** 17 **Following characteristics are for PU patient only:** **Duration of PU (mean months (SD); median months):** 4.4 (3.7); 2.0 **Ulcer area (mean cm² (SD); median months):** 22.5 (21.5); 15.6 **Group 2** **Randomised N:** 48 (15 with PU) **Completed N:** 39 (12	(CMC) and silver-coated fibres. Its tensile strength increases when in contact with wound exudate, facilitating its removal from exuding wounds. **Group 2:** Alginate dressing (Algosteril®, Brother Laboratories SA, France). Ulcers were cleansed with sterile saline. The dressing was applied and covered with a sterile pad and a hypoallergenic adhesive was used to secure these. The dressing was changed every two to three days as needed. Algosteril®: a sterile, non-woven pad composed 100% calcium alginate. **Both groups:** All ulcers were debrided (surgically or mechanically) as necessary.	index at week 4 **Outcome 5:** Proportion of patients with ulcer infection **Outcome 6:** Proportion of patients with ulcer aggravation **Outcome 7:** Proportion of patients with poor local acceptability and/or tolerability	**Group 2:** 115.3 (80.2) **PP analysis** **Group 1:** 87.3 (42.2) **Group 2:** 111.3 (74.2) **Group 1:** 1/13 **Group 2:** 2/15 **Group 1:** 2/13 **Group 2:** 4/15 **Group 1:** 1/13 **Group 2:** 0/15	unclear; no direct information on multiple ulcers; no information on preventive measures **Additional outcomes:** / **Notes:** Patient characteristics are for all patients. The outcome are for PU patients only.

intervals, a GLM procedure for repeated measures was performed. To deal with missing data, the last observed value was carried forward. The main efficacy parameter was the two-week global mASEPSIS score calculated on the ITT population. A second analysis was conducted for the PP population, defined as randomized without major violation of the protocol. Changes in wound surface are, percentage reduction in wound surface, and wound closure rate were calculated. Log-transformed data were used for statistical analysis. The proportion of closed/improved wounds at week 4 were compared using the chi-square test. Baseline differences: **No statistical difference between**	with PU) **Dropouts:** 9 (1 alginate dressing no longer indicated, 1 intercurrent event, 1 wound grafting, 2 wound infection, 4 wound aggravation) **Age (mean years (SD)):** 77.6 (10.9) **Gender (m/f):** 33/15 **BMI (mean kg/m² (SD)):** 25.9 (7.1) **Diabetes:** 6 **Following characteristics are for PU patient only:** **Duration of PU (mean months (SD); median months):** 3.7 (6.0); 2.0 **Ulcer area (mean cm² (SD); median months):** 22.4 (25.5); 18.7 **Inclusion criteria:** Ankle brachial pressure index > 0.7 within previous 6 months; grade III or IV PU; no clear signs of infection (investigators opinion); at least 50% of wound covered with yellow slough, discoloured or friable granulation tissue, pocketing or undermining at the base of the wound or foul odour.	

groups, except for age > 80 years and diabetes. Study power/sample size: **The required number of subjects per groups was determined to be 50 (bilateral test, power 0.8, alpha risk 0.05) to detect a maximal between groups difference of 8 to 10 points on this index.** Setting: **13 centers.** Length of study: **four weeks.** Assessment of PUs: **PU were classified according to the NPUAP classification. The mASEPSIS score was assessed (score 0—30).** **Wound appearance and closure were noted at each visit.** **The target ulcer was measured (planimetry) and photographed** Multiple ulcers: **indirectly: one ulcer per patient**	**Exclusion criteria:** receiving systematic antibiotics during previous five days; very poor life expectancy; condition that might interfere with healing such as active carcinoma, vasculitis, use of corticosteroids, immunosuppressive agents, radiotherapy or chemotherapy within 30 days; receiving topical chemical debriding agents within previous seven days.	

Table 83 – MOTTA 1999

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Motta (1999)** Title: **Clinical efficacy and cost-effectiveness of a new synthetic polymer sheet wound dressing.** Journal: **Ostomy/wound management, 45 (10); 41-49.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **no drop-out.** Statistical analysis: **not reported.** Baseline differences: **Difference not statistically measured.** Study power/sample size: **No a priori**	**Patient group:** Home care patients with a stage II or III PU. **All patients** **Randomised N:** 10 **Completed N:** 10 **Drop-outs:** 10 **Age (mean years range):** 60; 34-76 **Gender (m/f):** 5/5 **Duration of PU (mean days):** 49.8 **Ulcer location:** Foot/ankle: n=2 Coccyx: n=4 Buttocks: n=1 Sacrum: n=1 Elbow: n=2 **Ulcer stage:** Stage II: n=3 Stage III: n=7 **Group 1** **Randomised N:** 5 **Completed N:** 5 **Dropouts:** 0 **Ulcer location:** Coccyx: n=3 Sacrum: n=1 Elbow: n=1 **Ulcer stage:** Stage II: n=1	**Group 1:** Polymer hydrogel dressing (AcryDerm®, AcrylMed, Portland, Ore – now known as Flexigel®, Smith & Nephew, Largo, Fla) A/S, Denmark). The ulcers were cleansed and irrigated with sterile saline. The dressings were changed on an “as needed basis” but not less than once weekly. **Group 2:** Hydrocolloid dressing (DuoDermCGF®, ConvaTec, Skillman, NJ). The ulcers were cleansed and irrigated with sterile saline. The dressings were changed on an “as needed basis” but not less than once weekly. **Both groups:** All ulcers were lightly debrided.	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Mean healing rate (cm per day) **Outcome 3:** Mean percentage ulcer reduction	**Group 1:** 2/5 **Group 2:** 2/5 **Group 1:** 0.22 (0.24) **Group 2:** 0.35 (0.43) **Group 1:** 79.2 (33.8) **Group 2:** 88.6 (11.2)	**Funding:** Funded by an educational grant from AcryMed, Portland, Ore **Limitations:**; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; very small sample size; no measurement of statistical difference between groups; no information on PU classification; little information on PU assessment; no information on preventive measures **Additional outcomes:**

sample size calculation. Setting: **home care.** Length of study: **8 weeks of treatment.** Assessment of PUs: **PU classification not reported.** **Ulcers were assessed weekly using the Bates-Jensen Pressure Sore Status tool.** Multiple ulcers: **one ulcer per patient**	Stage III: n=4 **Group 2** **Randomised N:** 5 **Completed N:** 5 **Dropouts:** 0 **Ulcer location:** Foot/ankle: n=2 Coccyx: n=1 Buttocks: n=1 Elbow: n=1 **Ulcer stage:** Stage II: n=3 Stage III: n=2 **Inclusion criteria:** Stage II or III PU **Exclusion criteria:** /	Cost of treatment G1: $57.76 vs G2: $91.48 Average dressings used: G1: 3.38 vs G2: 8 **Notes:** /

Table 84 – MULDER 1993

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Mulder (1993)** Title: **Prospective randomized study of the efficacy of hydrogel, hydrocolloid, and saline solution -- moistened dressings on the management of pressure ulcers.** Journal: **Wound Repair and Regeneration, 1; 213-**	**Patient group:** Patients with a stage II or III PU. **All patients** **Randomised N:** 67 **Completed N:** unclear **Drop-outs:** unclear **Group 1** **Randomised N:** 23 **Completed N:** unclear **Dropouts:** unclear **Age (mean years (SD); range):** 56.7 (20.6), 23-	**Group 1:** Hydrogel dressing (Clearsite®, New Dimensions in Medicine, Dayton, Ohio). Dressings were changed twice a week. **Group 2:** Hydrocolloid dressing (DuoDermCGF®, ConvaTec, Bristol Myers-Squibb, Princeton, NJ). Dressings were changed twice a week. **Group 2:** Wet-to-moist gauze dressing. Dressings were changed three times a day.	**Outcome 1:** Mean percentage reduction in ulcer area **Outcome 2:** Median percentage reduction in ulcer area **Outcome 3:** proportion of patients with skin	**Group 1:** 8.0 (14.8) (n=20) **Group 2:** 3.3 (32.7) (n=21) **Group 3:** 5.1 (14.8) (n=20) **P-value:** > 0.05 **Group 1:** 5.6 (n=20) **Group 2:** 7.4 (n=21) **Group 3:** 7.0 (n=20) **P-value:** 0.89 **Group 1:** 0 **Group 2:** 2 **Group 3:** 0	**Funding:** / **Limitations:** no report on allocation concealment; no blinding; no information on preventive measures; multiple ulcers unclear; drop-out, number of patients/ulcers in

218 Study type: **randomized controlled trial** Sequence generation: **1:1:1 ratio by a computer generated scheme** Allocation concealment: **not reported** Blinding: **no blinding** Addressing incomplete outcome data: **drop-outs excluded** Statistical analysis: **For population comparability, continuous variables were assessed by analysis of variance. Categorical variables were assessed by Fischer's exact test. The nonparametric Brown median test was used to calculate statistical significance. SAS was used as software program.** Baseline differences: **No statistical difference between groups for age, gender and race.** Study power/sample	86 (evaluated on 21 patients) **Gender (m/f):** 18/5 **Ulcer stage:** unclear Stage II: 8 Stage III: 14 **Ulcer location:** Heel: 3 Buttock: 3 Hip: 1 Malleolus: 3 Sacrum: 3 Trochanter: 1 Ischium: 1 Other: 8 **Group 2** **Randomised N:** 23 **Completed N:** unclear **Dropouts:** unclear **Age (mean years (SD); range):** 63.1 (15.3); 36-82 (evaluated on 16 patients) **Gender (m/f):** 17/3 (evaluated on 20 patients) **Ulcer stage:** unclear-missings Stage II: 9 Stage III: 13 **Ulcer location:** Heel: 5 Buttock: 3 Hip: 2 Malleolus: 2 Sacrum: 0 Trochanter: 2	**Both groups:** /	irritation **Outcome 4:** Proportion of patients with inflammation **Outcome 5:** Proportion of patients with excoriation	**Group 1:** 1 **Group 2:** 0 **Group 3:** 0 **Group 1:** 1 **Group 2:** 0 **Group 3:** 0	analysis unclear; missings unclear **Additional outcomes:** / **Notes:** /

size: **no a priori sample size calculation** Setting: **in- and outpatients.** Length of study: **eight weeks of treatment or until complete healing** Assessment of PUs: **PUs classification not reported. Ulcers were photographed and measured. The perimeter was traced onto a plastic sheet with a permanent marker. All tracings were measured with a VIAS program.** Multiple ulcers: **unclear**	Ischium: 1 Other: 6 **Group 3** **Randomised N:** 21 **Completed N:** unclear **Dropouts:** unclear **Age (mean years (SD); range):** 57.2 (13.6); 26-75 (evaluated on 16 patients) **Gender (m/f):** 19/2 **Ulcer stage:** unclear-more ulcers? Stage II: 5 Stage III: 23 **Ulcer location:** Heel: 2 Buttock: 3 Hip: 3 Malleolus: 1 Sacrum: 3 Trochanter: 1 Ischium: 0 Other: 8 **Inclusion criteria:** Stage II or III PU; size between 1.5cm x 0.5cm and 10cm x 10cm; aged 18 years and older; life expectancy of at least 2 months **Exclusion criteria:** pregnant women; receiving chemotherapy; documented wound infection; extensive	

	undermining (>1.0cm) ulcer; positive test for HIV; receiving > 10mg/day corticosteroids				

Table 85 – MÛLLER 2001

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Müller (2001)** Title: **Economic evaluation of collagenase-containing ointment and hydrocolloid dressing in the treatment of pressure ulcers.** Journal: **PharmacoEconomics , 19 (12); 1209-1216.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **drop-out excluded.** Statistical analysis: **- rank for efficiency in**	**Patient group:** Hospitalized female patients with grade IV heel PUs. **All patients** **Randomised N:** 24 patients and 26 ulcers **Completed N:** 23 patients and 26 ulcers **Drop-outs:** 1 (failed treatment) **Group 1** **Randomised N:** 12 patients and 13 ulcers **Completed N:** 12 patients and 13 ulcers **Dropouts:** 0 **Age (mean years; range):** 74.6; 68-79 **Gender (m/f):** 0/12 **Group 2** **Randomised N:** 12 patients and 13 ulcers **Completed N:** 11 patients and 12 ulcers	**Group 1:** Collagenase ointment (Novuxol®). Ulcers were cleansed with saline 0.9%. Ulcers were treated with collagenase-containing ointment, paraffin gauze (Jelonet®) and an absorbent bandage. Ulcers were treated once a day. **Group 2:** Hydrocolloid dressing (DuoDerm®). Ulcers were cleansed with saline 0.9% and covered with the dressing. Ulcers were treated twice a week. **Both groups:** Before randomization autolysis and surgical debridement was performed. Occasionally remaining necrosis was treated with collagenase.	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Time to achieve complete healing (mean weeks; range)	**Group 1:** 11/12 **Group 2:** 7/11 **P value:** <0.005 **Group 1:** 10; 6-12 **Group 2:** 14; 11-16 **P value:** <0.005	**Funding:** Unrestricted grant from Knoll AG, Ludwigshafen, Germany. **Limitations:**; no report on sequence allocation; no report on allocation concealment; no report on blinding; no ITT analysis; sample size calculation unclear; very small sample size; no measurement of statistical difference between groups; no information on PU classification; little information on PU assessment; no

terms of the rate of complete healing and the Wilcoxon test for time to achieve complete healing were calculated. Tests were two-sided with p <0.05 Baseline differences: **Difference not statistically measured.** Study power/sample size: **The sample size (n=12) was calculated for the parameter 'time to achieve compete healing' for a power of 80%.** Setting: **Naaldhorst hospital, Naaldwijk in the Netherlands** Length of study: **not reported. Complete healing was achieved at maximum 16 weeks.** Assessment of PUs: **PU classification not reported. Ulcer size and depth was assessed weekly by a physician. Photographs were taken.** Multiple ulcers: **two patients had two ulcers**	**Dropouts:** 1 (failed treatment) **Age (mean years; range):** 72.4; 65-78 **Gender (m/f):** 0/12 **Inclusion criteria:** Grade IV PU **Exclusion criteria:** life expectancy of less than 6 months		information on preventive measures **Additional outcomes:** Cost-effectiveness **Notes:** /

Table 86 – MÜNTER 2006

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Münter (2006)** Title: **Effect of a sustained silver-releasing dressing on ulcers with delayed healing: the CONTOP study.** Journal: **Journal of Wound Care, 15 (5); 199-206.** Study type: **randomized controlled trial** Sequence generation: **a computer-generated list was used** Allocation concealment: **sealed envelopes were used** Blinding: **not reported** Addressing incomplete outcome data: **intention to treat analysis.** Statistical analysis: **The statistical analyses were carried out using SAS version 8.12. The obtained data were**	**Patient group:** Patients older than 18 years with a grade II or III PU (according to the EPUAP classification). Also patients with leg ulcers and diabetic foot ulcers were included. **All patients** **Randomised N:** 619 patients (43 PUs in ? patients) **Completed N:** not reported **Drop-outs:** not reported **Group 1** **Randomised N:** 326 (24 PUs in ? patients) **Completed N:** not reported **Dropouts:** not reported **Age (mean years (SD)):** 69.8 (13.7) **Gender (m/f):** 38/62 **Ulcer size (mean cm² (SD); median; range):** 52.9 (90.0; 20.0; 0.1-700 **Group 2** **Randomised N:** 293 (24 PUs in ? patients)	**Group 1:** Silver-releasing foam dressing (Contreet® foam, Coloplast). The dressings were changed weekly or depending on exudate. Concreet® foam silver: a soft hydrophilic polyurethane foam containing silver as an integral part of tits matric. The silver ions are present in a form that is really hydro-activated, with sustained silver release for up to seven days. Both adhesive and non-adhesive versions were used. **Group 2:** Local best practice, including foams/alginates (53%), hydrocolloids (12%), gauze (3%), silver dressings (17%); other antimicrobial dressings (9%) and other active dressings (6%) **Both groups:** /	**Outcome 1:** Mean percentage reduction in ulcer area	**Group 1:** 58.5 **Group 2:** 33.3	**Funding:** /. **Limitations:**; no report on blinding; little information on ulcer assessment; unclear how many patients had PUs **Additional outcomes:** / **Notes:** Patient characteristics are for all patients. The outcome are for PU patients only.

analyzed using the chi-square test, Wilcoxon signed rank test, Mann-Whitney U test and student' t-test. The level of significance was p<0.05. Subgroup analyses were performed. Baseline differences: **Difference not statistically measured.** Study power/sample size: **Based on an assumption of 80% power, a minimum relevant difference in means of 17.1 in relative ulcer are, a common standard deviation of 71.0 and a significance level of 5%, 272 in each group were measured as appropriate. A drop-out rate of 15% was set, resulting in a arbitrary target of 'over 600'** Setting: **80 specialist wound-care clinics in Germany, UK, Denmark, Italy, Switzerland, Belgium, Slovenia, Brazil and Canada.**	**Completed N:** not reported **Dropouts:** not reported **Age (mean years (SD)):** 68.8 (14.1) **Gender (m/f):** 39/61 **Ulcer size (mean cm² (SD); median; range):** 36.6 (64.4); 12.0; 0.1-400 **Inclusion criteria:** Aged 18 years and older; not pregnant or lactating; chronic wounds with delayed healing and producing moderate to high levels of exudate. **Exclusion criteria:** /	

Length of study: **four weeks of treatment.** Assessment of PUs: **PU were classified according to the EPUAP classification (1999).** **At each weekly visit ulcer size, odor, appearance, exudate level and number of dressing changes made since the last visit were assessed.** Multiple ulcers: **not reported**					

Table 87 – Nasar 1982

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Nasar (1982)** Title: **Cost effectiveness in treating deep pressure sores and ulcers.** Journal: **Practice of Medicine, 226; 307-310.** Study type: **randomized controlled trial** Sequence generation: **treatment was**	**Patient group:** Elderly patients with a deep pressure ulcer. **All patients** **Randomised N:** 12 patients and 18 ulcers, however unclear in text it seems 16 ulcers were included **Completed N:** 11 ulcers **Drop-outs:** 5 (1 patient discontinued due to pain, 1 died, 3 switched to other treatment)	**Group 1:** Debrisan - dextranomer. The Debrisan was applied in a stiff paste (four parts of Debrisan mixed with one part glycerol), twice daily for the first three days and daily thereafter. **Group 2:** Chlorinated lime solutions (Eusol) and paraffin packs. The solution was applied trice daily for the first three days and thereafter twice daily until the wounds healed. Melolin were used throughout and these were held in place with micropore	**Outcome 1:** Time (days) to healing (defined as granulating and < 25% of original surface area) **Outcome 2:** Proportion of patients with pain	**Group 1:** 39.3 (17.67) **Group 2:** 61.8 (13.86) **Group 1:** 1/? **Group 2:** 3/?	**Funding:** / **Limitations:** no report on sequence allocation, on allocation concealment, blinding, statistical analysis, PU classification, setting; no ITT analysis; no a priori sample size calculation; number of

selected on a random basis. Allocation concealment: **not reported.** Blinding: **not reported.** Addressing incomplete outcome data: **drop-out were excluded** Statistical analysis: **Not reported.** Baseline differences: **Not reported.** Study power/sample size: **No a priori sample size calculation.** Setting: **Not reported.** Length of study: **Until complete healing.** Assessment of PUs: **PU classification was not reported.** **Ulcers were measured with celluloid squares and photographed. Ulcers were measured every third day by an independent observer.** **Pain was recorded as yes or no.** Multiple ulcers: **12 patients with 18 ulcers were included. Ulcer was unit of analysis.**	**Group 1** **Randomised N:** 8 ulcers **Completed N:** 6 ulcers **Dropouts:** 2 (1 patient discontinued due to pain, 1 died) **Characteristics of completed N** **Age (mean years (SD)):** 83.17 (7.86) **Group 2** **Randomised N:** 8 ulcers **Completed N:** 5 ulcers **Dropouts:** 3 (switched to other treatment) **Characteristics of completed N** **Age (mean years (SD)):** 79.8 (3.27) **Inclusion criteria:** Patients with deep PUs. **Exclusion criteria:** Patients with an urinary tract infection.	tape. A Salvon sachet was used each time the dressing was changed. **Both groups:** Anaemia, hypoalbuminea, hypo vitaminosis and high blood urea were corrected if present. Scrupulous control of diabetic patients was ensured. Systematic antibiotics were only administered for organisms such as staphylococcus aureus and β haemolytic streptococci and no local antibiotic creams or lotions were applied. Patients with urinary incontinent were catheterized during the study period. Hardened sloughs were cut off at an early stage. All patients were nursed on a large cell ripple mattress. Concurrent therapy: ultraviolet light.		patients randomized and included unclear. **Additional outcomes:** cost-effectiveness **Notes:** /

Table 88 – NEILL 1989

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Neill (1989)** Title: **Pressure Sore Response to a New Hydrocolloid Dressing.** Journal: **Wounds: A compendium of Clinical Research and Practice, 1 (3); 173-185.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **drop-out excluded.** Statistical analysis: **Nonparametric test was used to compare distribution of healing between groups. Anova with PU grade, treatment group, and interaction as factor**	**Patient group:** Patients 18 years and older with grade II or III PUs (according to the Shea classification). **All patients** **Randomised N:** 100 ulcers **Completed N:** 65 patients and 87 ulcers **Drop-outs:** 13 ulcers (11 intercurrent medical events and 2 violated protocol) **Group 1** **Randomised N:** not reported **Completed N:** 42 ulcers **Dropouts:** not reported **Ulcer grade:** Stage II: n=25 Stage III: n=17 **Ulcer volume (mean cm² (SD); range):** 8.3 (9.9); 0.43-43.93 **Presence of necrosis:** 34 **Ulcers on hip, heel, or sacrum:** 31 **Group 2**	**Group 1:** Hydrocolloid dressing (Tegasorb™). Ulcers (free of debris) were irrigated with 50cc of a 1:1 solution of 3% hydrogen peroxide and sterile normal saline followed by 50cc saline rinse. Ulcers (with necrotic tissue, debris or faeces) were irrigated with 50cc of a 1:1 solution of 1% povidone-iodine and sterile saline solution between the hydrogen peroxide solution and the saline rinse. The skin was dried and the dressing was applied and changed every 7 days unless escar was present (every three days), or the dressing became non-adherent or leaked. Tegasorb™: contains polysaccharide, gelatine, pectin, and polyisobutylene. It consists of a flexible oval mass with an adherent hydrocolloid inner face, and an outer water and bacteria impermeable, adhesive-coated, polyurethane film. **Group 2:** Wet to damp saline gauze dressing. Ulcers (free of debris) were irrigated with	**Outcome 1:** Proportion of ulcers completely healed **Outcome 2:** Proportion of ulcers completely healed (grade II PUs) **Outcome 3:** Proportion of ulcers enlarged (grade II PUs) **Outcome 4:** Proportion of ulcers completely healed (grade III PUs) **Outcome 5:** Proportion of ulcers enlarged (grade III PUs) **Outcome 6:** Median percentage reduction in size (grade II PUs)	**Group 1:** 13/42 **Group 2:** 10/45 **Group 1:** 11/25 **Group 2:** 9/34 **P value:** > 0.05 **Group 1:** 7/25 **Group 2:** 11/34 **P value:** > 0.05 **Group 1:** 2/17 **Group 2:** 1/11 **P value:** > 0.05 **Group 1:** 7/17 **Group 2:** 4/11 **P value:** > 0.05 **Group 1:** 91 **Group 2:** 48 **P value:** > 0.05	**Funding:** Funded by the 3M Company, Medical-Surgical Division. **Limitations:**; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; no ITT analysis; no information on PU classification **Additional outcomes:** Nursing time; Organism growth **Notes:** /

in the model was applied to the data after transformation of the data into ranks. A p value less than 0.05 was considered significant. A logistic regression model was used to look at covariates of healing. Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **A tertiary care facility and its affiliated nursing home** Length of study: **eight weeks of treatment.** Assessment of PUs: **PU were classified according to the Shea classification. Ulcers edges were traced onto transparencies and photographs beside a metric ruler were taken using a Minolta Maxxum 7000 with a 50mm macro lens and a 80PX ring light with automated**	**Randomised N:** not reported **Completed N:** 45 ulcers **Dropouts:** not reported **Ulcer grade:** Stage II: n=34 Stage III: n=11 **Ulcer volume (mean cm² (SD); range):** 7.6 (8.6); 0.23-35.16 **Presence of necrosis:** 28 **Ulcers on hip, heel, or sacrum:** 34 **Inclusion criteria:** 18 years and older; ulcer < 1.5cm in depth, <5.6cm by 10cm in width and length; Grade II or III **Exclusion criteria:** inability of patient or guardian to give informed consent; presence of diabetes mellitus; history of skin hypersensitivity, skin disease, allergies to tape or adhesives; concurrent radiotherapy to PU area; medical condition that could interfere with study controls; pre-existing skin disease around the PU; clinical infection associated with PU; peripheral vascular ulcers evidenced by a	50cc of a 1:1 solution of 3% hydrogen peroxide and sterile normal saline followed by 50cc saline rinse. Ulcers (with necrotic tissue, debris or faeces) were irrigated with 50cc of a 1:1 solution of 1% povidone-iodine and sterile saline solution between the hydrogen peroxide solution and the saline rinse. After an open wide mesh gauze pad was moistened with sterile gauze and applied to the ulcer. A sterile gauze was applied as second dressing and secured with paper tape. The dressing was changed every eight hours **Both groups:** All subject received standard treatment for PUs: a pressure-reducing air mattress, and air-fluidized bed or a low air loss bed; an eggcrate wheelchair; turning and repositioning et least every two hours; control of incontinence with an external urine catheter and fecal incontinence collector.	**Outcome 7:** Median percentage reduction in size (grade III PUs) **Outcome 8:** Proportion of patients with adverse events	**Group 1:** 0.3 **Group 2:** 30 **P value:** > 0.05 **Group 1:** 9/50 (skin irritation) **Group 2:** 1/50 (ulcer worsened **P value:** < 0.06

exposure. A Zeiss IBAS Image Analyzer was used to calculate the ulcer surface area. Multiple ulcers: **A maximum of 2 PU per patients were included. The second ulcer received the alternate therapy**	Brachial Ankle Index ≤ 0.6; scars, contusions, abrasions, or open skin in the immediate PU area.				

Table 89 – NISI 2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Nisi (2005)** Title: **Use of protease-modulating matrix in the treatment of pressure sores.** Journal: **Chirurgia Italiana, 57 (4); 465-468.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **no**	**Patient group:** Hospitalized patients a stage II, III or IV PU (according to the NPUAP classification). **All patients** **Randomised N:** 80 **Completed N:** 80 **Drop-outs:** 0 **Age (mean years; range):** 45; 35-85 **Gender (m/f):** 53/27 Ulcer location: Sacrum: n=28 Back: n=2 Upper limb: n=8 Trochanter area: n=24 Heel: n=18 **Group 1**	**Group 1:** Protease-modulating matrix (Promogran®). Dressings were changed twice weekly or thrice weekly according to the wound exudation. Promogran®: 55% freeze-dried collagen and 45% oxidised regenerated cellulose. **Group 2:** Conventional dressing. Ulcers were disinfected with 50% povidine-iodine solution, saline wash, positioning of viscose-rayon gauze soaked in white vaseline and covering with a hydropolymer patch. **Both groups:** At start of the	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Time to complete healing (range days) **Outcome 3:** Proportion of patients with adverse events	**Group 1:** 36/40 **Group 2:** 28/40 **P value:** 0.59 **Group 1:** 6-15 **Group 2:** 14-52 **Group 1:** 0/40 **Group 2:** 0/40	**Funding:** / **Limitations:** no report on sequence allocation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priori sample size calculation; no report on statistical analysis; difference between groups not statistically measured; multiple ulcers not

drop-out. Statistical analysis: **no reported.** Baseline differences: **Difference not statistically measured.** Study power/sample size: **No a priori sample size calculation.** Setting: **Plastic surgery unit of the university hospital of Siena** Length of study: **time of treatment not reported. Six months of follow-up.** Assessment of PUs: **PU were classified according to the NPUAP classification. Ulcer extension and depth were recorded.** Multiple ulcers: **not reported**	**Randomised N:** 40 **Completed N:** 40 **Dropouts:** 40 **Group 2** **Randomised N:** 40 **Completed N:** 40 **Dropouts:** 0 **Inclusion criteria:** PU **Exclusion criteria:** decompensating diabetes; hypertension; severe hypoalbuminosis (<3.00g/100ml); clinical evidence of arterial or venous insufficiency; hematocrit values < 41% for male and 36% for female; treatment with steroid or immunosuppressive drugs	study (only one time) all ulcers were debrided surgically, disinfected with 50% povidine-iodine solution, saline wash, and use of hydrogels. Once ulcers were cleaned the study dressings were applied.			reported; insufficient information on treatments **Additional outcomes: /** **Notes:** /

Table 90 – OLEKSE 1986

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Oleske (1986)** Title: **A randomized clinical trial of two dressing methods for**	**Patient group:** Patients older than 21 years with stage I or II PUs (according to the Enis and Sarmiento	**Group 1:** Polyurethane self-adhesive dressing. Cleansing of the ulcer and application of the dressing was according to a standardized protocol. The	**Outcome 1:** Proportion of ulcers completely healed	**Group 1:** 1/9 **Group 2:** 0/10	**Funding:** the study was sponsored by the Department of Medical Nursing,

the treatment of low-grade pressure ulcers. Journal: **Journal of Enterostomal Therapy, 13 (3); 90-98.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **drop-out was excluded.** Statistical analysis: **One-way analysis of variance was used to compare the two treatments. A paired t test was used to compare the largest axis and surface are changes within treatment group. A standard chi-square test was used to compare the PU grades before and after therapy end to compare the two treatment groups. The significance of**	classification). **All patients** **Randomised N:** 16 patients **Completed N:** 15 patients and 19 ulcers **Drop-outs:** 1 (unanticipated transfer to nursing home). **Age (mean years (SD); range):** 69 (6); 52-93 **Ulcer location:** Gluteal and coccyx area **Group 1** **Randomised N:** not reported **Completed N:** 7 patients and 9 ulcers **Dropouts:** not reported **Ulcer grade:** Grade I: n=2 Grade II: n=7 **Ulcer area (mean cm² (SD):** 3.5 (1.2) **Group 2** **Randomised N:** not reported **Completed N:** 8 patients and 10 ulcers **Dropouts:** not reported **Ulcer grade:** Grade I: n=5 Grade II: n=5 **Ulcer area (mean cm² (SD):** 7.7 (8.6)	dressing was changed if it dislodged from the ulcer site. **Group 2:** Saline dressing. Cleansing of the ulcer and application of the dressing was according to a standardized protocol. The dressing was changed every four hours around the clock **Both groups:** All patients received the standardized nursing skin care: repositioning every 3 hours, daily administration of multivitamin tablets, use of a convoluted foam mattress (without sleeves)	**Outcome 2:** Proportion of ulcers worsened **Outcome 3:** Mean percentage surface area reduction	**Group 1:** 1/9 **Group 2:** 2/10 **Group 1:** 42.9 **Group 2:** 2.5	Rush-Presbyterian-St.Luke's Medical Centre and the Chicago Community trust. **Limitations:**; no report on sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; small sample size **Additional outcomes:** / **Notes:** /

the calculated statistics was determined by a two-tailed test with the level of alpha = 0.05 Baseline differences: **No statistical difference in terms of age, sex and race.** Study power/sample size: **No a priori sample size calculation.** Setting: **inpatient medicine unit.** Length of study: **10 days of treatment.** Assessment of PUs: **PU were classified according to the Enis and Sarmiento classification (1973). Wound healing was evaluated: ulcer grade, longest wound axis, total wound surface area. A transparent rule was used to measure the longest wound axis. Tracings of the ulcer surface were made onto sterile plastic sheets. Surface area were than computed by means of compensating polar planimeter.**	**Inclusion criteria:** Adults (21 years of age or over) with a PU grade I or II; afebrile (< 100°F orally or < 101°F rectally); confined to bed, wheelchair, or chair and expected to be so for at least two weeks: expected hospitalization of two weeks; ulcer caused by pressure; ulcer of at least 2cm diameter; not contained in an area currently being irradiated; no evidence of infection; hemoglobin level > 10g/dL **Exclusion criteria:** /	

Multiple ulcers: **15 patients with 19 ulcers**	

Table 91 – PARISH 1979

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Parish (1979)** Title: **Decubitus ulcers: a comparative study** Journal: **Cutis; 23 (1): 106-110** Study type: **Double-blinded study** Sequence generation: **Patients were assigned at random, but no randomization method was reported.** Allocation: **No details** Blinding: **Neither the principal investigator, nor the patients knew who was assigned to which treatment regimen. The authors state however that while the attempted to keep the study double-blinded, it became obvious which regimens were**	**Patient group:** Patients with pressure ulcers in a long-term care institution for the chronically ill and physically disabled. **All patients** **Randomised N:** Not reported **Completed N:** 17 **Drop-outs:** Not reported **Group 1** **Randomised N:** Not reported **Completed N:** 7 **Dropouts:** Not reported **Age:** 29-57 **Gender (m/f):** Not reported **Other relevant patient characteristics:** Number of ulcers (n=14) Average ulcer dimension in cm = 4.5 **Group 2** **Randomised N:** not	**Group 1:** Dextranomer powder is employed in the treatment of secreting skin lesions. Dextranomer (Debrisan, Pharmacia Laboratories) consists of beads of cross-linked dextran molecules 0.1 to 0.3 mm in diameter in a three-dimensional porous network. The beads are hydrophilic and each gm of dry beads has the capacity to absorb 4 ml of fluid. Experimental studies show dextranomer capable of transporting bacteria, inflammatory mediators and debris away from the wound surface and into the bead layers. Patients paced on the dextranomer program were given saline soaks. Dextranomer was poured into the ulcer in a layer of at least 3mm deep and the sores were then covered with dry dressings. The dextranomer dressings were changed one	**Outcome 1:** Proportion of ulcers improved **Outcome 2:** Proportion of patients improved **Outcome 3:** Proportion of ulcers completely healed **Outcome 4:** Proportion of patients completely healed **Outcome 5:**	**Group 1:** 12/14 **Group 2:** 5/11 **Group 3:** 0/9 **P-value: G1 vs G2:** <0.02 **P-value G1 vs G3:** <0.001 **P-value G2 vs G3:** > 0.05 **Group 1:** 7/7 **Group 2:** 2/5 **Group 3:** 0/5 **P-value: G1 vs G2:** <0.05 **P-value G1 vs G3:** <0.001 **P-value G2 vs G3:** > 0.05 **Group 1:** 6/14 **Group 2:** 1/11 **Group 3:** 0/9 **P-value: G1 vs G2:** >0.05 **P-value G1 vs G3:** <0.08 **P-value G2 vs G3:** > 0.05 **Group 1:** 4/7 **Group 2:** 1/5 **Group 3:** 0/5 **P-value: G1 vs G2:** >0.05 **P-value G1 vs G3:** < 0.05 **P-value G2 vs G3:** > 0.05 **Group 1:** 0/7	**Funding:** : **Limitations:** No inclusion or exclusion criteria reported; Small sample size; Blinding failed; Randomization method not reported ;Six patients changed treatment during the study. No information was given if there was a washing-out period **Additional outcomes:** All seven patients treated with dextranomer improved during the course of the study. In the collagenase group, two of five

being used. Addressing incomplete outcome data: **Not reported** Statistical analysis: **A fisher exact test was used to evaluate the data. Average ulcer dimension= square root of surface area.** Baseline differences: **Not reported.** Study power/sample size: **Not reported** Setting: **The Inglis House is a long-term care institution for the chronically ill and physically disabled. Patients in this institution have such incapacitating disorders as paraplegia, quadriplegia, Parkinson's disease, rheumatoid arthritis, cerebral palsy, and multiple sclerosis. Of approximately three hundred residents, about 10 percent have decubitus ulcers at any one time.** Length of study:	reported **Completed N:** 5 **Dropouts:** 1 (patient not responding to the collagenase treatment was switched to the dextranomer group). **Age:** 28-59 **Gender (m/f):** Not reported Other relevant patient characteristics: Number of ulcers (n=11) Average ulcer dimension in cm = 3.2 **Group 3** **Randomised N:** not reported **Completed N:** 5 **Dropouts:** 5 (patients not responding to the sugar and egg white treatment were switched to the dextranomer (n=4) or collagenase group (n=1)). **Age:** 32-70 **Gender (m/f):** Not reported Other relevant patient characteristics: Number of ulcers (n=9) Average ulcer dimension in cm = 2.4 **Inclusion criteria:** not reported	to three times daily depending on the amount of wound exudate. The removal of the dextranomer beads was accomplished by saline irrigation. **Group 2:** Patients receiving collagenase (Collagenase, Santyl, Knoll Pharmaceutical Co) were given a saline wash. Collagenase was then applied daily with a wooden applicator, and the ointment was covered with a dry dressing, as recommended by the package insert. **Group 3:** Patients receiving sugar and egg white were also given a saline wash. The mixture was applied liberally to the area four times daily and allowed to dry. **All groups:** if a patient did not respond satisfactorily to any treatment at the end of four weeks, the regimen was changed to one of the two other treatments.	Side effects	**Group 2:** 0/5 **Group 3:** 0/5	patients improved. None of the patients treated with sugar and egg white showed improvement. In four patients treated with dextranomer, improvement was observed within one week of the start of treatment and in two other patients improvement was seen within one month. In the collagenase group, none of the five patients improved within one week of treatment and two patients improved within one month of treatment. All five patients who failed to respond to the sugar and egg white treatment were changed to either dextranomer or collagenase treatment. The four patients

The initial study was to have lasted four weeks, but many subjects were treated and observed for up to four months or longer. Assessment of PUs: **Pressure ulcers were assessed as dry or moist. The authors believe that there is no purpose in further categorizing the ulcers.** Multiple ulcers: **All pressure ulcers of the included patients were treated and assessed.**	**Exclusion criteria:** not reported		switched to dextranomer all improved, with three patients attaining complete closure of their ulcers (four ulcers). One patient with four decubitus ulcers was switched to the group receiving collagenase. This patient improved, with one of four ulcers closing. One patient for whom collagenase treatment failed to produce an adequate response and who was crossed over into the dextranomer group also improved with one of two ulcers closing. The authors did not see any change in the progress of healing whether the patient was turned every two

			hours, as they had been initially or whether they were allowed to remain in the same position for many hours. Similarly, cleaning the patients and changing their linens frequently led to none but aesthetic improvements. All patients received the same diet as the other residents of the Inglis House. Sepsis did not develop during the course of the study. Bacteriologic cultures, both aerobic and anerobic were done before, during and after treatment, but no significant trends were noted. **Notes:** /

Table 92 – PAYNE 2004

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Payne (2004)** Title: **An exploratory study of dermal replacement therapy in the treatment of stage III pressure ulcers.** Journal: **The Journal of Applied Research, 4 (1); 12-23.** Study type: **randomized controlled trial** Sequence generation: **computer generated scheme.** Allocation concealment: **presealed envelops** Blinding: **single blind, no further information.** Addressing incomplete outcome data: **intention to treat analysis.** Statistical analysis: **Values for ulcer area and volume (as measured by the weight of alginate**	**Patient group:** Patients with a grade III PU. **All patients** **Randomised N:** 34 **Completed N:** 10 **Drop-outs:** 14 (reason not reported). **Ulcer location:** (one missing data) Sacrum: n=22/33 Trochanter: n=8/33 Ischium: n=3/33 **Incontinence:** Urine: n=1 Faecal: n=4 Both: n=26 **Group 1** **Randomised N:** 18 **Completed N:** 5 **Dropouts:** 13 (reason not reported). **Age (mean years (SD)):** 69.4 (16.5) **Gender (m/f):** 12/6 **Ulcer duration (mean weeks; range):** 30.2; 6-95.3 **Ulcer area (mean cm²; range):** 19.8; 5.2-60.7 **Group 2**	**Group 1:** Dermal replacement (Dermagraft®, Smith & Nephew, Inc., Heslington, York, UK). Two pieces were applied side by side to the ulcer weekly for the first three weeks. A combination of a non-adherent dressing, saline-moistened gauze and a non-adhesive foam dressing (Allevyn®, Smith & Nephew, Inc., Heslington, York, UK) were added. Dermagraft®: a human dermal replacement consisting of newborn dermal fibroblasts cultured in vitro onto a bioabsorbable mesh to produce living, metabolically active human, dermal tissue. **Group 2:** A combination of a non-adherent dressing, saline-moistened gauze and a non-adhesive foam dressing (Allevyn®, Smith & Nephew, Inc., Heslington, York, UK) were applied. **All groups:** Ulcers were debrided	**Outcome 1:** Proportion of patients completely healed by 24 weeks **Outcome 2:** Median percentage (range) reduction in wound area at 12 weeks for closed ulcers **Outcome 3:** Median percentage (range) reduction in wound area at 12 weeks for ulcers with incomplete closure **Outcome 4:** Mean percentage (range) reduction in ulcer volume area at 12 weeks **Outcome 5:** Median percentage	**Group 1:** 2/18 **Group 2:** 2/16 **Group 1:** 49.5 (-81.7-100.0) **Group 2:** 33.5 (-77.5-100.0) **Group 1:** 38.8 (-201.7-100.0) **Group 2:** 17.4 (-434.5-100.0) **Group 1:** 18.7 **Group 2:** 4.1 **Group 1:** 41.2 **Group 2:** 17.4	**Funding:** sponsored by Smith and Nephew, Inc. **Limitations:** insufficient information on blinding; no a priori sample size calculation; small sample size and high drop-out; little information on setting; PU classification not reported; no information on use of preventive measures. **Additional outcomes:** / **Notes:** /

mould) were calculated at Week 12, and compared using the Mann-Whitney U test. Hodges-Lehmann estimates of the difference in the medians of area and volume were calculated using a 95% confidence interval. The primary variable of complete healing by Week 24, and secondary variable of closure by Week 12 were compared between patients using Fischer's exact test. Statistical analysis was conducted using SAS (SAS/STAT Guide for Personal Computers, Version 8.2, Cary, North Carolina) Baseline differences: **Statistical difference only calculated for smoking (not significant). Groups were comparable.** Study power/sample size: **No a priori sample size calculation. The**	**Randomised N:** 16 **Completed N:** 5 **Dropouts:** 11 (reason not reported). **Age (mean years (SD)):** 69.1 (18.5) **Gender (m/f):** 11/5 **Ulcer duration (mean weeks; range):** 29.2; 4.0-104.0 **Ulcer area (mean cm²; range):** 21.1; 3.5-51.2 **Inclusion criteria:** Age > 18 years; stage III sacral pressure ulcer; ulcer (after debridement) is clean and free of both necrotic tissue and infection; ulcer present for at least 2 months, but not more than 24 months, prior to screening; ulcer is > 5 cm^2 and < 50 cm^2; if more than 1 ulcer, the distance between ulcers is > 10 cm; ulcer is due solely to pressure damage. **Exclusion criteria:** Stage I, II or IV pressure ulcers; patient has more than 3 full thickness (Stage III or IV) pressure ulcers; evidence of undermining, tunneling or sinus tracts > 1 cm	(range) reduction in ulcer volume area at 12 weeks **Outcome 6:** Proportion of patients with infected ulcers **Outcome 7:** Proportion of patients with adverse events related to the treatment	**Group 1:** 3/18 **Group 2:** 3/16 **Group 1:** 0/18 **Group 2:** 0/16

study was not powered to detect difference between groups Setting: **nine centres in the US.** Length of study: **maximum 24 weeks of treatment and a follow-up of 2 weeks after treatment.** Assessment of PUs: **PU classification not reported.** **Photographs of the ulcer site immediately before and after debridement were taken.** **Ulcer tracings were performed at the initial and subsequent weekly follow-up visits on a Zip-Loc plastic bag and transferred on to an ulcer area grid for planimetry.** **Pressure ulcer area was determined by direct measurement (length in cm x width in cm). Pressure ulcer volume was determined by alginate mold method.**	after debridement; ulcers previously treated with a surgical flap procedure; bacterial colonization; ulcer decreased or increased in size by 50% during the screening period; underlying non-pressure ulcer etiology	

Assessments were performed weekly until either, the patient had a second confirmation of wound closure, or Week 24 (through to Week 26 if the wound closure was first observed at Week 24). Multiple ulcers: **the largest ulcer meeting the inclusion and exclusion criteria was selected.**					

Table 93 – PAYNE 2009

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Payne (2009)** Title: **A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus a traditional saline gauze dressing in the treatment of stage II pressure ulcers.** Journal: **Ostomy/wound management 55(2); 50-55.**	**Patient group:** Patients 18 years and older with a stage II PU (according to the NPUAP classification). **All patients** **Randomised N:** 36 **Completed N:** 27 **Drop-outs:** 9 (5 died, 1 ulcer infection, 1 abscess unrelated to study ulcer, 1 became ineligible, 1 discharged) **Group 1**	**Group 1:** Polyurethane self-adhesive foam dressing (Allevyn® Thin, Smith & Nephew Inc, Largo, Fl). Ulcers were cleansed and dried. Ulcers were dressed with the dressing without secondary dressing or fixation. Dressing were changed determined by clinician. **Group 2:** Saline-soaked gauze dressing. Ulcers were cleansed and dried. Ulcers were dressed with the dressing and with a	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Median (days) time to healing (time at which 50% of the patients achieved complete healing)	**Group 1:** 10/20 **Group 2:** 6/16 **Group 1:** 28 **Group 2:** 28	**Funding:** travel grand and funding from Smith & Nephew **Limitations:** insufficient information on sequence generation;; no report on allocation concealment; no report on blinding; no measurement of statistical

Study type: **randomized controlled trial** Sequence generation: **randomized schedule.** Allocation concealment: **not reported.** Blinding: **not reported.** Addressing incomplete outcome data: **intention to treat analysis for all analysis except cost-effectiveness.** Statistical analysis: **An accelerated failure time model was used to test for differences between groups for time of healing after adjustment for study center, baseline ulcer area, and duration. Kaplan-Meier methods were used to estimate the median time to healing.** Baseline differences: **No calculation of the statistical difference between groups.** Study power/sample size: **To detect a $10 per week difference**	**Randomised N:** 20 **Completed N:** 14 **Dropouts:** 6 (3 died, 1 ulcer infection, 1 abscess unrelated to study ulcer, 1 became ineligible) **Age (mean years (SD); median years):** 72.5 (14.3); 74.0 **Gender (m/f):** 13/7 **Ulcer duration (mean weeks (SD); median weeks):** 56.1 (219.6); 3.5 **Ulcer area (mean cm² (SD); median cm²):** 5.6 (11.3); 1.8 **Ulcer location:** Hips/buttocks: n=7 Sacrum: n=8 Upper leg: n=1 Ankle/foot: n=4 Lower leg: n=0 **Group 2** **Randomised N:** 16 **Completed N:** 13 **Dropouts:** 3 (2 died, 1 became ineligible) **Age (mean years (SD); median years):** 73.3 (12.4); 71.5 **Gender (m/f):** 9/7 **Ulcer duration (mean weeks (SD); median weeks):** 7.0 (9.4); 2.0 **Ulcer area (mean cm²**	secondary dry sterile gauze pad held in place with tape. Dressing were changed determined by clinician. **All groups:** /	difference between groups; no information on use of preventive measures. **Additional outcomes:** cost-effectiveness **Notes:** /

in cost of dressing and other materials between groups assuming a standard deviation of $9.80. This was based on a two-sided unpaired t-test at the 5% level of significance and 80% power. A sample size of 19 patients per groups are required. Setting: **three hospital wards, one outpatient hospital clinic, one long-term residential care, one community care clinic.** Length of study: **four weeks of treatment or until complete healed, whichever came first.** Assessment of PUs: **PU were classified according to the NPUAP classification. Ulcers were measured at baseline and weekly using Visitrak (Smith&Nephew Inc. Largo, FL).** Multiple ulcers: **the largest ulcer was included in the study treatment.**	**(SD); median cm²):** 6.2 (7.2); 1.4 **Ulcer location:** Hips/buttocks: n=7 Sacrum: n=7 Upper leg: n=0 Ankle/foot: n=1 Lower leg: n=1 **Inclusion criteria:** 18 years and older; not pregnant or using contraception; stage II PU with light to moderate exudate. **Exclusion criteria:** Known history of poor compliance; presence of clinical infection in wound; previous participation in the evaluation	

Table 94 – RHODES 1979

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Rhodes (1979)** Title: **The treatment of pressure sores in geriatric patients: a trial of sterculia powder.** Journal: **Nursing Times, 75; 365-368.** Study type: **randomized controlled trial** Sequence generation: **the charge nurse allocated the subjects alternately to one of the groups whenever a PU occurred.** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **multiple ulcers were included but only the ulcer with the best healing rate was selected for analysis. Intention to treat analysis.**	**Patient group:** Geriatric patients with a PU. **All patients** **Randomised N:** 38 patients with 57 ulcers **Completed N:** 38 patients with 38 ulcers **Drop-outs:** 19 ulcers (only one ulcer per patient was included in the analysis) **Age (mean years; range):** 82; 71-92 **Gender (m/f):** 7/31 **Group 1** **Randomised N:** 29 ulcers **Completed N:** unclear **Dropouts:** unclear **Group 2** **Randomised N:** 28 ulcers **Completed N:** unclear **Dropouts:** unclear **Inclusion criteria:** PU **Exclusion criteria:** /	**Group 1:** Sterculia gum powder (Karaya gum powder, Hills Pharmaceuticals Ltd, Talbot Street, Briercliffe, Burnley). Ulcers got a simple wound toilet and the dressing was insufflated onto the surface. Dressings were changed every 24 hours. **Group 3:** Standard treatment such as zinc sulphate, tinct, benzoin or cod liver oil. **All groups:** /	**Outcome 1:** Proportion of ulcers completely healed **Outcome 2:** Mean healing index	**Group 1:** 16/17 **Group 2:** 9/21 **Group 1:** 16.8 **Group 2:** -3.8 **P-value:** 0.12	**Funding:** / **Limitations:** inadequate sequence allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; small sample size; little information on baseline characteristics and no measurement of difference between groups; length of study not reported; drop-outs unclear, reported as patients and ulcers; no inclusion or exclusion criteria; unclear if all stages of PU were included; no classification of PU; no report on

Statistical analysis: **To determine the differences in healing rate a Mann Whitney U test was applied. In one case this was converted to a z-score because the number of subjects in one groups was greater than 20. The level of significance was set at p<0.05, two tailed.** Baseline differences: **No information on baseline characteristics of groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **geriatric unit.** Length of study: **not reported** Assessment of PUs: **PU classification not reported.** **Ulcers were measured weekly. A transparent ruler was used to measure the longest wound axis in millimetres and a second measurement was taken at right angles to the first. A**		preventive measures or debridement **Additional outcomes:** / **Notes:** /

healing index (initial area – final area / time in days) was calculated for each lesion. Multiple ulcers: **multiple ulcers were included but only the ulcer with the best healing rate was selected for analysis.**					

Table 95 – RHODES 2001

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Rhodes (2001)** Title: **Topical phenytoin treatment of stage II decubitus ulcers in the elderly.** Journal: **The Annals of Pharmacotherapy, 35 (6); 675-681.** Study type: **randomized controlled trial** Sequence generation: **Patients were matched for age, gender, size and severity of the ulcers and were placed in one of the three groups based on the**	**Patient group:** Nursing home patients with a stage II PU (according to the AHCPR classification). **All patients** **Randomised N:** 47 **Completed N:** 39 **Drop-outs:** 8 (1 continually recurrent ulcers, 5 died, 2 were discharged) **Group 1** **Randomised N:** 18 **Completed N:** 15 **Dropouts:** 3 (1 continually recurrent ulcers, 2 died) **Age (mean years):** 75.5	**Group 1:** Phenytoin. Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with 100mg phenytoin suspension daily. A sterile gauze was soaked in the suspension and placed on the ulcer, followed by a layer of dry sterile gauze. Phenytoin suspension: a single 100 mg phenytoin cup containing 5ml of sterile NaCl 0.9% to form a suspension. **Group 2:** Hydrocolloid dressing (DuoDerm®). Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with dressing with the edges extending 1¼ inch beyond the wound. The dressing was changed every	**Outcome 1:** Mean time (days; range) to healing **Outcome 2:** Proportion of patients with treatment related adverse events **Outcome 2:** Proportion of patients pain	**Group 1:** 35.3 (14.3); 15-64 **Group 2:** 51.8 (19.6); 27-90 **Group 3:** 53.8 (8.5); 42-67 **P-value G1 vs G2:** 0.020 **P-value G1 vs G3:** 0.011 **Group 1:** 0/15 **Group 2:** 0/13 **Group 3:** 0/11 Minimal pain was reported in all groups	**Funding:** / **Limitations:**; no report on sequence allocation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priori sample size calculation; small sample size; little information on setting; little information on statistical analysis; no report on multiple ulcers

treatment preference of the randomly assigned physician prescribing the treatment plan. Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **drop-outs were excluded.** Statistical analysis: **Statistical analysis included the Levine test for homogeneity of variance, anova, and a post hoc Bonferroni adjustment for multiple pairs.** Baseline differences: **Difference was not statistically different.** Study power/sample size: **No a priori sample size calculation.** Setting: **veteran administration nursing home.** Length of study: **not reported** Assessment of PUs: **PU were classified according to the Agency Health Care Research and**	**Gender (m/f):** 16/2 **Group 2** **Randomised N:** 16 **Completed N:** 13 **Dropouts:** 3 (2 died, 1 was discharged) **Age (mean years):** 78.7 **Gender (m/f):** 15/1 **Group 3** **Randomised N:** 13 **Completed N:** 11 **Dropouts:** 2 (1 died, 1 was discharged) **Age (mean years):** 76.5 **Gender (m/f):** 12/1 **Inclusion criteria:** Age > 60 years; stage II PU **Exclusion criteria:** signs and symptoms of ulcer infection; anemia; malnutrition; folate deficiency; chronic use of immunosuppressive treatment; immobility; those receiving oral phenytoin; history of adverse events caused by phenytoin.	seven days or when it became uncomfortable, leaked, or the presence of infection signs. **Group 3:** Triple antibiotic ointment. Ulcers were cleansed with NaCl 0.9% and hydroxide, dried, and covered with a layer of TAO. Followed a sterile gauze was applied as cover. The dressing was changed every day. **All groups:** All ulcers were surgically debrided as necessary. All patients received preventive measures such as maximum mobilisation, adequate nutrition and hydration, and incontinence care.		**Additional outcomes:** / **Notes:** Hydrocolloid dressings was defined as a collagen dressing in this article

Quality's Pressure Ulcer Guideline Panel classification (1992). Ulcers were measured with a MediRule, which was centred over the area to be measured. This transparent, disposable ruler consists of concentric circles measured in centimetres around a cross hair ruled in millimetres. Photographs using a Polaroid Spectra AF were taken once weekly. Two light beams were placed at eight inches from the object. Multiple ulcers: **not reported**					

Table 96 – ROUTKOVSKY-NORVAL 1996

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Routkovsky-Norval (1996)** Title: **Randomized comparative study of two hydrocolloid dressings in the**	**Patient group:** Patients with a necrotic or granulating PU. **All patients** **Randomised N:** 61 **Completed N:** 61	**Group 1:** Hydrocolloid dressing (Comfeel®). Comfeel®: consists of sodium carboxymethylcellulose particles embedded in an adhesive, elastic mass. The side which faces away from	**Outcome 1:** Percentage reduction in surface area **Outcome 2:** Proportion of	**Group 1:** 44 **Group 2:** 49 **Group 1:** 2/31 (maceration, allergy)	**Funding:** / **Limitations:** no report on sequence allocation; no report on

treatment of decubitus ulcers. Journal: **Revue de Geriatrie, 21 (3); 213-218.** Study type: **randomized controlled trial** Sequence generation: **not reported.** Allocation concealment: **not reported.** Blinding: **not reported.** Addressing incomplete outcome data: **intention to treat analysis.** Statistical analysis: **Data were compared using the t-test with correction of Satterthwaite in case of unequal variation or by the nonparametric Wilcoxon test. For categorical variables a chi-square test or Fischer exact test was used. Absolute of cleanness and improvement were compared using the Fischer exact test. Adjusted data were determined with the**	**Drop-outs:** 0 **Group 1** **Randomised N:** 31 **Completed N:** 31 **Dropouts:** 0 **Age (mean years (SD); range):** 82.4 (9.5); 56-97 **Gender (m/f):** 15/16 **Ulcer area (mean cm (SD); range cm):** 165.7 (10.6); 140-185 **Necrotic:** 25 **Group 2** **Randomised N:** 30 **Completed N:** 30 **Dropouts:** 0 **Age (mean years (SD); range):** 79.5 (12.1); 48-94 **Gender (m/f):** 9/21 **Ulcer area (mean cm (SD); range cm):** 164 (9.2); 150-180 **Necrotic:** 29 **Inclusion criteria:** PU with necrosis or granulating; ulcers needed to be covered by a dressing of 15 x 15 cm; ulcer depth that did not needed to be filled with paste or hydrocolloid powder. **Exclusion criteria:** Ulcer with a loco-	the ulcer is covered with a polyurethane film. **Group 2:** Hydrocolloid dressing (Comfeel®Plus). Comfeel®Plus: consists of carboxymethylcellulose connecting a chain of polymers, which is more absorbent. This was covered with a vapour-permeable film. **All groups:** /	patients with dressing intolerance **Outcome 2:** Proportion of cases reporting the dressing as good to excellent for comfort at dressing change	**Group 2:** 3/30 (bleeding, infection) **Group 1:** 142/167 **Group 2:** 150/166	allocation concealment; no report on blinding; no a priori sample size calculation; statistical difference between groups for ulcer area and exudate; no information on setting; insufficient information on interventions; no information on PU classification; no information on multiple ulcers; no information on use of preventive measures. **Additional outcomes:** decrease in necrosis; time of debridement; number of dressings; quality of the dressing; ease of use **Notes:** /

survival Kaplan Meier and compared with the Log-rank test. Statistical analysis were performed using SAS. Baseline differences: **Difference between groups were not statistically significant except for ulcer area, exudate.** Study power/sample size: **No a priori sample size calculation.** Setting: **not reported.** Length of study: **eight weeks of treatment or until complete healed, whichever came first.** Assessment of PUs: **PU classification was not reported.** **Ulcers necrosis, peri-wound area, and quantity of exudate were measured.** **Depth and length of the ulcers were measured by tracing and photographs. Surfaces were measured by planimetry of the tracings and by software program to**	regional or generalized surinfection; ulcers in epithelisation phase; allergic to one of the dressings; immunosuppressive treatment; clinical signs of major anemia	

analyse images Multiple ulcers: **not reported**					

Table 97 – SAYAG 1996

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Sayag (1996)** Title: **Healing properties of calcium alginate dressings.** Journal: **Journal of Wound Care, 5 (8); 357-362** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **sealed envelopes** Blinding: **not reported** Addressing incomplete outcome data: **intention to treat analysis.** Statistical analysis: **Comparisons were made using chi-square and exact Fischer tests for qualitative variables and student's t-test**	**Patient group:** Patients with a grade III or IV PU (according to the Yarkony classification) **All patients** **Randomised N:** 92 **Completed N:** 60 **Drop-outs:** 32 (11 died, 2 were transferred, 1 deteriorated in health status, 1 had local adverse event, 17 deterioration or stagnation of PU) **Group 1** **Randomised N:** 47 **Completed N:** 37 **Dropouts:** 10 (5 died, 2 were transferred, 1 deteriorated in health status, 2 deterioration or stagnation of PU) **Age (mean years (SD); range):** 81.9 (8.9); 60-94 **Gender (m/f):** 12/35 **BMI (mean kg/m² (SD); range):** 21.9 (3.9); 12.1-	**Group 1:** Calium alginate dressing (Algosteril®). The dressing covered the entire area. A sterile gauze was applied as secondary dressing. Dressings were changed every day or at least every four days. **Group 2:** Dextranomer dressing (Debrisan®). The paste was applied uniformly to produce a 3mm layer. A sterile gauze was applied as secondary dressing. Dressings were changed every day or at least every four days. **Both groups:** /	**Outcome 1:** Proportion of patients improved (> 75%) **Outcome 2:** Proportion of patients improved (> 40%) **Outcome 3:** Mean reduction in ulcer area (cm²/week) **Outcome 4:** Mean reduction in ulcer area in patients improved > 40% (cm²/week) **Outcome 5:** Proportion of patients stagnated or deteriorated **Outcome 6:** Proportion of	**Group 1:** 15/47 **Group 2:** 6/45 **Group 1:** 35/47 **Group 2:** 19/45 **P-value:** 0.002 **Group 1:** 2.39 (3.54) **Group 2:** 0.27 (3.21) **P-value:** 0.0001 **Group 1:** 3.55 (2.18) **Group 2:** 2.15 (3.60) **P-value:** 0.0004 **Group 1:** 2/47 **Group 2:** 15/45 **Group 1:** 2/47	**Funding:** supported by Les Laboratoires Brothier **Limitations:** no report on sequence generation; no report on blinding; no information on preventive measures. **Additional outcomes:** number of dressing changes per week **Notes:** /

for quantitative variables. The time to the study endpoint was compared by the Logrank test. All calculations were performed on a DEC station by means of SAS/Ultrix software. Baseline differences: **No statistical difference between groups.** Study power/sample size: **Interim analysis (not a priori calculation) based on the first 53 patients, indicated that 90 subjects would be required (two-tailed, alpha risk 0.05, beta risk 0.20).** Setting: **17 specialized centres in care of elderly people and 3 centres specialized in dermatology.** Length of study: **maximum eight weeks** Assessment of PUs: **PUs were classified according to the Yarkony classification (1990). Ulcers were**	28.7 **Ulcer grade:** Grade III: 33 Grade IV: 14 **Ulcer location:** Pelvis area: 14 Heel: 30 Other: 3 **Ulcer area (mean cm² (SD); range):** 20.1 (12.9); 4.2-53.2 **Duration of PU (mean months (SD); range):** 3.5 (3.8); 1-21 **Group 2** **Randomised N:** 45 **Completed N:** 23 **Dropouts:** 22 (6 died, 1 local adverse event, 15 deterioration or stagnation of PU) **Age (mean years (SD); range):** 80.4 (9.1); 60-96 **Gender (m/f):** 12/33 **BMI (mean kg/m² (SD); range):** 21.8 (4.0); 14.3-29.9 **Ulcer grade:** Grade III: 30 Grade IV: 15 **Ulcer location:** Pelvis area: 23 Heel: 22 Other: 0 **Ulcer area (mean cm² (SD); range):** 16.1 (12.5); 4.9-62.3	patients with an infection **Outcome 7:** Proportion of patients with hypergranulation **Outcome 8:** Proportion of patients with pain **Outcome 9:** Proportion of patients with skin irritation **Outcome 10:** Proportion of patients with bleeding at dressing change **Outcome 11:** Proportion of patients with pruritus	**Group 2:** 2/45 **Group 1:** 1/47 **Group 2:** 3/45 **Group 1:** 0/47 **Group 2:** 5/45 **Group 1:** 1/47 **Group 2:** 1/45 **Group 1:** 0/47 **Group 2:** 3/45 **Group 1:** 0/47 **Group 2:** 1/45

photographed and planimetry was used. Planimetric drawing were digitalized twice by using a graphic table and areas were calculated using Autocad software. Multiple ulcers: **only one ulcer per patient was selected for the study.**	**Duration of PU (mean months (SD); range):** 3.0 (3.2); 1-15 **Inclusion criteria:** Aged 60 years and older; hospitalized for at least eight weeks; PU grade III or IV; surface area between 5 and 100 cm²; PU at sacrum, ischium, trochanters or heels **Exclusion criteria:** more than half the total ulcer area was comprised with granulation tissue; PU covered with necrotic plaque; PU with an active infection; severe renal failure requiring dialysis; heel PU combined with end-stage arteriopathy; treated with radiotherapy or cytotoxic drugs				

Table 98 – SCEVOLA 2010

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Scevola (2010)** Title: **Allogenic platelet gel in the treatment of pressure**	**Patient group:** Patients with a spinal cord injury and a grade III or IV PU (according to the NPUAP classification).	**Group 1:** Allogenic platelet gel. The gel was applied to the clean wound bed using a sterile syringe. The ulcer was then covered with a	**Outcome 1:** Proportion of ulcers completely healed by 10 weeks.	**Group 1:** 0/8 **Group 2:** 0/8	**Funding:** / **Limitations:** no report on sequence

sores: A pilot study. Journal: **International Wound Journal, 7; 184-190.** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **drop-outs were excluded.** Statistical analysis: **The absolute and percentage differences between volumes at each time between day 0 and week 10 were both considered. The trend of volume changes was tested with descriptive statistics, the t-test, the Mann-Whitney test and the variance analysis.** **Efficacy evaluation at 10 weeks. Safety evaluation at 14 weeks.** Baseline differences: **No baseline**	**All patients** **Randomised N:** 13 patients and 16 ulcers **Completed N at 10 weeks:** 13 patients and 16 ulcers **Completed N at 14 weeks:** 11 ulcers **Drop-outs:** 5 ulcers **Gender (m/f):** 10/3 **Ulcer location:** Sacrum: n=10 Ischium: n=6 **Group 1** **Randomised N:** 8 ulcers **Completed N at 10 weeks:** 8 ulcers **Completed N at 14 weeks:** 4 ulcers **Dropouts:** 4 ulcers **Group 2** **Randomised N:** 8 ulcers **Completed N at 10 weeks:** 8 ulcers **Completed N at 14 weeks:** 7 ulcers **Dropouts:** 1 ulcers **Inclusion criteria:** Grade III or IV PU; no signs of necrosis or infection; stable after at least 2 months **Exclusion criteria:** Metabolic, endocrine,	polyurethane sponge/semi-permeable film dressing system (Biatain Coloplast®). Platelet gel: the gel was prepared in a Petri dish blending 4-8ml of concentrated platelet preparation, including at least $2x10^{10}$ platelets, with 2-4ml of plasma activated with Calcium Chloride. The gel was then frozen to -80°C. The preparation was run in an absolute sterile modality. The ulcers were treated twice a week for 8 weeks. **Group 2:** Standard treatment. Ulcers were cleansed with saline at room temperature. The ulcers were covered a 10% iodoform impregnated gauze or sodium/alginate foams or cadexomer iodine powder and/or vacuum assisted closure therapy. **All groups:** All patients used pressure-relieving devices and followed their two hourly postural change.	**Outcome 2:** Proportion of ulcers improved by 10 weeks. **Outcome 2:** Mean percentage reduction in ulcer volume by 10 weeks.	**Group 1:** 8/8 **Group 2:** 7/8 **Group 1:** 55.0 (22.9) **Group 2:** 17.2 (98.1)	allocation; no report on allocation concealment; no report on blinding; no a priori sample size calculation; small sample size **Additional outcomes:** / **Notes:** /

characteristics were reported. Study power/sample size: **No a priori sample size calculation.** Setting: **Plastic and reconstructive surgery unit of the 'Salvatore Maugeri' foundation hospital of Pavia, Italy.** Length of study: **eight weeks of treatment and up to 14 weeks of follow-up** Assessment of PUs: **PU were classified according to the NPUAP classification (2007).** **Ulcers volume was calculated in millilitre by filling the cavity up to the skin surface plane with a liquid transparent gel using a graduated syringe. Granulation tissue and bleeding were assessed. Ulcer dimensions were taken every two weeks and photos were collected.** Multiple ulcers: **12 patients with 16 ulcers were included**	and collagen pathologies; ischemic cardiopathy; corticosteroid or immunosuppressive therapy; obesity; malignancies; organ failure				

in the study

Table 99 – SEAMAN 2000

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Seaman (2000)** Title: **Simplifying modern wound management for nonprofessional caregivers.** Journal: **Ostomy/wound management, 46; 18-27.** Study type: **randomized controlled trial** Sequence generation: **randomized schedule was generated by the Department of Data Management and Biostatistics at ConvaTec.** Allocation concealment: **sequentially numbered envelopes** Blinding: **not reported.** Addressing incomplete outcome data:	**Patient group:** Patients with a stage II, III or IV PU (according to the AHCPR classification). **All patients** **Randomised N:** 35 **Completed N:** 13 **Drop-outs:** 22 **Group 1** **Randomised N:** 17 **Completed:** not reported **Dropouts:** not reported **Age (mean years):** 78 **Gender (m/f):** 5/12 **Diabetes:** 2 **Incontinence:** Urine: 0 Faecal: 6 Both: 4 **Ulcer area (mean cm² (SD)):** 4.2 (6.1) **Group 2** **Randomised N:** 18 **Completed N:** not reported	**Group 1:** Hydrocolloid dressing (SignaDress®, ConvaTec, Bristol-Myers Squibb Company, Princeton, NJ). **Group 2:** Hydrocolloid dressing (Comfeel Plus®, Coloplast Corporation, Marietta, Ga). **All groups:** Wound filler if ulcers were deep enough: moderate to heavily exuding ulcers: Aquacal® Hydrofiber™ (ConvaTec, Bristol-Myers Squibb Company, Princeton, NJ); minimal exudate: DuoDerm® Hyrdocative®; Bristol-Myers Squibb Company, Princeton, NJ) 94% of the patients received regular repositioning and 74% received pressure relief	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Percentage reduction in ulcer area **Outcome 3:** Percentage reduction in ulcer area per week **Outcome 4:** Proportion of patients dressing related adverse events	**Group 1:** 6/17 **Group 2:** 1/18 **P-value:** 0.04 **Group 1:** 60 **Group 2:** 22 **P-value:** 0.01 **Group 1:** 33.8 **Group 2:** 7.0 **Group 1:** 0/17 **Group 2:** 0/18	**Funding:** funding provided by ConvaTec, Bristol-Myers Squibb Company **Limitations:** allocation concealment by sequentially numbered envelopes; no report on blinding; no a priori sample size calculation; high drop-out; little information on ulcer assessment; little information on interventions; no report on multiple ulcers **Additional outcomes:** dressing performance (wear time, ease of application)

intention to treat analysis for all subjects wearing at least one dressing. Statistical analysis: **Dressing wear time and change in ulcer surface area were analyzed using analysis of variance (anova) for the effect of treatment, center, and treatment-by-center interaction. All data were analyzed using the SAS system, with a probability of a type I error selected as 0.05** Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **Home care and long-term care.** Length of study: **five dressing changes or unless healing occurred first** Assessment of PUs: **PU were classified according to the AHCPR classification.**	**Dropouts:** not reported **Age (mean years):** 66 **Gender (m/f):** 9/9 **Diabetes:** 7 **Incontinence:** Urine: 2 Faecal: 7 Both: 3 **Ulcer area (mean cm² (SD)):** 4.9 (4.1) **Inclusion criteria:** Stage II, III or IV PU; legal consenting age; informed consent **Exclusion criteria:** PU > 2½“ x 2½“ at maximum length and width; radiation treatment to the area; known hypersensitivity to one of the dressings; involved in other concomitant research		**Notes:** /

Ulcers tracing and photographs. Multiple ulcers: **not reported**					

Table 100 – SEBERN 1986

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Sebern (1986)** Title: **Pressure ulcer management in home health care: Efficacy and cost effectiveness of moisture vapor permeable dressing.** Journal: **Archives of Physical Medicine and Rehabilitation, 67; 726-729.** Study type: **randomized controlled trial** Sequence generation: **a sequential list of 100 random numbers (50 G1 and 50 G2) was used.** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **drop-**	**Patient group:** Home care patients with grade II or III PUs (according to the Shea classification). **All patients** **Randomised N:** 100 ulcers **Completed N:** 48 patients and 77 ulcers **Drop-outs:** 23 ulcers (death, hospitalization, non-adherence to study protocol) **Group 1** **Randomised N:** 50 ulcers **Completed:** 37 ulcers **Dropouts:** 13 ulcers (death, hospitalization, non-adherence to study protocol) **Age (mean years (SD)):** 76.3 (17.3) **Ulcers grade:** Grade II: 22 Grade III: 15	**Group 1:** Moisture vapour permeable dressing (Tegarderm™, 3M Medical division, St Paul). The dressing was changed daily to three times a week, depending on adherence of the dressing. Tegarderm™: polyurethane adhesive dressing, coated with an acrylate adhesive, but permeable to moisture vapour and oxygen. Some were pouch dressings: the dressing is perforated to allow fluid to pass through it into a film pouch. Once in the pouch, fluid may readily evaporate trough the film. **Group 2:** Wet to dry gauze dressing. Physiologic saline was used on the contact layer of gauze, which was covered with dry gauze and an ABD pad. Two-inch paper tape secured the dressing. The dressing was changed every 24 hours. All ulcers were	**Outcome 1:** Proportion of ulcers completely healed (grade II) **Outcome 2:** Proportion of ulcers with no change (grade II) **Outcome 3:** Proportion of ulcers worsened (grade II) **Outcome 4:** Decrease in ulcer grade in grade II PUs **Outcome 5:** Increase in ulcer grade in grade II PUs **Outcome 6:** Median percentage	**Group 1:** 14/22 **Group 2:** 0/12 **P-value:** <0.01 **Group 1:** 1/22 **Group 2:** 1/12 **P-value:** <0.01 **Group 1:** 3/22 **Group 2:** 7/12 **P-value:** <0.01 **Group 1:** 16/22 **Group 2:** 0/12 **P-value:** <0.01 **Group 1:** 1/22 **Group 2:** 5/12 **P-value:** <0.01 **Group 1:** 100 **Group 2:** 52 **P-value:** <0.01	**Funding:** Partly by a grant award from Sigma Theta Tau, Delta Gamma Chapter, and Marquette University College of Nursing. Financial support was awarded by 3M Medical division, St Paul **Limitations:** little information on sequence generation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priori sample size calculation. **Additional outcomes:** cost

outs excluded. Statistical analysis: **Indirect (reported next to the tables and figures): Student t-test was used to compare baseline difference between groups. Chi-square test was used to analyze difference between groups for healing status in grade II PUs and the final grade of grade II PUs. The Wilcoxon rank sum test was used to measure the difference between groups for median % decrease in ulcer area and total cost.** Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **Home care.** Length of study: **five dressing changes or unless healing occurred first** Assessment of PUs: **PU were classified according to the**	**Group 2** **Randomised N:** 50 ulcers **Completed:** 40 ulcers **Dropouts:** 10 ulcers (death, hospitalization, non-adherence to study protocol) **Age (mean years (SD)):** 72.4 (17.0) **Ulcers grade:** Grade II: 22 Grade III: 15 **Inclusion criteria:** Grade II or III PU **Exclusion criteria:** Eschar; terminal patient; white count below 4000; more than 3 PUs	irrigated at each dressing with half strength hydrogen peroxide and were rinsed with physiologic saline. If the ulcers was contaminated with urine and stool, povidine iodine was applied for two minutes and then rinsed away with physiologic saline. **All groups:** The protocol included a turning schedule and wheelchair pushups.	reduction in ulcer area (grade II) **Outcome 7:** Median percentage reduction in ulcer area (grade III) **Outcome 2:** Proportion of ulcers with skin maceration	**Group 1:** 67 **Group 2:** 44 **P-value:** > 0.05 **Group 1:** 17/22 **Group 2:** 10/12 **P-value:** >0.05	**Notes:** /

Shea classification (1975). **Ulcers length and width were measured with a clear plastic measuring card and the area was calculated by assuming an elliptical shape.** Multiple ulcers: **48 patients and 77 ulcers were analysed**					

Table 101 – SEELEY 1999

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Seeley (1999)** Title: **A randomized clinical study comparing a hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers.** Journal: **Ostomy/wound management, 45 (6); 39-47.** Study type: **randomized controlled trial**	**Patient group:** Patients with stage II or III PU (according to the AHCPR classification). **All patients** **Randomised N:** 40 **Completed N:** 26 **Drop-outs:** 14 (1 request of patient, 3 lost to follow-up, 8 adverse event, 2 died) **Group 1** **Randomised N:** 20 **Completed:** 12 **Dropouts:** 8 (1 request of patient, 3 lost to follow-up, 3 adverse	**Group 1:** Adhesive hydrocellular dressing (Allevyn® Adhesive, Smith & Nephew Medical, Hull, England). Ulcers were cleansed with dermal wound cleanser (CarraKlenz) prior to each dressing application. Dressings change was determined by judgement of the clinical investigator. **Group 2:** Hydrocolloid dressing (DuodermCGF®, ConvaTec, Princeton, NJ). Ulcers were cleansed with dermal wound cleanser (CarraKlenz) prior to each dressing application. Dressings change was	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Mean percentage reduction in ulcer area **Outcome 3:** Mean wound pain (0: none – 3: severe) **Outcome 4:** Mean wound odour (0: none – 3: severe)	**Group 1:** 8/20 **Group 2:** 8/20 **Group 1:** 50 **Group 2:** 52 **P-value:** 0.31 **Group 1:** 0.15 (0.8) **Group 2:** 0.47 (0.9) **Group 1:** 0.16 (0.5) **Group 2:** 0.47 (0.8)	**Funding:** / **Limitations:** inadequate allocation concealment; no report on blinding; no a priori sample size calculation; no report on preventive measures. **Additional outcomes:** dressing application (ease of application and removal; wear

Sequence generation: **computer generated randomized list.** Allocation concealment: **stratified according to initial ulcer size** Blinding: **not reported.** Addressing incomplete outcome data: **intention to treat analysis, one patient was excluded because of death shortly after enrolment.** Statistical analysis: **The Fischer's exact test was used to test the difference between number of patients whose ulcers improved and did not improve in appearance and developed inflammation and maceration and did not. A mean odour and pain was calculated and difference between groups were tested by the Mann Whitney U test. The Mann Whitney U test was used to measure the difference between**	event, 1 died) **Age (mean years (SD)):** 75.7 (18.6) **Gender (m/f):** 9/11 **Duration of ulcer (mean weeks (SD); median):** 11.8 (7.4); 9 **Ulcers stage:** Stage II: 3 Stage III: 17 **Ulcer location:** Sacrum or coccyx: 4 Heel: 7 Foot or ankle: 3 Trochanter: 1 Ischium: 1 Thigh: 2 Buttocks: 1 Other: 1 **Ulcer area (mean cm² (SD)):** 6.84 (8.19) **Group 2** **Randomised N:** 20 (one excluded from baseline characteristics and analysis) **Completed:** 14 **Dropouts:** 6 (5 adverse event, 1 died) **Age (mean years (SD)):** 76.7 (19.5) **Gender (m/f):** 9/10 **Duration of ulcer (mean weeks (SD); median):** 23.1 (38.9); 10 **Ulcers stage:** Stage II: 2	determined by judgement of the clinical investigator. **All groups:** /	**Outcome 5:** Proportion of patients with inflammation or maceration **Outcome 6:** Proportion of patients with adverse events (unknown if dressing related)	**Group 1:** 12/20 **Group 2:** 6/19 **Group 1:** 3/20 **Group 2:** 5/20	time; number of dressing changes **Notes:** /

groups for the percentage change in ulcer area over the duration of the study. All test were two-sided and the significance level 5% was considered significant. SAS system was used to analyse the data. Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **Home care and several long-term care facilities.** Length of study: **eight weeks of treatment** Assessment of PUs: **PU were classified according to the AHCPR classification (1992). Ulcers were traced, and photographed. Ulcer area was calculated from tracing using digital image analysis.** Multiple ulcers: **only the largest ulcer was selected for the study**	Stage III: 17 **Ulcer location:** Sacrum or coccyx: 5 Heel: 3 Foot or ankle: 4 Trochanter: 1 Ischium: 1 Thigh: 1 Buttocks: 2 Other: 2 **Ulcer area (mean cm² (SD)):** 4.61 (5.56) **Inclusion criteria:** Older than 18 years; stage II or III PU **Exclusion criteria:** Ulcer smaller than 1cm² or larger than 50 cm²; clinical infection of ulcer; uncontrolled diabetes; known history of poor compliance with medical treatment	

Table 102 – SIPPONEN 2008

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Sipponen (2008)** Title: **Beneficial effect of resin salve in treatment of severe pressure ulcers: A prospective, randomized and controlled multicentre trial.** Journal: **British Journal of Dermatology, 158 (5); 1055-1062.** Study type: **randomized controlled trial** Sequence generation: **permuted block sizes of four according to a random list designed by a specialist in biometrics.** Allocation concealment: **closed envelopes** Blinding: **no blinding** Addressing incomplete outcome data: **drop-**	**Patient group:** Hospitalized patients with a grade II to IV PU (according to the EPUAP). **All patients** **Randomised N:** 37 patients and 45 ulcers **Completed N:** 22 patients and 29 ulcers **Drop-outs:** 15 patients and 16 ulcers (7 deaths, 2 operated, 1 allergic skin reaction, 1 misdiagnosed, 4 patients-based refusal) **Group 1** **Randomised N:** 21 patients and 27 ulcers **Completed N:** 13 patients and 18 ulcers **Dropouts:** 8 patients and 9 ulcers (3 deaths, 2 operated, 1 allergic skin reaction, 1 misdiagnosed, 1 patients-based refusal) **Age (mean years (SD);**	**Group 1:** Resin salve (from the Norway spruce (Picea abies). An even layer of resin +/- 1 mm thick was spread between loose sterile cotton gauze. The gauze was placed on both infected and noninfected areas of the pressure ulcer to cover the ulcer area with resin fully. The resin–gauze dressing was changed daily if the ulcer was infected or produced a discharge; if this were not the case, the dressing was changed every third day. **Group 2:** sodium carboxymethylcellulose hydrocolloid polymer without or with ionic silver (Aquacel® or Aquacel Ag®; ConvaTec Ltd, London, U.K.). The Aquacel–hydrocolloid dressing was changed daily if the ulcer produced excessive discharge, but if there was no secretion the dressing was changed every third day, as for the resin–gauze.	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Proportion of ulcers completely healed **Outcome 3:** Proportion of ulcers improved **Outcome 4:** Proportion of ulcers worsened **Outcome 5:** Mean percentage reduction in ulcer width **Outcome 6:** Mean percentage reduction in ulcer depth **Outcome 7:** speed of healing	**Group 1:** 12/13 **Group 2:** 4/9 **P-value:** 0.003 **Group 1:** 17/18 **Group 2:** 4/11 **P-value:** 0.003 **Group 1:** 18/18 **Group 2:** 10/11 **Group 1:** 0/18 **Group 2:** 1/11 **P-value:** 0.003 **Group 1:** 93.75 **Group 2:** 57.14 **Group 1:** 88.46 **Group 2:** -1.89	**Funding:** grant to A.s. in support of this investigation and the Lappish Resin project **Limitations:** no blinding; no ITT analysis; final sample size lower than calculated **Additional outcomes:** bacterial cultures **Notes:** /

outs were excluded Statistical analysis: **Differences between parallel groups were compared with the $\chi 2$ test or Fisher's exact test, as appropriate.** **Mean and SD were computed for continuous variables and proportions were compared after distribution analysis with the nonparametric Mann–Whitney U-test or Student's t-test, as appropriate. The healing of the ulcers over time was assessed by Kaplan–Meier analysis and the log-rank test was used to estimate the differences in the final outcome and healing time between the parallel groups. P < 0.05 was considered statistically significant. SPSS 14.0 was used for the statistical calculations (SPSS, Chicago, IL,**	**range):** 80 (10); 58-98 **Gender (m/f):** 6/7 **BMI (mean kg/m² (SD); range):** 21.8 (7.1); 15.9-35.5 **Diabetes:** 6 **Ulcer width (mean cm (SD)):** 3.2 (2.4) **Ulcer depth (mean mm (SD)):** 5.2 (10.3) **Ulcer location:** Calcaneus: 8 Trochanter: 3 Sacrum: 1 Ischium: 1 Other: 5 **Ulcer grade:** Grade II: 7 Grade III: 9 Grade IV: 2 **Group 2** **Randomised N:** 16 patients and 18 ulcers **Completed N:** 9 patients and 11 ulcers **Dropouts:** 7 patients and 7 ulcers (4 deaths, 3 patients-based refusal) **Age (mean years (SD); range):** 74 (8); 60-88 **Gender (m/f):** 3/6	**Both groups:** 3 patients received a pressure ulcer mattress.	(days) (log-rank-test) **Outcome 8:** Proportion of patients allergic skin reaction	**P-value:** 0.013 (favour G1) **Group 1:** 1/21 **Group 2:** 0/16

U.S.A.). Baseline differences: **No statistical difference between groups.** Study power/sample size: **A two group** **χ2 test with a 0.05 two-sided significance level will have 80% power to detect the difference between a group 1 proportion of 0.900 and a group 2 proportion of** **0.500 (odds ratio 0.111) when the sample size in each group is 20.** Setting: **11 primary care hospitals in Finland** Length of study: **six months** Assessment of PUs: **PU were classified according to the EPUAP classification.** **Ulcer localization, ulcer grade, color, width and depth were measured at the beginning of the study and thereafter**	**BMI (mean kg/m² (SD); range):** 21.9 (6.6); 16.9-34.7 **Diabetes:** 1 **Ulcer width (mean cm (SD)):** 4.2 (2.8) **Ulcer depth (mean mm (SD)):** 5.3 (6.5) **Ulcer location:** Calcaneus: 2 Trochanter: 1 Sacrum: 2 Ischium: 5 Other: 1 **Ulcer grade:** Grade II: 5 Grade III: 5 Grade IV: 1 **Inclusion criteria:** One or several severe PU (grade II to IV); with or without an infection **Exclusion criteria:** Life expectancy < 6 months; advanced malignant disease	

monthly for 6 months. All ulcers were photographed and planimetry analysis was performed. Multiple ulcers: **37 patients and 45 ulcers**					

Table 103 – SMALL 2002

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Small (2002)** Title: **A comparative analysis of pressure sore treatment modalities in community settings.** Journal: **Curationis, 25; 74-82.** Study type: **randomized controlled trial** Sequence generation: **computer generated randomized list provided by the Department Biostatistics, University of the Free State**	**Patient group:** Patients with stage II, III or IV PU (according to the Stirling classification). **All patients** **Randomised N:** 58 **Completed N:** 41 **Drop-outs:** 17 (10 died, 4 moved, 2 developed an ulcer infection, and 1 was hospitalized) **Group 1** **Randomised N:** 28 **Completed:** 23 **Dropouts:** 5 (3 died, 1 moved, 1 developed an ulcer infection) **Age (median years; range):** 76.5; 19-89 **Gender (m/f):** 7/21	**Group 1:** Hydrogel (IntraSite™ gel, Smith & Nephew), Foam dressing (Allevyn™ hydrocellular or Allevyn™adhesive), or Transparant film dressing (OpSite Flexigrid™). Ulcers were cleansed with a gentle, hypoallergenic soap and water and dried with gauze. Ulcers were than aseptically cleansed with warm sterile, physiological saline. Ulcers were irrigated or ulcer bed was gently patted. Non-viable tissue: a thin layer of IntraSite™ gel was applied and covered with Allevyn™ non adhesive hydrocellular sheet or Allevyn ™ adhesive. Granulating tissue: Allevyn™ non adhesive hydrocellular	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Percentage healed per week (log-rank test) **Outcome 3:** Proportion of patients dressing related adverse events **Outcome 4:** Proportion of patients reporting the application of dressing as comfortable	**Group 1:** 15/23 **Group 2:** 9/18 **Group 1:** / **Group 2:** / **P-value:** 0.15 **Group 1:** 0/28 **Group 2:** 0/30 **Group 1:** 14/14 **Group 2:** 6/7	**Funding:** / **Limitations:** inadequate allocation concealment; no report on blinding; no ITT analysis; inadequate a priori sample size determination; no report on preventive measures. **Additional outcomes:** dressing application (ease of application and removal) Cost

Allocation concealment: **randomization by pressure sore stage** Blinding: **not reported.** Addressing incomplete outcome data: **drop-outs were excluded.** Statistical analysis: **Demographic and baseline information was summarized by groups. Numeric variables were summarized by medians and percentiles as distribution were skew. Categorical variables were summarized by frequencies and percentages. Changes between baseline and consecutive treatment information were summarized per group by medians and percentiles or percentages, as appropriate for the difference between the groups, with a 95% confidence intervals. The log-rank-survival test was used to calculate**	**BMI (median kg/m²; range):** 22; 17-27 **Ulcer location:** Sacrum: 11 Trochanter: 6 Malleolus: 3 Iliac: 2 Ischium: 2 Heel: 2 Wrist: 1 Foot: 1 Elbow: 0 Scapula: 0 **Group 2** **Randomised N:** 30 **Completed:** 18 **Dropouts:** 12 (7 died, 3 moved, 1 developed an ulcer infection, 1 was hospitalized) **Age (median years; range):** 78; 24-97 **Gender (m/f):** 16/14 **BMI (median kg/m²; range):** 21; 13-28 **Ulcer location:** Sacrum: 15 Trochanter: 6 Malleolus: 0 Iliac: 2 Ischium: 1 Heel: 3 Wrist: 0 Foot: 0 Elbow: 2 Scapula: 1	sheet or Allevyn ™ adhesive as applied. Epithelializing tissue: Transparant OpSite Flexigrid™ dressing **Group 2:** Standard treatment: Cotton wool, alginates, hydrocolloid, gauze impregnated or gauze. Ulcers were cleansed with a gentle, hypoallergenic soap and water and dried with gauze. The wound was then aseptically cleansed (different cleansers) and covered with a dressing. **All groups:** /	**Outcome 3:** Proportion of patients reporting discomfort at dressing removal	**Group 1:** 0/14 **Group 2:** 1/7	**Notes:** /

the percentage of patients that healed buy the end of each week. Baseline differences: **No statistical difference between groups.** Study power/sample size: **In collaboration with a biostatistician was decided that a sample size of at least 40 patients was a statically adequate number.** Setting: **Primary health care clinics, community health care.** Length of study: **six weeks of treatment or until complete healing, withdrawal of the patient, or occurrence of adverse events** Assessment of PUs: **PU were classified according to the Stirling classification (1996).** **Rate of healing was assessed by standardized digital wound photographs, tracing of wound edges, and**	**Inclusion criteria:** Aged 18 years and older; clinically uninfected PU; stage II, III or IV PU; informed consent; willing and able to comply with treatment **Exclusion criteria:** /	

measurements of the ulcer and its appearance. Multiple ulcers: **one sore was chosen at random for inclusion in the study**					

Table 104 – SOPATA 2002

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Sopata (2002)** Title: **Effect of bacteriological status on pressure ulcer healing in patients with advanced cancer.** Journal: **Journal of Wound Care, 11 (3); 107-110** Study type: **randomized controlled trial** Sequence generation: **computer numbering system** Allocation concealment: **not reported** Blinding: **not reported** Addressing incomplete outcome data: **drop out not excluded.**	**Patient group:** Palliative care patients with a grade II or III PU (according to the Torrance classification) **All patients** **Randomised N:** 34 patients and 38 ulcers **Completed N:** 29 patients **Drop-outs:** 5 patients (died) **Group 1** **Randomised N:** 17 patients and 18 ulcers **Completed N:** 15 patients and 16 ulcers **Dropouts:** 2 patients (died) **Age (mean years (SD)):** 58.5 (16.92) **Gender (m/f):** 7/10 **Ulcer grade:**	**Group 1:** Polyurethane foam dressing (Lyofoam®, Seton, UK). Dressings were changed according to clinical need. **Group 2:** Hydrogel dressing (Aquacel®, Wytw. Opatrunkow, Poland). Dressings were changed according to clinical need. **Both groups:** /	**Outcome 1:** Proportion of ulcers completely healed **Outcome 2:** Proportion of ulcers completely healed (grade II) **Outcome 3:** Proportion of ulcers completely healed (grade III) **Outcome 4:** Proportion of ulcers improved **Outcome 5:** Proportion of ulcers improved (grade III) **Outcome 6:**	**Group 1:** 15/18 **Group 2:** 15/20 **Group 1:** 6/6 **Group 2:** 6/6 **Group 1:** 9/12 **Group 2:** 9/14 **Group 1:** 18/18 **Group 2:** 19/20 **Group 1:** 12/12 **Group 2:** 13/14 **Group 1:** 1.23 (1.33)	**Funding:** / **Limitations:** no report on allocation concealment; no report on blinding; little information on ulcer assessment and statistical analysis; little information on interventions; no information on preventive measures. **Additional outcomes:** bacterial assessment **Notes:** /

Statistical analysis: **The Mann-Whitney U test, chi-square test and Fischer's exact test were used. All means were compared at the significance level (p=0.05.** Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **Palliative care department at the University of Medical Sciences, Poznan, Poland.** Length of study: **eight weeks of treatment or until complete healing** Assessment of PUs: **PUs were classified according to the Torrance classification (1983). Ulcers were traced with a pen on acetate and photographed from a fixed distance. Rate of healing was calculated using computer planimetry.**	Grade II: 6 Grade III: 12 **Ulcer location:** Buttocks: 6 Coccyx: 8 Sacrum: 2 Other: 2 **Ulcer area (mean cm² (SD)):** 11.04 (11.65) **Duration of PU (mean weeks (SD)):** 2.46 (0.24) **Group 2** **Randomised N:** 17 patients and 20 ulcers **Completed N:** 14 patients and 16 ulcers **Dropouts:** 3 patients (died) **Age (mean years (SD)):** 58.7 (14.11) **Gender (m/f):** 9/8 **Ulcer grade:** Grade II: 6 Grade III: 14 **Ulcer location:** Buttocks: 6 Coccyx: 3 Sacrum: 4 Other: 7 **Ulcer area (mean cm² (SD)):** 8.28 (13.90) **Duration of PU (mean weeks (SD)):** 2.45 (1.60) **Inclusion criteria:** Advanced cancer; life expectancy > 8 weeks	Mean healing rate for healed ulcers grade II (cm²/day)	**Group 2:** 0.67 (0.37)
		Outcome 7: Mean healing rate for healed ulcers grade III (cm²/day)	**Group 1:** 0.44 (0.27) **Group 2:** 0.31 (0.21)
		Outcome 8: Mean healing rate for improved ulcers grade III (cm²/day)	**Group 1:** 0.70 (0.63) **Group 2:** 0.27 (0.11)
		Outcome 9: Mean healing rate of ulcer not improved grade III (cm²/day)	**Group 2:** -0.68

Multiple ulcers: **34 patients with 38 ulcers**	**Exclusion criteria:** poor general condition; very low level of haemoglobin (<7mmol/l) and albumin (<2.5g/dl); use of drugs such as corticosteroids that could affect wound healing				

Table 105 – THOMAS 1997

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Thomas (1997)** Title: **A comparison of two dressings in the management of chronic wounds.** Journal: **Journal of Wound Care, 6 (8); 383-386.** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **sealed envelopes** Blinding: **not reported.** Addressing incomplete outcome data: **missing data excluded.** Statistical analysis:	**Patient group:** Patients with grade II or III PU (according to the Stirling classification). Also patients with leg ulcers were included (separate analysis) **All patients** **Randomised N:** 99 **Completed N:** 96 **Drop-outs:** 3 (missing data) **Group 1** **Randomised N:** 50 **Completed:** 48 **Dropouts:** 2 (missing data) **Age (mean years; (SD)):** 80.1 (10.2) **Gender (m/f):** 45/35 **Duration of PU:** (1 missing data)	**Group 1:** Hydropolymer dressing (Tielle®). Ulcers were cleansed using a sterile solution of sodium chloride 0.9%. After the dressing was applied. Dressing were changed only at leakage or when exudate was seen to be approaching the edge of the dressing. Tielle®: consists of a polyurethane adhesive and an absorbent island of a hydrophilic polyurethane foam. A non-woven fabric layer located between these two components facilitates the lateral dispersion of exudate and thus maximises the utilisation of the central island. **Group 2:** Hyrdocolloid dressing (Granuflex®). Ulcers were cleansed using a sterile	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Proportion of patients improved **Outcome 3:** Proportion of patients not changed **Outcome 4:** Proportion of patients worsened **Outcome 5:** Mean percentage reduction in ulcer size **Outcome 6:**	**Group 1:** 10/48 **Group 2:** 16/48 **Group 1:** 39/48 **Group 2:** 39/48 **Group 1:** 4/48 **Group 2:** 2/48 **Group 1:** 5/48 **Group 2:** 7/48 **Group 1:** not reported; figure unclear **Group 2:** not reported; figure	**Funding:** / **Limitations:** no report on sequence generation; no report on blinding; no ITT analysis; no a priori sample size calculation; no report on multiple ulcers. **Additional outcomes:** dressing application (ease of application and removal; dressing changes) **Notes:** Patient characteristics are for PU patients

For continuous measurements the two sample t-test was employed, unless validity was in doubt, in which case than Mann-Whitney sum of ranks test was used. Categorical data were analysed using a conventional chi-squared test or, where appropriate, the Fischer Exact test. Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **Two centers in the community.** Length of study: **six weeks of treatment.** Assessment of PUs: **PU were classified according to the Stirling classification. Ulcers were photographed and planimetry was used to determine the ulcer area from tracing.** Multiple ulcers: **not**	< 1 month: 8 1-3 month: 21 > 3 months: 20 **Ulcer grade:** Grade II: 27 Grade III: 23 **Ulcer location:** Heel: 23 Buttock: 6 Sacrum: 10 Hip: 2 Other: 9 **Group 2** **Randomised N:** 49 **Completed:** 48 **Dropouts:** 1 (missing data) **Age (mean years; (SD)):** 78.6 (14.3) **Gender (m/f):** 16/33 **Duration of PU:** (1 missing data) < 1 month: 9 1-4 month: 18 > 3 months: 21 **Ulcer grade:** Grade II: 30 Grade III: 19 **Ulcer location:** Heel: 25 Buttock: 2 Sacrum: 6 Hip: 4 Other: 12 **Inclusion criteria:**	solution of sodium chloride 0.9%. After the dressing was applied. Dressing were changed only at leakage or when exudate was seen to be approaching the edge of the dressing. Granuflex®: consists of a thin polyurethane foams sheet bearing an adhesive polymer matrix containing the gel forming agents gelatine, pectin, and sodium carboxymethylcellulose. **All groups:** Pressure relieving devices were used.	Proportion of patients with maceration **Outcome 7:** Proportion of patients with bleeding **Outcome 8:** Proportion of patients with excess granulation tissue	unclear **Group 1:** 0/50 **Group 2:** 4/49 **Group 1:** 0/50 **Group 2:** 2/49 **Group 1:** 0/50 **Group 2:** 0/49	only as all information was reported separately for PU and leg ulcer patients.

reported	Grade II or III PU; ulcer less than 10cm deep and maximum 8cm diameter (allow use of a single dressing) **Exclusion criteria:** under 16 years; history of poor compliance to medical treatment; insulin dependent diabetes; unlikely to survive the study period; previously demonstrated; clinically infected ulcer.				

Table 106 – THOMAS 1998

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Thomas (1998)** Title: **Acemannan hydrogel dressing versus saline dressing for pressure ulcers. A randomized, controlled trial.** Journal: **Advances in Wound Care, 11 (6); 273-276.** Study type: **randomized controlled trial** Sequence generation:	**Patient group:** Patients older than 18 years with stage II, III or IV PU. **All patients** **Randomised N:** 41 **Completed N:** 30 **Drop-outs:** 11 (6 died, 2 worsened, 2 hospitalized, 1 violated protocol) **Age (mean years (SD); range):** 77 (12); 35-97 **Gender (m/f):** 19/22 **Ulcer stage:** Stage II: 15 Stage III: 20	**Group 1:** Amorphous hydrogel dressing (Carrasyn® gel, Carrington Laboratories, Inc., Irving, TX). Ulcers were cleansed with saline and gently mechanical wiped with gauze. Ulcers were treated with a 1/8 inch layer of hydrogel and covered with a dry sterile nonwoven gauze, held in place with a thick gauze dressing. Dressings were changed daily. Carrasyn®: the active ingredient is thought to be acemannan, a complex carbohydrate derived from	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Percentage healing rate **Outcome 3:** Mean time to healing (weeks) **Outcome 4:** Proportion of patients worsened	**Group 1:** 10/16 **Group 2:** 9/14 **Odds ratio:** 0.93 (95% CI: 0.16-5.2) **P-value:** 0.92 **Group 1:** 63 **Group 2:** 64 **Group 1:** 5.3 (2.3) **Group 2:** 5.2 (2.4) **P-value:** 0.87 **Group 1:** 1/22 **Group 2:** 1/19	**Funding:** grant from Carrington Labaratories, Inc. Irving, Tx. **Limitations:** no report on sequence generation; no report on allocation concealment; no report on blinding; no ITT analysis; no a priori sample size calculation; no report on

not reported Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **drop-outs were excluded.** Statistical analysis: **Comparison of dichotomous variables was performed by chi-square test. Fischer's exact test was used when a cell value was less than 5. Distributions of continuous variables were compared by the Kruskal-Wallis test for groups. Data were analysed using EPI6..** Baseline differences: **No statistical difference between groups for the characteristics of the patients after exclusion of drop-outs** Study power/sample size: **The study had a power of 80% to detect 25% difference at alpha significance 0.05. Unclear if a**	Stage IV: 6 **Group 1** **Randomised N:** 22 **Completed:** 16 **Dropouts:** 6 (4 died, 1 worsened, 1 hospitalized) **Characteristics are form completed N** **Age (mean years (SD)):** 79 (9) **Gender (m/f):** 7/9 **Ulcer stage:** Stage II: 8 Stage III: 6 Stage IV: 2 **Ulcer area (mean cm² (SD)):** 8.9 (9.3) **Incontinence:** Urine: 9 Faecal: 12 **Group 2** **Randomised N:** 19 **Completed N:** 14 **Drop-outs:** 5 (2 died, 1 worsened, 1 hospitalized, 1 violated protocol) **Characteristics are form completed N** **Age (mean years (SD)):** 72 (13) **Gender (m/f):** 9/5 **Ulcer stage:** Stage II: 6	the aloe vera plant. **Group 2:** Moist saline gauze dressing. Ulcers were cleansed with saline and gently mechanical wiped with gauze. Ulcers were covered with a sterile nonwoven saline soaked gauze and a dry sterile nonwoven gauze, held in place with a thick gauze dressing. Dressings were changed daily. **All groups:** Pressure relieving devices were used in 26.7% of the patients		classification of PU **Additional outcomes:** healing rate and subject characteristics (odds ratio's) **Notes:** /

priori calculation. Setting: **skilled nursing facilities and home health care agencies.** Length of study: **10 weeks of treatment or until complete healing, whichever came first.** Assessment of PUs: **PU classification not reported.** **Ulcers were photographed and tracing were made.** Multiple ulcers: **only one ulcer par subject was evaluated**	Stage III: 7 Stage IV: 1 **Ulcer area (mean cm² (SD)):** 5.9 (6.0) **Incontinence:** Urine: 7 Faecal: 12 **Inclusion criteria:** Age 18 years and older; stage II, III or IV PU; ulcer area ≥ 1.0cm² **Exclusion criteria:** venous or arterial insufficiency or other non-pressure etiology; ulcers with sinus tracts and/or undermining greater than 1 cm; clinically infected ulcers; concomitant use of other topical medication or systemic steroid therapy; severe medical condition; estimated survival of less than 6 months ; HIV, currently abusing alcohol or drugs; pregnant, breast feeding or not on acceptable means of anti- contraception; diagnose of cancer; receiving chemotherapy		

Table 107 – THOMAS 2005

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Thomas (2005)** Title: **A controlled, randomized, comparative study of a radiant heat bandage on the healing of stage 3-4 pressure ulcers: A pilot study.** Journal: **Journal of the American Medical Directors Association, 6; 46-49.** Study type: **randomized controlled trial** Sequence generation: **standard computer-generated** Allocation concealment: **block stratification using opaque envelopes** Blinding: **not reported.** Addressing incomplete outcome data: **reported as intention to treat analysis. However drop-outs (and exclusion) are**	**Patient group:** Patients older than 18 years with stage III or IV PU. **All patients** **Randomised N:** 41 **Completed N:** 41 **Drop-outs:** 0 **Age (mean years (SD)):** 75.5 (12.6) **Gender (m/f):** 21/20 **Ulcer stage:** Stage III: 22 Stage IV: 19 **Ulcer location:** Sacrum: 17 Ischium: 9 Coccyx: 6 Other: 9 **Group 1** **Randomised N:** 21 **Completed:** 21 **Dropouts:** 0 **Age (mean years (SD)):** 74.1 (13.8) **Gender (m/f):** 12/16 **Ulcer stage:** Stage III: 11 Stage IV: 10 **Ulcer area (mean cm² (SD)):** 11.0 (9.5) **Braden score (mean**	**Group 1:** Radiant heat dressing (Warm-Up™, Augustine Medical Inc., Eden Prairie, MN). The warming card was used for a 1-hour treatment every 8 hours for the duration of the study. The dressing was changed every 7 days or when the occlusive seal was broken. Warm-Up™: consists of two layers of plastic film (semi-occlusive and water vapor permeable) supported by and attached to an open-cell pad that adheres to the skin surrounding the wound area. The window portion of the bandage, centered over the wound, is a two layered pocket into which the warming card (heating element) is inserted. The warming card delivers heat at 38°C, warming the wound and periwound area, without coming into direct contact with the wound tissue. **Group 2:** Hydrocolloid dressing (Duoderm™, ConvaTec, Inc., Princeton, NJ with or without a calcium alginate filler (Sorbasan™,	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Proportion of patients completely healed (stage III PU) **Outcome 3:** Proportion of patients completely healed (stage IV PU)	**Group 1:** 8 (unclear if 8 of 14 patients = 56% as reported or 8 of 21 because ITT analysis) **Group 2:** 7 (unclear if 7 of 16 patients = 44% as reported or 7 of 20 because ITT analysis) **Group 1:** unclear **Group 2:** unclear **Group 1:** unclear **Group 2:** unclear	**Funding:** / **Limitations:** no report on blinding; unclear if ITT analysis was used; no a priori sample size calculation; no report on classification of PU **Additional outcomes:** / **Notes:** /

suspected. Statistical analysis: **A contingency table was constructed using chi-square techniques to compare healing rates. Kaplan-Meier survival analysis was performed to compare the probability of healing between groups. Statistical analysis was performed using Statistica.** Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size calculation.** Setting: **outpatient clinics, long-term care nursing homes, and a rehabilitation center.** Length of study: **12 weeks of treatment.** Assessment of PUs: **PU classification not reported.** **Ulcer area (length, width, and depth) of the wound was measured and a**	**(SD):** 12.8 (2.1) **BMI (mean kg/m² (SD)):** 23.9 (4.6) **Group 2** **Randomised N:** 20 **Completed:** 20 **Dropouts:** 0 **Age (mean years (SD)):** 77.0 (11.5) **Gender (m/f):** 9/4 **Ulcer stage:** Stage III: 13 Stage IV: 9 **Ulcer area (mean cm² (SD)):** 12.1 (18.2) **Braden score (mean (SD):** 13.7 (2.9) **BMI (mean kg/m² (SD)):** 23.8 (7.7) **Inclusion criteria:** 18 years or old; non-infected stage II or IV PU; ulcer area ≥ 1.0cm²; truncal PU **Exclusion criteria:** history of sensitivity to adhesive products; ulcer with a sinus tract and/or extensive undermining (> 1 cm); non-pressure ulcer (venous stasis or arterial insufficiency or vasculitis or diabetic ulcer) based on the investigator's diagnosis; infected ulcer;	Smith & Nephew, Inc. Largo, Fl.) depending in exudate. The dressing was changed every 7 days **All groups:** Both groups received standard offloading and pressure reducing devices.

plastic acetate tracing of the wound perimeter was made using a felt pin pen. The wound was assessed using the Pressure Ulcer Status for Healing (PUSH) tool Multiple ulcers: **only one ulcer was evaluated per subject**	concomitant use of other topical medication to study ulcer; human immune deficiency virus positive; pregnant, breast-feeding or not on acceptable means of contraception in premenopausal women; current diagnosis of cancer; chemotherapy; severe generalized medical condition with estimated survival of less than 6 months; concomitant systemic steroid therapy at a dose equivalent to > 10 mg prednisone daily; current alcohol or drug abuse.				

Table 108 – TRIAL 2010

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Trial (2010)** Title: **Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT.** Journal: **Journal of Wound Care, 19 (1);**	**Patient group:** Patients older than 18 years with a PU. Also patients with diabetic foot ulcers, leg ulcers and acute wounds were included (separate analysis) **All patients** **Randomised N:** 24 **Completed N:** 24	**Group 1:** Silver alginate matrix dressing (Askina® Calgitrol® Ag, Braun Medical SAS, Boulogne-Billancourt, France). Askina® Calgitrol® Ag: consists of a proprietary ionic silver alginate matrix and an absorbent polyurethane foam layer. Delivery of ions is controlled and sustained over	**Outcome 1:** Percentage decrease in infection score	**Group 1:** 52.2% **Group 2:** 50.0%	**Funding:** sponsored by Braun Medical SAS, Boulogne-Billancourt, France **Limitations:** no report on sequence generation; no

20-26. Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **sealed envelopes** Blinding: **not reported.** Addressing incomplete outcome data: **no drop outs** Statistical analysis: **Descriptive analysis (mean and SD; median) and comparisons based on the t-test were performed with Excel. Chi-square test, Wilcoxon singed rank test, Mann-Whitney U test were performed with Statview.** Baseline differences: **No statistical difference between groups.** Study power/sample size: **Based on an observed standard deviation of 5 for the score of infection, 40 patients (20 per groups) were needed to reach a difference**	**Drop-outs:** 0 **Age males (mean years (SD)):** 65.5 (17.7) **Age females (mean years (SD)):** 80.9 (9.0) **Gender (m/f):** 13/11 **Ulcer location:** Sacrum: 15 Other: 9 **Ulcer stage:** Superficial tissue damage plus exuding blister: 11 Tissue damage that did not extend to the bone: 8 **Norton score:** ≥ 10: 19 ≥ 15: 9 **Group 1** **Randomised N:** 11 **Completed:** 11 **Dropouts:** 0 **Group 2** **Randomised N:** 13 **Completed:** 13 **Dropouts:** 0 **Inclusion criteria:** PU; one or more signs of local infection **Exclusion criteria:** known allergy to the dressings; burns; ulcer whose etiology is associated with infectious disease such	72 hours due to the bonding characteristics of the silver alginate molecule. **Group 2:** Silver free alginate dressing (Algosteril®, Laboratories Brothier, France). **All groups:** /	report on blinding; sample size lower than calculated; no report on classification of PU and unclear if all stages were included; no report on preventive measures; little information on dressings; no report on multiple ulcers **Additional outcomes:** / **Notes:** Only data for PU patients are reported.

of 4.7 at day 15 with an alpha risk of 5% and a beta risk of 20%. Setting: **wound clinical and Montpellier University Hospital.** Length of study: **15 days of treatment.** Assessment of PUs: **PU classification not reported.** **Local infection was assessed by the study investigator using an 18 point scale (0: no infection – 18: infection).** Multiple ulcers: **not reported**	as tuberculosis; use of coagulants; aged under 18 and over 80				

Table 109 – WILD 2012

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Wild (2012)** Title: **Eradication of methicillin-resistant Staphylococcus aureus in pressure ulcers comparing a polyhexanide-containing cellulose**	**Patient group:** Patients a grade II, III, IV PU and MRSA (according to the NPUAP classification) **All patients** **Randomised N:** 30 **Completed N:** 30 **Drop-outs:** 0	**Group 1:** Polyhexanide containing cellulose dressing (Suprasorb® [Lohmann & Rauscher, Topeka, Kansas]+ Prontosan® [B. Barun, Bethlehem, Pennsylvania]). Ulcers were cleansed using saline and the assigned treatment was applied. A foam dressing (Suprasorb)	**Outcome 1:** Percentage reduction in pain score **Outcome 1:** Proportion of patients MRSA eradicated	**Group 1:** 82.4 **Group 2:** 52.6 **Group 1:** 15/15 **Group 2:** 10/15	**Funding:** sponsored by Lohman & Rauscher GmbH. **Limitations:** no blinding of patient and nurses; no a priori sample size calculation; no

dressing with polyhexanide swabs in a prospective randomized study. Journal: **Advances in Skin & Wound Care, 25 (1); 17-22.** Study type: **randomized controlled trial** Sequence generation: **computer generated code** Allocation concealment: **sealed envelopes** Blinding: **blinding of assessor.** Addressing incomplete outcome data: **intention to treat analysis** Statistical analysis: **Statistical evaluation was performed using SPSS and where appropriate, tests were performed at the 5% significance level, with repeated-measures analysis of variance. The confidence interval was 95%. In appropriate cases, a Student t test was used to determine**	**Group 1** **Randomised N:** 15 **Completed:** 15 **Dropouts:** 0 **Age (mean years (SD); range):** 70.9 (5.22); 59-77 **Gender (m/f):** 7/8 **Ulcer location:** Sacrum: 11 Ischium: 1 Heel: 3 **Ulcer grade:** Grade II: 2 Grade III: 6 Grade IV: 7 **Ulcer area (mean cm² (SD); range):** 47.67 (22.75); 12.0-81.0 **Group 2** **Randomised N:** 13 **Completed:** 13 **Dropouts:** 0 **Age (mean years (SD); range):** 66.5 (9.59); 42-79 **Gender (m/f):** 8/7 **Ulcer location:** Sacrum: 10 Ischium: 3 Heel: 2 **Ulcer grade:** Grade II: 2 Grade III: 6 Grade IV: 7 **Ulcer area (mean cm² (SD); range):** 35.80	was used as secondary dressing. Dressing were changed on average at 2-day interval. **Group 2:** Polyhexanide swab (Prontosan® [B. Barun, Bethlehem, Pennsylvania]). Ulcers were cleansed using saline and the assigned treatment was applied. A foam dressing (Suprasorb) was used as secondary dressing. Dressing were changed on average at 2-day interval. **All groups:** All patients had PUs with long-term intractable MRSA colonization in which disinfection had not been achieved despite several lege artis attempts at disinfection, such as the use of iodine, silver, and so on, during a 2-week washout period.		measurement of statical difference between groups; no report on multiple ulcers, no report on use of preventive measures **Additional outcomes:** / **Notes:** /

significance. Baseline differences: **Difference not measured statically.** Study power/sample size: **No a priori sample size calculation.** Setting: **in– and out-patients.** Length of study: **14 days of treatment.** Assessment of PUs: **PU were classified according to the NPUAP classification. Ulcers were photographed on a weekly basis using a high-resolution digital camera. Photographs were analyzed using a digital tool, which was applied for both assessing wound size and evolution of the wound bed. Computer-supported digital software W.H.A.T. was used for the analysis of the digital photographs. For pain analysis upon dressing changes, a 10-point visual analog scale**	(13.47); 15.0-62.0 **Inclusion criteria:** MRSA containing PU; grade II, III, IV PU **Exclusion criteria:** /

(VAS) was used. Multiple ulcers: **not reported**					

Table 110 – WINTER 1990

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Winter (1990)** Title: **Testing a hydrocolloid.** Journal: **Nursing Times, 86 (50); 59-62.** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **drop-outs excluded** Statistical analysis: **not reported.** Baseline differences: **No statistical difference measured between groups.** Study power/sample size: **no a priori sample size**	**Patient group:** Patients with a PU. Also patients with leg ulcers were included (separate analysis) **All patients** **Randomised N:** 114 patients and 141 ulcers (38 patients with PUs, number of ulcers not reported) **Completed N:** 46 patients (11 patients with PUs) **Drop-outs:** 68 (2 rash, inflammation, allergy, 9 infection, 21 changed dressing, 7 died, 4 wound deterioration, 6 patient request, 19 other reasons) **Age (median years; range):** 74; 25-93 **Gender (m/f):** 38/76 **Group 1** **Randomised N:** 58 patients (20 patients with	**Group 1:** Hydrocolloid dressing (Comfeel®, Coloplast). Ulcers were cleansed with normal saline only. Comfeel paste and powder was used in conjunction with the Comfeel sheet if necessary. **Group 2:** Paraffin gauze dressing (Jelonet®, Johnson and Johnson) **All groups:** all patient received comparable pressure relieving aids.	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Proportion of patients improved **Outcome 3:** Proportion of patients not improved	**Group 1:** 5/6 **Group 2:** 3/5 **Group 1:** 6/6 **Group 2:** 5/5 **Group 1:** 0/6 **Group 2:** 0/5	**Funding:** Funded by Coloplast Ltd. **Limitations:** no report on sequence generation; no report on blinding; no ITT analysis; high drop-out; no statistical measurement of difference between groups; no a priori sample size calculation; low number of patients with PUs; little information on ulcer assessment; no information on PU stage and classification; multiple ulcers were included but unclear; little information on dressings; no

calculation. Setting: **general practice, community, hospital.** Length of study: **12 weeks of treatment.** Assessment of PUs: **PU classification not reported. Photographs and size tracings were made** Multiple ulcers: **patients with multiple ulcers included**	PUs) **Completed:** 25 patients (6 patients with PUs) **Dropouts:** 33 (1 rash, inflammation, allergy, 5 infection, 8 changed dressing, 3 died, 3 wound deterioration, 3 patient request, 10 other reasons) **Group 2** **Randomised N:** 56 patients (18 patients with PUs) **Completed:** 21 patients (5 patients with PUs) **Dropouts:** 35 (1 rash, inflammation, allergy, 4 infection, 13 changed dressing, 4 died, 1 wound deterioration, 3 patient request, 9 other reasons) **16 patients switched to Comfeel during trial!** **Inclusion criteria:** PU **Exclusion criteria:** Terminal illness; ulcer area < 1cm²		information on patients who switched to comfeel; reported results are questionable! **Additional outcomes:** / **Notes:** Patient characteristics are for all patients. The outcome are for PU patients only.

Table 111 – XAKELLIS 1992

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Xakellis (1992)** Title: **Hydrocolloid versus saline-gauze dressings in treating pressure ulcers: A cost-effectiveness analysis.** Journal: **Archives of Physical Medicine and Rehabilitation, 73; 463-469.** Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **intention to treat analysis** Statistical analysis: **Two-tailed chi-square or Fisher exact tests were performed for all categorical variables.**	**Patient group:** Patients with a stage II or III PU (according to the Shea classification). **All patients** **Randomised N:** 39 **Completed N:** 34 **Drop-outs:** 5 (1 hospitalized, 1 withdrawal of consent, 3 died) **Group 1** **Randomised N:** 18 **Completed:** 16 **Dropouts:** 2 (1 hospitalized, and 1 withdrawal of consent) **Age (mean years (SD)):** 77.3 (16.9) **Gender (m/f):** 2/16 **Ulcer location:** Sacrum: 6 Pelvic area: 8 Other: 4 **Ulcer grade:** Grade II: 18 Grade III: 0 **Ulcer area (mean cm²; range):** 0.66; 0.12-13.4 **Incontinence:** Occasionally: 1	**Group 1:** Hydrocolloid dressing (DuoDermCGF®, ConvaTec, Princeton, NJ). Ulcers were cleansed with normal saline only. The dressing was applied and rimmed with tape. The dressing was changed twice weekly or if non-occlusive. **Group 2:** Saline wet-to-moist gauze dressing. The gauze consists of a non-sterile eight ply gauze dressing moistened with saline and placed on the ulcer. This was covered with an additional gauze dressing and rimmed with tape. The dressing was remoistened with 3cc saline after four hours and changed after eight hours. **All groups:** All patients with necrotic tissue were sharp debrided as necessary All patient received routine care: repositioning every two hours, cleaning of incontinence with warm water, placing on an air-mattress and air-filled wheelchair cushion, and	**Outcome 1:** Proportion of patients completely healed **Outcome 2:** Median time to healing (days)	**Group 1:** 16/18 **Group 2:** 18/21 **Group 1:** 9 **Group 2:** 11 **P-value:** 0.12	**Funding:** supported by ConvaTec Princeton, NJ and Family Health Foundation of America. **Limitations:** no report on sequence generation; no report on blinding; no a priori sample size calculation; small sample size; little information on ulcer assessment **Additional outcomes:** Cost; multivariate analysis **Notes:** /

Continuous and ordinal data were analysed with the Wilcoxon rank-sum test using the t-approximation for the significance level. The Cox proportional-hazards regression model for survival data was used to determine the factors related to healing time. Logrank statistics were calculated to test the univariate associations between baseline characteristics and healing time. Multivariate analysis was performed using Cox proportional-hazard regression analysis to determine the factors associated independently and significantly (p≤0.05) with healing time. Baseline differences: **No statistical difference between groups.** Study power/sample size: **No a priori sample size**	Usually: 5 Urine and faeces: 12 **BMI (mean kg/m² (SD)):** 20.2 (5) **Norton score (mean score (SD)):** 11.4 (2.8) **Group 2** **Randomised N:** 21 **Completed:** 18 **Dropouts:** 3 (died) **Age (mean years (SD)):** 83.5 (10.6) **Gender (m/f):** 1/20 **Ulcer location:** Sacrum: 8 Pelvic area: 6 Other: 7 **Ulcer grade:** Grade II: 19 Grade III: 2 **Ulcer area (mean cm²; range):** 0.38; 0.04-24.6 **Incontinence:** Occasionally: 0 Usually: 3 Urine and faeces: 13 **BMI (mean kg/m² (SD)):** 21.1 (5) **Norton score (mean score (SD)):** 12.8 (3.0) **Inclusion criteria:** Grade II or III **Exclusion criteria:** rapidly fatal disease; anticipated discharge	record of diet.

calculation. Setting: **long-term care facility.** Length of study: **six months of treatment.** Assessment of PUs: **PU were classified according to the Shea classification (1975).** **Ulcer circumference was traced on clear plastic film two times weekly.** Multiple ulcers: **only one ulcer determined by coin toss was included in the study**	within one week: ulcers from other causes than pressure such as venous stasis				

Table 112 – YASTRUB 2004

Reference	Patient Characteristics	Intervention Comparison	Outcome measures	Effect sizes	Comments
Author and year: **Yastrub (2004)** Title: **Relationship between type of treatment and degree of wound healing among institutionalized geriatric patients with stage II pressure ulcers.** Journal: **Care Management Journal, 5 (4); 213-218.**	**Patient group:** Patients with a stage II PU (according to the AHCPR classification). **All patients** **Randomised N:** 50 **Completed N:** 44 **Drop-outs:** 6 (reason not reported) - unclear **Group 1** **Randomised N:** 21 **Completed:** 19	**Group 1:** Polymeric membrane dressing (Polymen®). Dressing were changed as per protocol. **Group 2:** Dry clean dressing and antibiotic ointment. **All groups:** All patient received: nutritional supplements, vitamin C and zinc sulphate, pressure relief mattress, foam cushion and repositioning every 2 hours	**Outcome 1:** Proportion of patients improved **Outcome 2:** Mean PUSH score	**Group 1:** 18/21 **Group 2:** 15/23 **Group 1:** 3.24 **Group 2:** 1.61 **P-value:** > 0.05	**Funding:** Partial funding by NPUAP award. **Limitations:** no report on sequence generation; no report on allocation concealment; no report on blinding; ITT analysis unclear; drop-outs

Study type: **randomized controlled trial** Sequence generation: **not reported** Allocation concealment: **not reported** Blinding: **not reported.** Addressing incomplete outcome data: **not reported** Statistical analysis: **The t-test was used to determine the difference between PUSH scores of the different groups. Descriptive statistics were computed using SPSS.** Baseline differences: **Baseline characteristics not reported.** Study power/sample size: **No a priori sample size calculation.** Setting: **long-term care facility in Queens, New York.** Length of study: **four weeks** Assessment of PUs: **PU were classified according to the**	**Dropouts:** 2 missings **Group 2** **Randomised N:** 23 **Completed:** 23 **Dropouts:** 0 **Inclusion criteria:** > 65 years; limitation in ADL; PU stage II **Exclusion criteria:** /	unclear; no baseline characteristics reported, comparison between groups unclear; no a priori sample size calculation; little information on ulcer assessment; multiple ulcers not reported; little information on dressings. **Additional outcomes:** / **Notes:** /

AHCPR classification (1994). **Ulcer were weekly assessed using the Pressure Ulcer Scale for Healing (PUSH).** Multiple ulcers: **not reported**		

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