

# AUTOLOGOUS BREAST RECONSTRUCTION TECHNIQUES AFTER MAMMARY RESECTION: TIME MEASUREMENTS FOR A POTENTIAL RE-EVALUATION OF THE SURGEON FEE





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## LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
BFM	Budget van Financiële Middelen
BMF	Budget des Moyens Financiers
DIEP	Deep Inferior Epigastric Perforator
ETL	Data Extraction, Transformation and Loading
FU	Follow up
FTE	Full Time Equivalent
GAP	Gluteal Artery Perforator
HBD	Hospital Billing Data
HERM	Hetero-lateral breast remodelling
HTA	Health Technology Assessment
ICD-9-CM	International Classification of Diseases, version 9, Clinical Modification
IGAP	Inferior Gluteal Artery Perforator
LAP	Lumbar Artery Perforator
LDF	Latissimus Dorsi flap
LOS	Length Of Stays
LT	Intervention Lead Time
MCD	Minimal Clinical Data
MoH	Federal Ministry of Health
MSVA	MicroSurgical Vascular Anastomosis
NEC	Not Elsewhere Classified (used in ICD-9-CM code labelling)
NHDB	National Hospitals stays Database
HI	National Health Insurers
NOS	Not Otherwise Specified (used in ICD-9-CM code labelling)
OR	Operating Room
PAP	Profunda artery perforator
RIZIV-INAMI	National Institute for Health and Disability Insurance
SD	Standard Deviation
SGAP	Superior Gluteal Artery Perforator



SIEA	Superficial Inferior Epigastric Artery
SIEP	Superficial Inferior Epigastric Perforator
SOI	Severity Of Illness, on a scale 1 to 4: minor, moderate, severe and extreme
SS	Surgical Site
SSC	Surgical Site Complications
SW	Surgical wound
TAP / TDAP	Thoracodorsal Artery Perforator
TMG	Transverse Musculocutaneous Gracilis
TRAM	Transverse Abdominal Muscle
TUG	Transverse Upper Gracilis
UPP	Unique Patient Pseudonym



## ■ SCIENTIFIC REPORT

### 1 INTRODUCTION

#### 1.1 Background and objectives

In the past years, complaints have grown by women who must pay considerable supplements for autologous breast reconstruction after mastectomy. As current reimbursement levels are considered insufficient by plastic surgeons, so-called “aesthetic supplements” are charged. The position of the national institute for health and disability insurance (RIZIV-INAMI), however, is that the reimbursement of the procedure should cover the full procedure and that no “aesthetic supplements” should be billed. Past negotiations between the plastic surgeons and the RIZIV-INAMI already led to reappraisals of the tariffs. These reappraisals however were judged insufficient by the plastic surgeons. They insisted with the former Minister of Health for an increased reimbursement. It is in response to this question that the former Minister commissioned a costing study to the KCE. The primary aim of this study is therefore to calculate the “surgeon cost” for a full autologous breast reconstruction procedure, including adjustments, to serve as a basis of discussions for a possible revision of the RIZIV-INAMI fee based on objective data.

A secondary aim is to give some elements about the medical context regarding autologous breast reconstruction in terms of effectiveness and safety of these procedures compared to alternatives as well as a description of the current practice in Belgium.

#### 1.2 Research questions

The study aims at answering the following research questions

- What is the efficacy and safety of autologous breast reconstruction techniques compared to the alternatives? With the following sub-questions:
  - In women who underwent a mastectomy, what is the clinical effectiveness in terms of patient satisfaction (quality of life, body image, sexuality, etc.) in those women who had an autologous breast reconstruction, compared with women who had a breast reconstruction with implants, or a mastectomy without reconstruction?



- What are the adverse outcomes associated with autologous breast reconstruction?
- What is the impact of radiotherapy on autologous breast reconstruction?
- What is the current Belgian practice?
- What is the estimated “surgeon cost” for the different types and subcomponents of an autologous breast reconstruction episode?

Research question 3 was mainly outsourced to Möbius Business Redesign nv/sa. The data collection was performed in collaboration with Belgian hospitals performing autologous reconstructions.

### 1.3 Description of autologous breast reconstruction interventions

#### 1.3.1 *The primary reconstruction or the flap transfer*

Autologous breast reconstruction interventions clinically can be categorized as:

- Unilateral (i.e. reconstruction of one breast) or bilateral interventions (i.e. reconstruction of both breasts);
- Immediate (i.e. at the same time of the mastectomy) or delayed (i.e. at a different time; e.g. after chemo- and/or radiotherapy).

Based on main surgical characteristics we can group autologous breast reconstructions in two main types:

- Reconstructions by means of an autologous myo-cutaneous flap with a vascular pedicle that is preserved (the tissue remains partly attached to the donor site). Such flaps are called pedicled, transposition flaps or tunnelled flaps. Standard TRAM as well as LDF belong to this category. Yet other variants exist; (see Table 1)
- Reconstructions by means of an autologous myo-cutaneous flap with a vascular pedicle that is carefully prepared, next cut and then re-implanted on a new axillo-pectoral or intercostal vascular pedicle by means of a micro-surgical vascular anastomosis (MSVA) involving an OR microscope. Such flaps are called free flaps. Examples are DIEP, SIEA and GAP, but other variants exist. (see Table 1)

Anatomically, free flaps can be sub classified in:

- Perforator flaps where pedicle dissection extents to the deeper sub aponeurotic vessels.
- Non-perforator flaps where pedicle dissection only involves supra-aponeurotic vessels.

Finally, based on the number of pedicles prepared, we differentiate:

- Mono-pedicled flaps, having only one pedicle
- Bi-pedicled flaps having two pedicles.

The different techniques are described in Table 1.




**Table 1 – Description of the autologous breast reconstruction with flap<sup>1, 2</sup>**

Donor site	Abbreviation	Full term	Description	RIZIV-INAMI code	Tariff
<b>Abdomen</b>	Pedicle (or attached) TRAM flap	Pedicle (or attached) Transverse Rectus Abdominis Myo-cutaneous flap	<p>For the breast reconstruction, a part of the rectus abdominis muscle and its fat, skin, and blood vessels are tunneled under the skin from the lower abdomen up into the chest.</p> <p>To ensure the vascularization, blood vessels of the muscle are left attached to the original blood supply in the abdomen. Either only one side of the rectus abdominis muscles or both sides of the rectus abdominis muscle can be moved up (bilateral reconstruction).</p> <p>The area where the muscle was moved must be repaired. A mesh is usually needed to reinforce the abdomen.</p>	252534-252545	814.53 €
	Free TRAM flap	Free Transverse Rectus Abdominis Myo-cutaneous flap	<p>For the breast reconstruction, a part of the rectus abdominis muscle and its fat, skin, and blood vessels are prepared on either one (= mono-pedicle flap) , either 2 vascular pedicles (= bi-pedicle flap), that are cut and moved up to the chest.</p> <p>The area where the muscle was moved must be repaired. A mesh is usually needed to reinforce the abdomen.</p>	252556-252560	1323.60 €
	DIEP flap	Deep Inferior Epigastric Perforator Artery	<p>For the breast reconstruction, fat, skin, and deep inferior epigastric vessels (but no muscle) of the lower abdominal wall are cut and moved up to the chest.</p> <p>To ensure revascularization, branches of the deep inferior epigastric vessels that perforate the rectus abdominis and its fascia are anastomosed to blood vessels in the chest using microsurgery.</p> <p>The flap is considered bi-pedicle when both sides of epigastric pedicles (left and right) are prepared and anastomosed autonomously and mono-pedicle when epigastric pedicles of only one side (left or right) are prepared and anastomosed.</p>	252571-252582	1527.24 €



	SIEA flap / SIEP flap	Superficial Inferior Epigastric Artery flap / (also called) Superficial Inferior Epigastric Perforator	<p>For the breast reconstruction, fat, skin, and superficial inferior epigastric vessels (but no muscle) of the lower abdominal wall are cut and moved up to the chest.</p> <p>To ensure revascularization, branches of the superficial inferior epigastric vessels are anastomosed to blood vessels in the chest using microsurgery.</p> <p>Compared to a DIEP flap, a different section of blood vessels in the abdomen is used. Because the DIEP use the deep inferior epigastric artery instead of the superficial artery, the DIEP flap requires a small incision in the layer that covers the rectus abdominis muscle (the fascia). Such an incision is not required for the SIEA flap.</p>	252571-252582	1527.24 €
<b>Back</b>	LDF	Latissimus Dorsi Flap	<p>For the breast reconstruction, a part of the latissimus dorsi muscle and its fat, skin, and blood vessels are tunneled under the skin from the upper back up into the chest.</p> <p>To ensure vascularization, blood vessels of the muscle are left attached to the original blood supply in the back.</p> <p>The flap contains a significant amount of muscle, so it is considered as a muscle-transfer type of flap. An implant is frequently required to achieve the desired shape, size, and projection.</p>	252475-252486	488.72 €
	LAP flap	Lumbar Artery Perforator Flap	<p>For the breast reconstruction, fat, skin, and lumbar vessels (no muscle) of the lower back and flanks are cut and moved up to the chest.</p> <p>To ensure revascularization, branches of the lumbar vessels are anastomosed to blood vessels in the chest using microsurgery.</p>	252571-252582	1527.24 €
<b>Hip/buttocks</b>	SGAP flap / Hip flap	Superior gluteal artery perforator flap or gluteal perforator hip flap	<p>For the breast reconstruction, fat, skin, and superior gluteal vessels (no muscle) of the upper buttocks/hip are cut and moved up to the chest.</p> <p>To ensure revascularization, branches of the superior gluteal vessels are anastomosed to blood vessels in the chest using microsurgery.</p>	252571-252582	1527.24 €



		IGAP flap	Inferior gluteal artery perforator flap	For the breast reconstruction, fat, skin, and inferior gluteal vessels (no muscle) of the lower buttocks are cut and moved up to the chest. To ensure revascularization, branches of the inferior gluteal vessels of the flap are anastomosed to blood vessels in the chest using microsurgery.	252571-252582	1527.24 €
<b>Upper thighs</b>	<b>inner</b>	TUG/TMG flap	Transverse upper gracilis flap / transverse musculocutaneous gracilis	For the breast reconstruction, a part of the transverse upper gracilis muscle and its fat, skin, and blood vessels are cut and moved up to the chest. To ensure revascularization, blood vessels of the muscle are anastomosed to blood vessels in the chest using microsurgery.	252571-252582	1527.24 €
		PAP flap	Profunda artery perforator flap	For the breast reconstruction, fat, skin, and profunda vessels (no muscle) of the upper inner thigh are cut and moved up to the chest. To ensure revascularization, branches of the profunda vessels are anastomosed to blood vessels in the chest using microsurgery.	252571-252582	1527.24 €

*Multi-component or "hybrid" flap reconstruction such as stacked DIEP Flap, Body Lift Perforator Flap, Stacked/"Hybrid" GAP Flap are not described in this report. Autologous breast reconstruction using fat tissue (fat grafting) is also not described here.*



### 1.3.2 Secondary interventions

Following the primary breast reconstruction (or the flap transfer), additional interventions can be performed and concern symmetrization procedures, adjustments of the flap and nipple reconstruction as well as other adjustments such as scar corrections and adjustments of the donor site. Most of these interventions can be immediate (i.e. during the reconstruction) or delayed.

#### Adjustments of the flap and nipple reconstruction

The following adjustments can be done on the reconstructed breast, i.e. reconstruction of the nipple-areola complex, reconstruction or tattooing of the areola (the dark circle around the nipple), implantation of a prosthesis (e.g. for LDF or TAP flap), or fat grafting (i.e. fat is removed from the thighs, flanks or abdomen using liposuction and is injected into the reconstructed breast (lipofilling) after having processed the fat to extract the living cells).

Among these adjustments, only nipple reconstruction and tattoo of the areola are currently reimbursed in Belgium (see Table 2).

#### Symmetrization procedures

In case of unilateral reconstruction, the reconstructed breast may not droop like the natural breast and symmetrization procedures on the natural breast can be done, such as augmentation (implantation of a prosthesis), reduction or lifting/mastopexy of the breast. Symmetrization procedures can currently be reimbursed under one RIZIV-INAMI code (see Table 2).

#### Other adjustments

Beside the acceptor site, liposuction or lipofilling can also be done on the donor site and other sites. Other interventions on the donor sites can concern for example reconstruction of the umbilicus. Hernias or bulges can also occur in the abdominal donor site and surgical repair in this case can be performed.

Table 2 – Reimbursed secondary interventions

Secondary intervention	RIZIV-INAMI code	Tariff
<b>Tattoo of the areola</b>	252615-252626	48.57 €
<b>Reconstruction of the nipple-areola complex</b>	252490-252501	146.61 € (*1.5 for bilateral reconstruction)
<b>Hetero-lateral remodeling (i.e. symmetrization procedures)</b>	252512-252523	366.54 €



## 2 THE CLINICAL EFFECTIVENESS AND SAFETY OF AUTOLOGOUS BREAST RECONSTRUCTION

### 2.1 Introduction

The following medical review is solely based on systematic reviews included in the databases Medline and PreMedline (OVID), Embase, and the Cochrane library. This choice was made because of time constraints and because the main focus of the report is on the cost of breast reconstructions. More recent studies, not yet adopted in systematic literature reviews, are hence not included. The details of the searches can be found in the following section.

### 2.2 Methods

As the current chapter is only intended to set the scene of the present report, the research questions elaborated in the present chapter are limited to the following questions. The comparison of different autologous reconstruction techniques was considered out of scope. Research questions and PICOs

**Question 1: In women who underwent a mastectomy, what is the clinical effectiveness in terms of patient satisfaction (quality of life, body image, sexuality, etc.) in those women who had an autologous breast reconstruction, compared with women who had a breast reconstruction with implants, or a mastectomy without reconstruction?**

**Question 2: What are the adverse outcomes associated with autologous breast reconstruction?**

#### *Population*

Female breast cancer patients who have undergone (prophylactic or therapeutic) mastectomy

#### *Interventions*

The assessment will include autologous breast reconstruction techniques.

#### *Comparators*

The comparator will include:

- No reconstruction
- Tissue expander/implant (TE/I) reconstruction

#### *Outcomes*

The following outcomes will be considered (short-term and long-term):

- Quality of life (QoL)(RQ1)
- Adverse outcomes (RQ2)

**Question 3: What is the impact of radiotherapy on autologous breast reconstruction?**

#### *Population*

Female breast cancer patients who have undergone (prophylactic or therapeutic) mastectomy and breast reconstruction.

#### *Interventions*

Radiotherapy

#### *Comparators*

The comparator will include:

- No radiotherapy

#### *Outcomes*

The following outcomes will be considered (short-term and long-term):

- Adverse outcomes

#### 2.2.1 Literature search

Outcomes of interest were assessed through a review of existing systematic reviews (SR). Reviews were identified through a systematic literature search in Medline and PreMedline (OVID), Embase, and the Cochrane library (CDSR, CENTRAL, DARE, HTA database). More details of these searches can be found in the appendix. Searches were run on February 17, 2015; they were limited to the preceding 10 years (i.e. 2005-2015).



Reviews published in languages other than English, French or Dutch were excluded. The search yielded 368 unique references. From these 340 were excluded based on title and abstract. The full-text of 28 papers was evaluated, and finally 10 systematic reviews were included.

The CRD database was also searched for systematic reviews (on February 23, 2015), but it did not yield any additional reference.

### 2.2.2 Quality appraisal and data extraction

The AMSTAR checklist was used (<http://amstar.ca>) for the quality appraisal of systematic reviews; the appraisal was done by one reviewer. Detailed results are reported in the appendix. Data extraction was done by the same reviewer; the evidence tables can also be found in the appendix.

## 2.3 Results

**Question 1:** In women who underwent a mastectomy, what is the clinical effectiveness in terms of patient satisfaction (quality of life, body image, sexuality, etc.) in those women who had an autologous breast reconstruction, compared with women who had a breast reconstruction with implants, or a mastectomy without reconstruction?

Four systematic reviews yielded information for this research question: Tsoi et al. 2014<sup>3</sup>, Winters et al., Lee et al. 2009<sup>5</sup> and Guyomard et al. 2007<sup>6</sup>.

Tsoi et al. (2014) included 15 publications, representing 9 unique studies (8 cohort studies and 1 cross-sectional study) exploring how patient related outcomes differ over time between patients receiving tissue expander/implant (TE/I) and abdominal tissue reconstruction (ATF) recipients.<sup>3</sup> All ATF reconstructions studied were either free or pedicled TRAM flap procedures. Most studies included both immediate and delayed reconstructions, with a single study including only immediate reconstructions. All included studies used simple survey instruments, with only a minority using a validated measurement tool. Due to the lack of randomised controlled trials (RCTs), the lack of consistent measurement methods and the varied follow-up duration, the review authors could not pool the results from the individual studies.

Winters et al. (2010) included 34 studies that compared outcomes of mastectomy alone and mastectomy with breast reconstruction (immediate

or delayed), which also included psychosocial outcomes.<sup>4</sup> But, as the evaluation of mastectomy versus immediate breast reconstruction did not discriminate between TE/I and ATF based procedures and since all studies evaluating the different types of breast reconstruction were all adopted in the Tsoi et al. review, the Winters et al. study is not further discussed here.

Lee et al. (2009) evaluated 28 studies (21 cross-sectional surveys and 7 prospective cohorts) examining patient-reported outcomes of breast reconstruction after mastectomy for breast cancer, compared with mastectomy alone.<sup>5</sup> Only one cohort study surveyed women before treatment and at several occasions postoperatively; three retrospective studies asked women to recall their behaviour and feelings before operation. Nine of 28 studies used multivariate analysis to adjust for confounding; 9 articles were published before 2000.

Guyomard et al. (2007) included 30 studies related to patient satisfaction with breast reconstruction after mastectomy (28 related to cosmetic results and 2 related to pain management).<sup>6</sup> Again, “due to the heterogeneous nature of the studies, the dearth of randomised controlled trials and the heterogeneity of the study methods, no formal statistical analyses such as meta-analysis could be performed”. The authors performed a broad qualitative overview of the data, which is partially adopted in the discussion of this section.

*Question 1a: How satisfied are women who had autologous breast reconstruction compared with women who had mastectomy only?*

### Body image

Lee et al. noted that nine of 16 studies that evaluated body image found no substantial differences between women who had reconstruction and women who had mastectomy only.<sup>5</sup> Seven studies reported better body image in women who had reconstruction. Each of the three higher-quality studies<sup>a</sup> evaluating body image found no significant difference (in body image) between reconstruction and mastectomy only.<sup>5</sup>



### Quality of life

Quality of life was assessed in variable ways, often using simple survey instruments, with only a minority using a validated measurement tool.

Lee et al. reported that most of the studies on quality of life (7 of 11), including all of the higher-quality studies<sup>a</sup>, did not find statistically significant differences in quality of life between women who had reconstruction and women who had mastectomy only.<sup>5</sup> Three studies reported better quality of life among women who had mastectomy with reconstruction compared with women who had mastectomy without reconstruction and one study of younger women reported poorer quality of life among those who had mastectomy with reconstruction compared with those who had mastectomy only. It's important to note that four of the studies that did not find a difference in quality of life between mastectomy alone and mastectomy with reconstruction also found no difference in quality of life between breast conservation and mastectomy (with or without reconstruction), raising – according to the review authors – the possibility that their measures lacked adequate sensitivity.<sup>5</sup>

### Sexuality and sexual functioning

Lee et al. found that seven of the 12 studies that measured sexuality or sexual functioning found no difference between women who had reconstruction and women who had mastectomy only.<sup>5</sup> Three studies found improved sexual outcomes with reconstruction, and two studies found poorer sexual outcomes with reconstruction. The three higher-quality studies<sup>a</sup> of sexuality found equivalent or poorer outcomes with reconstruction.<sup>5</sup>

*Question 1b: How satisfied are women who had autologous breast reconstruction compared with women who had breast reconstruction with implants?*

### Aesthetic and general satisfaction

Tsoi et al. identified 7 studies on general satisfaction and 8 studies on aesthetic satisfaction.<sup>3</sup> Three studies reported better general satisfaction and four studies reported better aesthetic satisfaction for ATF compared to TE/I reconstruction. They further observed that among studies suggesting similar satisfaction rates across different approaches to reconstruction, all had small sample sizes (<100 patients), while in the remaining studies with larger sample sizes (>100 patients), a significant difference in aesthetic and/or general satisfaction between the reconstructive procedures was found. For instance, a prospective cohort study demonstrated that recipients of ATF reconstruction tended to be aesthetically and generally more satisfied than women receiving TE/I up to 2 years post reconstruction and these analyses were adjusted for age, preoperative physical activity level, and timing of reconstruction. ATF reconstruction continued to be associated with significantly greater aesthetic satisfaction than TE/I reconstruction at 1 and 2 year follow-up, while the significant differences in general satisfaction by the method of reconstruction converged by the second year.<sup>7</sup>

Tsoi et al. further noted that patients with ATF reconstruction had stable measures of aesthetic satisfaction, which was not the case in the TE/I cohort. One study reported that patients who had undergone TE/I breast reconstruction more than 8 years earlier, compared with those who had undergone TE/I reconstruction less than 5 years ago, were significantly less satisfied with their breast appearance, softness and size.<sup>8</sup>

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<sup>a</sup> In this systematic review cohort studies, population-based studies, and studies that used multivariate adjustment were considered higher-quality.





### Psychosocial or functional outcomes

Six of the seven included studies evaluating psychosocial or functional aspects reported equivalent outcomes irrespective of the reconstruction technique (the seventh study did not perform a direct comparison).<sup>3</sup> Tsoi et al further noticed that four studies suggest that measures of social life were significantly improved post reconstruction, irrespective of the approach, although only 1 study controlled for age and preoperative score.<sup>3</sup>

Based on 2 studies it was further concluded that so far no difference in **social well-being** according to procedure type has been found, while in one of these studies an interaction between timing of reconstruction and method of reconstruction was observed.<sup>3, 9</sup> Social well-being scores did not vary by procedure type among patients receiving immediate reconstruction; in patients undergoing delayed reconstruction, recipients of TE/I reported significantly greater gains on the FACT-B social well-being subscale compared with women receiving TRAM reconstruction in the first postoperative year.<sup>9</sup> By the second year post reconstruction, patients receiving immediate reconstruction with pedicled-TRAM and TE/I had a decline in social well-being, while the free-TRAM patients' scores increased, when controlled for age and preoperative scores. In delayed reconstruction, no procedure differences were observed because all approaches led to a decline in the social well-being scale by the second postoperative year.<sup>10</sup>

Tsoi et al. further noticed that 2 studies reported that **sexual life** remained unchanged after reconstruction across the different methods of reconstruction.<sup>3</sup>

Two included studies further reported that both **mental and emotional health** were found to improve irrespective of the approach to breast reconstruction.<sup>3</sup> With respect to body image, recipients of TRAM (including both pedicle and free TRAM flaps) had greater adjusted gains than TE/I patients at both the first and second year post reconstruction, which was significant among patients receiving delayed breast reconstruction.<sup>3</sup>

### Post reconstruction pain

Tsoi et al. further identified 2 studies that evaluated post reconstruction pain; none of both observed a difference in the adjusted general pain score at 1 year and 2 years post reconstruction.<sup>3</sup> A multiple regression analysis reported in one of the studies revealed that after controlling for baseline pain

scores and ethnicity the TRAM patients were significantly more likely to report abdominal pain and tightness than TE/I patients.

### Willingness to repeat and recommend reconstruction

Based on two studies, Tsoi et al. concluded that overall, patients' willingness to repeat the procedure and recommend it to a friend were similarly high for both approaches to reconstruction.<sup>3</sup>

Since there were no randomized studies, and we restricted the search to systematic reviews that appeared to be based on short-term observational studies, the level of evidence of the reported finding is low.

### Discussion

The results described above should be interpreted with caution since the primary studies the systematic reviews are based on had serious methodological limitations, which were also identified by the review authors:

- Many studies had small sample sizes, in many studies no power calculation was included (to ensure that the study was adequately powered to detect clinically meaningful differences), some had, when indicated, low response rates and in many studies attrition rates were high. Different types of reconstruction procedures are included, with inherent different patterns of postoperative/longterm pain, body image etc.
- Patient selection criteria were often not clearly specified or there were no formal selection criteria.
- Many studies used convenience samples, which may lead to selection bias in favour of those likely to be positive about breast reconstruction. The ideal approach to reducing selection bias would be to randomize patients, but in the case of breast reconstruction, treatment choice depends largely on a patient's personal preference. Only patients who are completely undecided could ethically qualify for such randomization, making such a trial difficult to perform.





- Women who choose breast reconstruction may differ from women who do not, in terms of their preoperative quality of life, body image, or sexuality. If women who choose reconstruction start out with poorer quality of life, body image, or sexuality before operation, then equivalent postoperative outcomes in the two groups can actually reflect improvements from baseline after reconstruction. On the other hand, if women who choose reconstruction have better baseline quality of life, body image, or sexuality, then equivalent postoperative outcomes would suggest that reconstruction causes some impairment. Without knowing the preoperative characteristics of women in both groups, it is difficult to know the effects of reconstruction.
  - Methodologies used for assessing satisfaction were not clearly specified in many studies, making interpretation and comparison of results impossible.
  - Many studies sought to measure whether patients would recommend breast reconstruction or were “satisfied” with it, but only few studies defined what satisfaction meant. When recorded on a scale, satisfaction was often analysed as a binary variable, so information may have been lost. In addition, satisfaction scoring systems differed from one study to another, making comparisons difficult and no information was provided on the validity or reliability of the measurement.
  - Only a minority of studies used validated questionnaires. In addition, self-reported data may have introduced the risk of misclassification and misleading information.
  - In some studies women were asked to recall their behaviours and feelings before the operation. Such a retrospective approach is subject to recall bias.
  - Very few studies adjusted for potential confounders (e.g. age, tumour stage, adjuvant therapy, smoking, emotional and psychological mental state at the time of the survey).
  - Post-operative timing of the questionnaire and duration of the follow-up also varied from study to study. Many studies presented only initial impressions and failed to explore what happened to patient satisfaction over time, thereby making it possible that the “psychological and emotional impact of feeling normal again” resulted in a positive bias. Moreover, the ideal time to measure outcomes of mastectomy and reconstruction for breast cancer is also unclear.
  - The generalisability of much of the published research is limited because of effect modifiers such as study setting (e.g. age group, socio-economic data) which are often not documented.
- Other considerations** (raised by clinical experts):
- Differences in patient satisfaction, comparing breast conservative treatment and mastectomy, also decrease after 2 years, so it is not surprising that Alderman et al. observed that general satisfaction by the method of reconstruction converged by the second year.
  - It is generally accepted that satisfaction after implants decreases over the years, while re-surgery for complications increases over the years; this impacts satisfaction.
  - The first weeks (and months) after a TRAM procedure are very painful. Patients suffer less pain after DIEP, SIEA, S-GAP and enjoy faster recuperation of physical activities. In addition, after a pedicled TRAM (pTRAM) procedure, there may be an abdominal wall defect and a risk for herniation.
  - TE/I procedure should be compared with DIEP, SIEA, S-GAP as these procedures are currently more used. Since these procedures have been used only recently, only a limited number of primary studies on these techniques have been included in the SR retrieved in the search of this report.

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**Conclusion:**

- At present, there is insufficient scientific evidence to support or to refute that patient satisfaction is better, equal or worse in women who had an autologous breast reconstruction compared with women who had a breast reconstruction with implants, or a mastectomy without reconstruction.
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**Question 2:** What are the adverse outcomes associated with autologous breast reconstruction?

Among the retrieved systematic reviews, three yielded information for this research question.<sup>11-13</sup>

Tsoi et al. (2014) included 14 observational studies (among which 5 consecutive) comparing surgical complications after primary breast reconstruction with tissue expander/implant versus autologous abdominal tissue procedures after total mastectomy for breast cancer in adult women.<sup>11</sup> Sample sizes ranged between 38 and 1542; mean follow-up ranged between 6 and 60 months.

Wormald et al. (2014) included 17 case series (13 consecutive and 4 non-consecutive) in order to compare adverse outcomes of unilateral versus bilateral DIEP flap breast reconstruction in adult women.<sup>12</sup> It should be noted that not all of the included studies had patients in both study arms. Sample sizes ranged between 54 and 407; mean follow-up ranged between 14.6 and 40 months (reported in 8 studies).

The third systematic review, by Khansa et al., merely focused on fat necrosis.<sup>13</sup> Based on a search limited to Pubmed, they identified 70 articles on 41 'distinct cohorts'; the follow-up of the included studies was not specified. For more information on the included studies, the reader is referred to the evidence tables in the appendix.

The systematic review authors performed meta-analyses, but adhering to the instructions of the Cochrane Handbook on Systematic Reviews not to pool data retrieved from non-randomized studies, the pooled effect estimates are not reported here.<sup>14</sup> Instead, ranges of reported incidences are reported.

**Major complications**

In one SR, major complications (i.e. composite outcome as any complication requiring reoperation, revision surgery, or rehospitalisation) were reported from 8 primary studies: they arose in 0-49% of patients receiving autologous abdominal tissue reconstruction (ATF) and in 0-71% of patients receiving tissue expander/implant (TE/I).<sup>11</sup> Major complications necessitating return to

the operation room (based on 5 studies) were reported in 0-26% of women receiving ATF and in 0-39% receiving TE/I. <sup>11</sup> Wormald et al. did not report an overall (composite) complication incidence rate.

**Short term reconstructive failure**

Tsoi et al. reported reconstructive failure as a pooled variable that incorporated implant failure (defined as extrusion of the prosthesis, implant rupture, implant rippling, implant malposition, implant failure or implant exposure) and flap failure (defined as total flap loss or flap failure); the duration of follow-up was not specified.<sup>11</sup> Reconstructive failure (with or without return to the operation room, based on 7 studies) was observed in 0-3% of autologous breast reconstruction patients and 0-28% of TE/I patients; reconstructive failure necessitating return to the operation room (based on 4 studies) was observed in 0-1% of autologous breast reconstruction patients and 4-28% of TE/I patients. It should be noted that the high upper limit of the range in TE/I patients is actually due to 1 study<sup>15</sup> which reported a much higher rate (28%) than the ones of the other studies (0-11%).

Wormald et al. reported that total **flap failures** were observed in 0-6% (8 studies) and 0-10% (6 studies) of women receiving unilateral and bilateral DIEP reconstructions, respectively.<sup>12</sup> Partial flap failures were observed in 0-16% (6 studies) and 0-4% (4 studies) of women receiving unilateral and bilateral DIEP reconstruction, respectively. The authors hypothesize in the discussion that "the difference in risk of partial flap failure is most likely to be due to the increased sample size of the unilateral group rather than any true difference in risk."

**Wound dehiscence**

Wound dehiscence with or without return to the operation room was noted in 0-4% of autologous breast reconstruction recipients and 4-12% of TE/I recipients (6 studies).<sup>11</sup> No incidence rates for wound dehiscence were reported in the Wormald et al. review.

**Flap infection (excluding donor-site infection)**

Tsoi et al. reported incidence rates ranging between 0 and 13% for autologous breast reconstruction recipients versus 0-35% for TE/I recipients, based on 9 studies.<sup>11</sup> Surgical site infections necessitating a return to the operation room occurred in 0-2% of autologous breast reconstruction recipients and in none of the TE/I recipients (based on 2 studies). Post-operative infections were reported in 3-24% of unilateral and 0-7% of bilateral DIEP recipients.<sup>12</sup> The review authors do not give any explanation for these seemingly contradictory results.<sup>12</sup>

**Fat necrosis<sup>b</sup>**

Eleven studies included in the Tsoi et al. review reported on skin/fat necrosis; incidence rates ranged between 0 and 24% in the autologous breast reconstruction recipients and between 0 and 8% in the TE/I recipients.<sup>11</sup> The incidence rates for the unilateral DIEP recipients ranged between 6 and 46% (7 studies), whereas for the bilateral DIEP recipients they ranged between 2 and 38% (6 studies).<sup>12</sup>

Khansa et al. (2013) focused their systematic literature review on fat necrosis in autologous abdomen-based breast reconstruction.<sup>13</sup> The ranges of fat necrosis incidence rates were reported by autologous breast reconstruction procedure: pTRAM: 6.8-60%, fTRAM: 2.1-28.6%, DIEP: 3.3-42.9% and SIEA: 5.7-13.5%.

**Haematoma or seroma<sup>c</sup>**

In the Tsoi et al. systematic review haematoma and seroma were taken together. They were reported in 0-5% of autologous breast reconstruction recipients and 0-10% of TE/I recipients (7 studies).<sup>11</sup> Breast haematoma were observed in 0-10% (5 studies) and breast seroma in 0-6% (3 studies)

of unilateral DIEP recipients; the respective ranges for the bilateral recipients were 5-10% (3 studies) and 2-13% (2 studies).<sup>12</sup> The increased incidence of haematoma in bilateral DIEP flap breast reconstruction may – according to the review authors – be related to the propensity for bilateral reconstructions to be performed as immediate procedures, whereas unilateral reconstructions may be more often delayed and apparently immediate reconstruction carries a higher risk of haematoma than delayed. The review authors refer to the Sullivan et al. (2008) publication which observed a higher incidence of haematoma in the immediate reconstruction group compared to the delayed group.<sup>19</sup>

**Vascular complications**

In the Tsoi et al. systematic review vascular complications (i.e. venous thrombosis/pulmonary embolism) were reported in 1-8% of autologous breast reconstruction recipients and 0-10% of TE/I recipients (4 studies).<sup>11</sup> In the Wormald et al. systematic review, vascular complications as a whole (by the review authors defined as 'all complications related to vascular compromise of the flap, i.e. venous congestion/thrombosis, arterial ischaemia/thrombosis) were reported in 1-20% of women receiving a unilateral DIEP reconstruction (7 studies) and 0-13% of women with a bilateral DIEP reconstruction (6 studies).<sup>12</sup>

Since there were no randomized studies, and we restricted the search to systematic reviews that appeared to be based on short-term observational studies, the level of evidence of the reported finding is low.

**2.3.1.1 Discussion**

The results described above should be interpreted with caution since the primary studies on which the systematic reviews are based had serious methodological limitations (see evidence tables in the Appendix). The most

<sup>b</sup> Fat necrosis is a common complication in autologous breast reconstruction.<sup>13</sup> It presents as a nodule or mass that can be palpated after reconstruction.<sup>16</sup> It is caused by ischemia of the subcutaneous adipose tissue, leading to adipose cell necrosis, scarring, and sometimes calcification. Although fat necrosis is not inherently dangerous, it can mimic breast cancer recurrence both clinically and radiographically. Clinically, it may feel benign when it consists of a smooth round nodule, but it can be an irregular, fixed mass with skin retraction.<sup>16</sup> On mammography, it can appear as an irregular density,

spiculated mass, or microcalcifications.<sup>17</sup> When it mimics cancer recurrence, fat necrosis can lead to patient anxiety and additional biopsies.<sup>18</sup> Fat necrosis can also negatively affect cosmetic outcome by causing distortion of the reconstructed breast.<sup>13</sup>

<sup>c</sup> Not defined by the authors.



important limitation is the fact that none of the studies were randomised, hence selection bias is highly probable. Some studies adjusted for confounding factors, but many studies did not report baseline patient characteristics hence “it was impossible to explore the potential effects of confounding and selection bias.”<sup>11</sup> Outcome reporting may have been impacted by reporting bias as blinding was not possible due to scar variation. The review authors also noted that short-term follow-up (as observed in many studies) may not adequately capture all complications. On the other hand, it is yet unclear for several complications how long optimal follow-up should be. Tsoi et al. also highlighted that in none of the included studies the surgeon’s qualification is reported, while studies in surgery suggest a learning curve (greater experience with a surgical technique may lead to fewer complications and better outcomes, e.g. Hofer et al. 2007<sup>d</sup>). As such, there is the potential that different reconstruction approaches may observe different complication rates simply because of the surgeon’s (lack of) experience.

**Other considerations** (raised by clinical experts):

- For implants it may take 15 tot 20 years before a lot of ‘complications’ appear. Hence short-term studies (included also in the above reviews) may not be appropriate to capture fully this drawback of breast implants.
- According to the FDA Update on the Safety of Silicone Gel-Filled Breast Implants (2011), the longer a woman has breast implants, the more likely she is to experience local complications or adverse outcomes. Women with breast implants will need to monitor their breasts for local complications for the rest of their lives. The most frequent complications and adverse outcomes experienced by breast implant patients include capsular contracture, reoperation, and implant removal (with or without replacement). Other frequent complications include implant rupture, wrinkling, asymmetry, scarring, pain, and infection, among others. These observations are consistent with the local complications and adverse outcomes that were known at the time of approval.

<sup>d</sup> A learning curve was found showing a risk for flap complications in the first 30 DIEP flaps of 40% and in flaps 31 to 175 of 13.8% ( $p < 0.012$ ).<sup>20</sup>

**Conclusion:**

- At present, there is insufficient scientific evidence to support or to refute that adverse outcomes are more prevalent and/or more serious in women who had an autologous breast reconstruction compared with women who had a breast reconstruction with implants.

**Question 3:** What is the impact of radiotherapy on autologous breast reconstruction?

Among the retrieved systematic reviews, 3 yielded information for this research question.<sup>21-23</sup> Rochlin et al. (2015) included 11 retrospective studies (among which 3 comparative) in order to evaluate the effect of **post-reconstruction radiation therapy** (RT) on immediate autologous breast reconstruction.<sup>24</sup> The number of flaps per study arm ranged between 14 and 149; mean follow-up ranged between 18 and 40 months (follow-up data were not provided in 4 included studies). Schaverien et al. (2013) included 25 studies (among which 10 comparative) to evaluate the impact of post-reconstruction RT on immediate autologous breast reconstruction.<sup>25</sup> The characteristics of included studies were scarcely described.

No systematic review was identified that evaluated the impact of **pre-reconstruction radiation therapy** by comparing the clinical outcomes in women who had an autologous breast reconstruction performed after radiotherapy with women who had an autologous breast reconstruction without radiotherapy. In order to evaluate the impact of pre-reconstructive radiotherapy on the clinical outcomes of an autologous breast reconstruction, we had to rely on studies comparing immediate breast reconstruction (IBR) followed by radiotherapy with radiotherapy followed by delayed breast reconstruction (DBR). In the systematic review of Berbers et al. (2014) 37 prospective and retrospective studies were included, among which 7 made a direct comparison between reconstruction before or after RT.<sup>22</sup> A total of 2683 patients were identified from these studies, of whom 1635 were treated with autologous reconstruction, including 175 patients



with an additional implant (autologous as well as TE/I reconstructions were evaluated). Follow-up length was not analysed. In the systematic review by Schaverien et al. (2013) 16 studies (among which 14 comparative) were included to evaluate the impact of timing of RT on the outcomes of reconstruction.<sup>23</sup> The characteristics of included studies were scarcely described.

For more information on the included studies, the reader is referred to the evidence tables in the Appendix.

The systematic review authors performed meta-analyses, but adhering to the instructions of the Cochrane Handbook on Systematic Reviews not to pool data retrieved from non-randomized studies, the pooled effect estimates are not reported here.<sup>14</sup> Instead, ranges of reported incidences are reported.

### Overall complication rate

Five comparative studies adopted in the systematic review of Schaverien et al. revealed that the incidence of overall complications ranged between 26 and 50% in the group that received RT after reconstruction compared to 18-50% in the group that did not get RT.<sup>23</sup>

Berbers et al. reported that the total complication rate ranged between 26 and 47% (6 studies) in patients who received RT before reconstruction, compared to 9-70% (2 studies) in women who had RT after reconstruction.<sup>22</sup> The respective incidence rates reported in the systematic review by Schaverien et al. ranged between 26-50% and 25-58% and were based on 6 comparative studies.<sup>23</sup>

### Reconstructive failure

Rochlin et al. reported that **total flap loss** was observed in 0-7% (8 studies) of women who received RT after reconstruction and in none of the women (1 study, n=14) who did not have RT.<sup>24</sup> **Partial flap loss** was observed in none of the women who received RT (7 studies) and in 0-2% of women who did not get RT (2 studies).<sup>24</sup>

<sup>e</sup> No difference is made between total and partial flap failure.

Berbers et al. reported that flap failure<sup>e</sup> was reported in 1-10% (5 studies) of patients who received RT before reconstruction and in 7-8% (2 studies) of patients who had RT after reconstruction.<sup>22</sup>

### Fat necrosis<sup>b</sup>

Rochlin et al. noted that fat necrosis was observed in 9-34% (6 studies) of women who received RT after reconstruction and in 0-15% of the patients (3 studies) who did not have RT.<sup>24</sup> The respective incidence rates<sup>f</sup> reported in the systematic review by Schaverien et al. ranged between 11-34% and 0-15% and were based on 6 comparative studies.<sup>23</sup>

Schaverien et al. reported that the fat necrosis rate ranged between 0 and 15% in patients who received RT before reconstruction, compared to 9-24% in women who had RT after reconstruction; these data are based on 7 comparative studies.<sup>23</sup>

### Need for revisional surgery

Rochlin et al. noted that the need for revisional surgery was observed in 0-67% (5 studies) of women who received RT after reconstruction and in 19-87% of the patients (2 studies) who did not have RT.<sup>24</sup> The respective incidence rates<sup>f</sup> reported in the systematic review by Schaverien et al. ranged between 12-67% and 17-87% and were based on 3 comparative studies.<sup>23</sup>

Schaverien et al. reported that the need for revisional surgery ranged between 6-28% in patients who received RT before reconstruction, compared to 0-18% in women who had RT after reconstruction; these data are based on 4 comparative studies.<sup>23</sup> The review authors commented on these results that "the higher percentages of revisional surgery in the IBR compared with the DBR group may be related more to the timing of surgery than to the radiotherapy."

<sup>f</sup> Not all incidence rates reported in Schaverien et al. were correctly extrapolated from the primary studies; they were checked with the original data.





### Volume loss

Rochlin et al. noted that volume loss was observed in 6-36% (2 studies) of women who received RT after reconstruction with a TRAM flap; no data were available for the no RT arms.<sup>24</sup>

### Fibrosis and/or contracture

Fibrosis and/or contracture events were reported in 3 studies included by Rochlin et al.: incidence rates ranged between 36-77% for the RT groups (3 studies) versus 0% for the no RT arms.<sup>24</sup>

Since there were no randomized studies, and we restricted the search to systematic reviews that appeared to be based on short-term observational studies, the level of evidence of the reported finding is low.

#### 2.3.1.2 Discussion

The results described above should be interpreted with caution since the primary studies the systematic reviews are based on had serious methodological limitations (see also previous discussion sections and evidence tables in the Appendix).

Also, the included primary studies varied in study design and methods. For instance, in some comparative studies (e.g. Tran et al. 2010<sup>26</sup>) contralateral breasts were compared in patients who had bilateral reconstruction but unilateral irradiation (to the breast with the higher risk of local recurrence) whereas in other comparative studies patients receiving radiation therapy after autologous reconstruction were compared with patients who underwent breast reconstruction without radiation. Some studies did not specify the number of flaps and hence it was assumed by some review authors that the number of flaps irradiated was equal to the number of patients. There were significant variations in RT treatment variables between and within the studies (e.g. fraction size, fractionation schedule, use of a boost, total dose delivered). In addition, there were insufficient data to determine whether differences existed between different flap types.

It is unclear why some studies adopted in the Schaverien et al. (2013) systematic review were not adopted in the more recent Rochlin et al. (2015) systematic review (e.g. Lee et al. 2010<sup>27</sup>, Spear et al. 2005<sup>28</sup>, Williams et al. 1997<sup>29</sup>). The reported in- and exclusion criteria do not give a plausible explanation. It could be related to the fact that Rochlin et al. limited their

search to Medline, whereas Schaverien et al. also searched in Embase and Cochrane. Last but not least, the Schaverien et al. (2013) as well as the Berbers et al. (2014) systematic review suffered from inaccurate data extraction.

### Other considerations (raised by clinical experts)

- In order to fully explore the impact of radiation therapy, long term follow-up is necessary.
- Prior RT to the parasternal, internal mammary chain may influence the patency of the microanastomosis and may result in related complications.

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### Conclusion:

- At present, there is insufficient scientific evidence to conclude that radiotherapy after autologous breast reconstruction increases the overall complication rate, the chance of reconstructive failure, fat necrosis, need for revisional surgery or volume loss. The existing scientific evidence suggests that radiotherapy after autologous breast reconstruction may increase the chance of fibrosis and/or contracture events.
  - At present, there is insufficient scientific evidence to evaluate the impact of pre-reconstructive radiotherapy on the clinical outcomes of an autologous breast reconstruction.
- 

## 2.4 General conclusions

- From a methodological point of view, the **level of evidence was low** for all research questions: none of the included studies were randomized, many studies used convenience samples (which may lead to selection bias in favour of those likely to be positive about breast reconstruction) and all suffered from serious methodological limitations. The ideal approach to evaluating the clinical effectiveness of a medical procedure would be randomized controlled clinical trials, but in the case of breast reconstruction, treatment choice depends largely on a patient's personal preference. Only patients who are completely undecided could ethically qualify for such randomization, making such a trial difficult to perform.
-



- Most included primary studies had a **short follow-up** period (or did not even mention the follow-up period), hence the long-term clinical effectiveness of the procedure is not known and not all complications may have been captured in this short period. On the other hand, it is yet unclear for several complications how long optimal follow-up should be and what the ideal time is to measure outcomes of mastectomy and reconstruction for breast cancer.
- Based on the retrieved systematic reviews, it is unclear if women who had post-mastectomy autologous breast reconstruction are more, less or equally **satisfied** than women who had post mastectomy tissue expander/implant reconstruction or women who did not have a reconstruction after mastectomy.
- Based on the retrieved systematic reviews, it is not possible to support or to refute that **adverse outcomes** are more prevalent and/or more serious in women who had an autologous breast reconstruction compared with women who had a breast reconstruction with implants.
- Based on the retrieved systematic reviews, it is unclear if **radiotherapy after autologous breast reconstruction** increases the overall complication rate, the chance of reconstructive failure, fat necrosis, need for revisional surgery or volume loss. The existing scientific evidence suggests that radiotherapy after autologous breast reconstruction may increase the chance of fibrosis and/or contracture events.
- Based on the retrieved systematic reviews, it is not possible to evaluate the impact of **pre-reconstructive radiotherapy** on the clinical outcomes of an autologous breast reconstruction

### 3 BELGIAN PRACTICE: ANALYSES OF BELGIAN HOSPITAL ADMINISTRATIVE DATA

#### 3.1 Introduction

The aim of this part of the research project is to get an insight in actual Belgian hospital practice concerning breast reconstructions and their aftermath. To do so we have at our disposal the entire national hospital stays database (NHDB) including coded clinical data (Minimal Clinical Data - MCD) as well as refund data under national health insurance covering (Hospital Billing data - HBD).

##### 3.1.1 Main characteristics of the data sources

Essential characteristics of this hospital stays database, obtained by linkage of the two above mentioned sources, are outlined in Appendix 2. However, it is important to emphasize that MCD registration being mandatory for each inpatient as well as day-care stay in every licensed Belgian general hospital, the resulting database reflects full (hospital) population data. HBD, on the other hand, only contain refunds under compulsory health insurance, hence excluding all other payments (private insurance, labour accidents,...) as well as patients' shares (not all 'official' co-payments are registered and data on paid supplements are entirely lacking). Apart from these latter restrictions, HBD contain all refunds, directly or indirectly paid for by national health insurance (RIZIV-INAMI). In this perspective they are fully comprehensive.

The difference in scope between the two sources implicates that:

- MCD always count more stays than HBD (in fact all stays versus all RIZIV-INAMI refunded stays).
- Linkage of both MCD and HBD is only possible for stays under compulsory health insurance refund regime.



### 3.1.2 Cross-sectional data window

At present the last available year of linked hospital data is 2011. Since 2007 was hallmarked by profound changes in hospital financing – especially for surgical day-care – as well as a fundamental reform of the MCD data registration model, we took 2008 as starting year, even if in that year RIZIV-INAMI nomenclature of mammary resections was thoroughly upgraded to current ‘state of the art’ surgical practice, with obsolete codes being abrogated and many new ones being introduced. The consequences are briefly illustrated in Appendix 4.

## 3.2 Methods

### 3.2.1 Research questions

From a clinical perspective mammary reconstructions typically comprise a set of successive interventions, starting first of all with the removal, partial or total, of the autologous organ (mammary resection). However, not all women seek to have their breast reconstructed and different options to do so are available. Hence, it is worth knowing how many of the mastectomized patients go over to getting a reconstruction and at what time interval: immediate, early or delayed. The same questions arise for any following intervention to ‘complete’ the reconstruction.

Closely related to previous set of questions, there are yet more to be answered. For instance: how many women prefer the technically less complicated prosthesis implant instead of a more far-reaching (and more expensive) autologous reconstruction? And how many of them continue on with subsequent completion interventions? And how many need (or seek) to have their other breast ‘remodelled’ to restore satisfactory symmetry?

Next, do complications and their rates differ among types of reconstruction? And what is the long term fate of the reconstructed breast? Is long term surgical aftercare needed and under what form?

Finally, can we make any projections on future needs/demands for breast reconstructions? From the point of view of health care budgetary planning, it would be useful to have overall estimation data at hand, i.e. all-inclusive cost data per type of core intervention, expressed as reference costs for a corresponding entire hospital stay.

As for the effects of adjuvant radiotherapy of the mammary region and axilla: since this kind of external radiotherapy usually is administered on an outpatient base, hospital data records seldom contain such information (as we verified in pre-assessment). So it is beyond data coverage and consequently cannot be studied here.

In a structured manner, suitable for data-analyses, all above mentioned items can be bundled in 4 sets of research questions:

#### 3.2.1.1 Question set 1: general descriptive statistics

**Characteristics and frequencies of breast reconstructions and ensuing interventions.**

**How frequent are intervention related complications?**

Obviously, a first set of parameters to look for concerns classical general descriptive statistic such as:

- sex- and age distributions (males get mastectomies and reconstructions too)
- typology of interventions based on coding, both ICD-9-CM and RIZIV-INAMI nomenclature
- the spectre of complications and their rates
- in-hospital mortality

#### 3.2.1.2 Question set 2: can we robustly estimate time intervals between interventions?

#### 3.2.1.3 Question set 3: what are the respective fractions and ratios?

#### 3.2.1.4 Question set 4: can we calculate referential NHI cost data for those interventions?

As the current chapter is only intended to set the scene of the present report, the analyses in the present chapter are limited to these four sets of questions. Detailed analyses such as for example subpopulations differences were not considered.





### 3.2.2 Target interventions

From previous section follows that several 'target' interventions need to be spotted and investigated. Mammary reconstructions alone will not be sufficient, especially if we want to measure and compare intervals between interventions. Consequently we need to investigate a rather broad spectre of surgical interventions on the breast and their intervention dates:

- All mammary resections in all kinds, total, subtotal, partial or even less (resections for e.g. micro-calcifications can be mutilating).
- All mammary reconstructions, whatever method used.
- All following secondary completion interventions, in particular hetero-lateral mammary remodelling (HERM), nipple reconstruction and tattooing of the areola (provided sufficient sample sizes).
- Interventions for specific complications, such as implant removal or implant revision.

### 3.2.3 Selection criteria for data extractions

To extract all needed records from the voluminous NHDB we need to establish lists of selection criteria based on the presence in these records of specific codes, in first instance those representing the target interventions. Unfortunately, MCD and HBD use different coding systems for interventions: Belgian ICD-9-CM procedure codes in MCD and RIZIV-INAMI nomenclature codes for HBD. Matching both is seldom straightforward, since they have totally different rationales and objectives (hospital case-mix monitoring versus primarily health insurance accountancy for hospital care). Moreover, for a well thought and representative extraction the applied selection criteria (code lists) need to be as specific as possible, which regrettably not always is the case. Consequently we need to make a judicious balance between specificity (resulting in extraction confinement) and sensitivity (getting sufficient extractions and hence acceptable exhaustiveness). Since we investigate several target interventions, code flags were added indicating which target is involved. Some codes, however can cover two targets, as is for instance the case with codes for mammary resection combined with simultaneous reconstruction by mammary prosthesis.

Next, and mainly for elimination purposes, some subsidiary flags were added: (1) for mammoplasties, either for reduction, either for augmentation

(by prosthesis) and (2) for other mammary interventions, not classifiable in one of the other groups.

#### 3.2.3.1 Selection criteria based on ICD-9-CM procedure codes

The methodology for elaboration of this list is extensively described in Appendix 3. The resulting selection list in Table 3 of the latter comprises a set of relevant ICD-9-CM procedure codes, each code flagged for suitability (or not) for record selection and primary extraction.

#### 3.2.3.2 Selection criteria based on RIZIV-INAMI billing codes

Full details and comprehensive listing of relevant RIZIV-INAMI codes is presented in Appendix 4. However, as with ICD-9-CM codes, some of them are not suitable for primary selection, since they are insufficiently specific and hence would induce extraction of unwanted stays, as is flagged in Table 3 of the latter. Table 4 flags them for target intervention.

#### 3.2.3.3 Selection criteria based on ICD-9-CM diagnoses codes

Composing a list of relevant ICD-9-CM diagnosis codes follows the same methodological principles as for procedure codes. Full detail is given in Appendix 5. Since our project primarily focusses on interventions, ICD-9-CM diagnosis codes play a secondary role for actual selection and extraction. Nevertheless, if we are to investigate complication rates of and indications for those interventions (i.e. underlying diagnoses), some selection based on relevant diagnosis codes is necessary. Moreover, some ICD-9-CM V-codes concerning factors influencing health status and contact with health services (code range V01-V92) can give us an unambiguous clue to indications for planned plastic surgery interventions, e.g. V5041 - prophylactic breast removal. Consequently Table 3 in appendix 5 will also be necessary for record extraction.

### 3.2.4 Data extraction, transformation and loading (ETL)

ETL of selected hospital data records typically requires several operational components (Figure 1).

First extraction of all records matching one (or more) of the primary selection code lists. Next, for all linked stays – i.e. having an unambiguous unique patient identifier (UPP) – we can longitudinally extract all other stays of those patients in the 2008-2011 data window. Indeed, if we are to



investigate delayed complications we need to examine not only stays of the target interventions (index stays) but also any ensuing stay. Moreover, in order to classify patients into clinical subgroups – for instance the breast cancer group – it certainly can prove worthwhile to look at preceding stays, possibly containing relevant diagnostic clues.

Between first and second extraction rounds, as well as after the second round some data transformation is needed by adding qualitative and quantitative variables: the former mainly by adding subgroup flags, the latter by calculating age at intervention – in so far not yet provided by the source data – followed by grouping per age range (in 5 years intervals), as well as calculation of the (data)follow-up duration, i.e. time from index intervention to end of observation period (31/12/2011). To complete this work a flag 'in-hospital death' is added (derived from two source data variables).

Another important added variable is an inclusion-exclusion flag for each extracted stay (see Appendix 6).

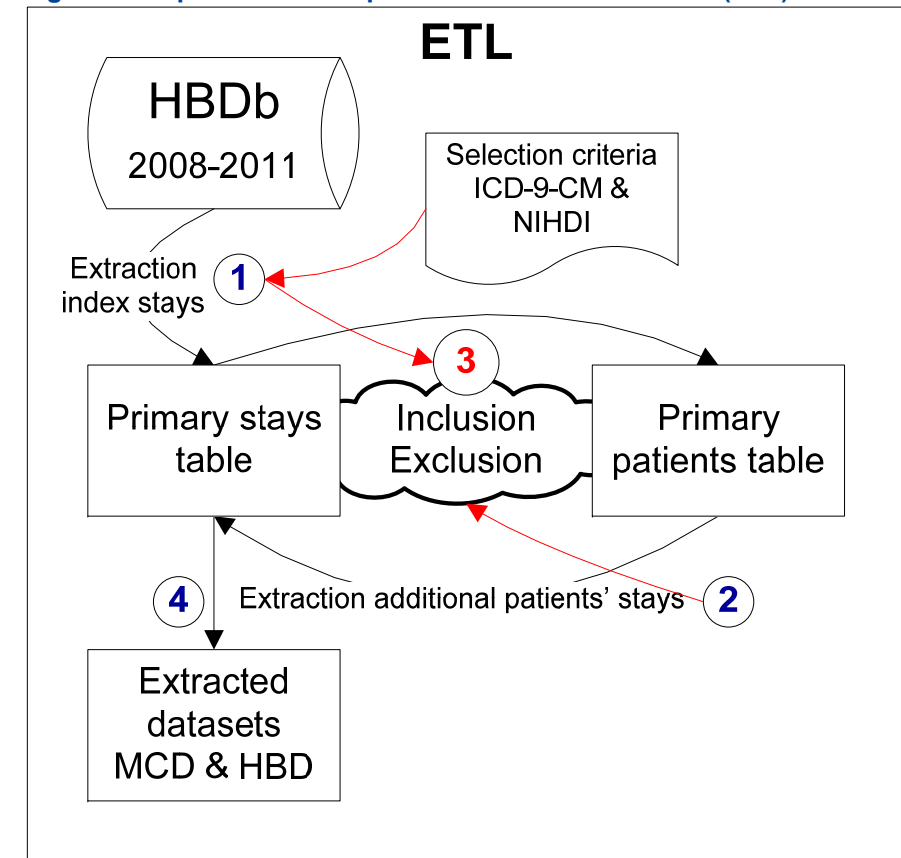
All extracted data records with all added subgroup and exclusion variables are assembled in a first main table, the *primary stays table*. Its primary key is the stay record identification number. From this first table a second one is derived, having the UPP as primary key and serving as a container for all patient related data.

This *primary patients table*, of course, will only contain records of patients with unambiguous UPP. It assembles, besides the UPP, all patient related variables present in the source data such as sex and year of birth, as well as the same subgroup flags and the inclusion-exclusion flag, be it assigned at patient level. The latter is obtained by per patient grouping of all stays' flags followed by:

- for each subgroup flag: attributing a score 1 to the patient, if present in at least one of her/his stays;
- for the inclusion-exclusion flag: attributing the least stay-level score found, e.g. if all stays of a same patient have an exclusion score 4 – meaning age at admission under 15 years – the corresponding patient flag will be 4, meaning that this patient will be totally excluded. If however the patient has at least one stay with admission age 15 or more years, her/his overall exclusion score will be 0, i.e. she will be included.

In the final phase of ETL, we need to extract all data of selected stays figuring in the secondary NHDB data sets (step 4 in figure 1; see also Appendix 2 for details of secondary NHDB data sets).

**Figure 1 – Operational components of data extractions (ETL)**





### 3.2.5 Checking exhaustiveness of data extraction

After the inclusion-exclusion exercise, exhaustiveness is checked for all principal target interventions. For each of the corresponding RIZIV-INAMI code pairs exhaustiveness is expressed as percentage of included interventions compared to interventions in the entire 2008-2011 HBD. The same exercise is done for ICD-9-CM procedures in MCD and for stays in the principal breast related APR-DRG. For more details: see Appendix 7.

Anyhow, achieved levels of exhaustiveness match a more than satisfactory representativeness.

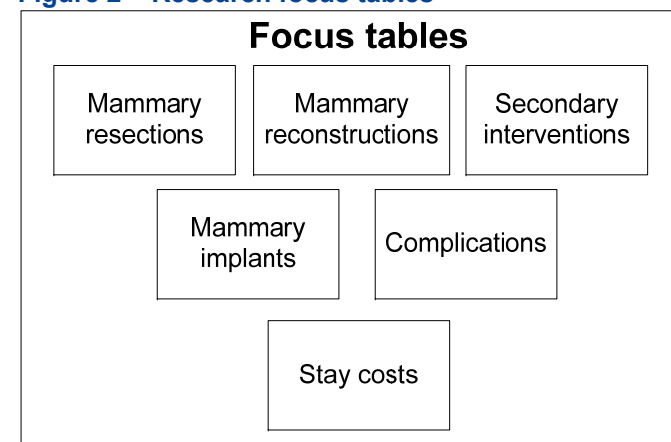
### 3.2.6 Check marking codes and stays for breast cancer

Looking at breast cancer involvement for stays and patients entails a specific clinical subgroup flag, intended to differentiate breast cancer related cases from non-breast cancer cases. Its assignment (1 or 0) however is quite complex, involving besides direct criteria (specific breast cancer codes) a number of less straightforward, contextual criteria, discussed in Appendix 8.

### 3.2.7 Research focus tables

Having now at our disposal 2 primary tables containing all essential stays' and patients' characteristics and added flags, it seems rather straightforward to create a number of focus tables, one for each research target (Figure 2).

Figure 2 – Research focus tables



However, some considerations concerning their primary key are needed. The latter, a fortiori, will be a composite one with added variables. Indeed, if we are to compare types of reconstruction, we need to consider numbers of interventions, not numbers of stays since multiple interventions can occur during the same stays (synchronous or metachronous) and patients can have more than one mammary reconstruction: obviously bilateral mammary reconstructions exist (synchronous or metachronous), moreover patients can get redo reconstructions too.

Consequently, the primary key for each focus table must contain following mandatory variables (index fields):

- The primary stay key
- The date of the intervention
- The type of intervention, as is discussed in section 3.2.8
- A flag indicating synchronous intervention, bilateral or unilateral multiple (in fact a counter: value 1 or 2)

In other words, it is important, in looking at the results of this study, to constantly keep in mind what units actually are counted: patients, hospital stays or interventions. Essential differences between are highlighted in Table 3.

**Table 3 – Distinctions between counting patients, stays and interventions**

3 distinct numerators		Context
N_patients	Counts patients having a distinct UPP, regardless number of stays or interventions (independent counting). Omits all records without UPP: 1. no primary linkage: mostly 'private insurance stays' i.e. not reimbursed by compulsory health insurance 2. rejected linkage: non matching UPP or non-unique 'pseudo UPP' (foreign patients) or rejection based on tertiary validation (stays with diff. birth year and/or sex for same UPP)	
N_stays	Counts stays, regardless number of interventions during stay	
N_interventions	Counts actual number of interventions: 1. for HBD records: by differentiating based on norm code: value 0 = principal intervention; 5 = any additional related intervention (can be more than 1) 2. for MCD records: ICD-9-CM procedure codes explicitly referring to unilateralism → counter = 1; those explicitly referring to bilateralism → counter = 2 3. Coded 'number of procedures same day': proofed unreliable	
UPP = Unique Personal Pseudonym		
HBD = Hospital Billing Data = AZV/ADH (NI) = SHA/HJA (Fr)		
MCD = Minimal Clinical Data = MKG (NI) = RCM (Fr)		

For complications, however, breakdown to intervention level is practically impossible since the majority of complications are registered at stay/department level (a fortiori either on admission, either occurring in-hospital) and not at actual intervention level. So for complications maximum (attainable) granularity is at stay level.

### 3.2.8 Grouping interventions and complications

Besides the index fields, each focus tables contains a field indicating the specific subgroup the corresponding intervention or complication is assigned to. Indeed all targeted interventions come in many technical variants, each with different code(s). So they need some kind of well thought grouping. Obtaining practical operability without losing clinical relevance is our principal objective and in doing so we considerably simplify future querying.

Based on main surgical characteristics we can group breast reconstructions in three main types:

- Reconstructions by means of a mammary implant, i.e. an implantable silicone prosthesis.
  - Reconstructions by means of an autologous myo-cutaneous flap with a vascular pedicle that is preserved; such flaps are called transposition flaps or tunneled flaps.
  - Reconstructions by means of an autologous myo-cutaneous flap with a vascular pedicle that is carefully prepared, next cut and then re-implanted on a new axillo-pectoral or intercostal vascular pedicle by means of a micro-vascular surgical anastomosis involving an OR microscope. Such flaps are called free flaps.
  - The latter two groups have different subtypes, depending on the donor site of the flap.
- Complications can be grouped in four main categories:
- Implant related complications, early (infection, rejection) as well as delayed (relative size, capsular contraction)



- Flap related complications, usually early (flap ischaemia or even necrosis)
- Surgical site complications, either early and related to impaired wound healing (bleeding, infection, disruption), either delayed and related to impaired scar formation (keloid, granuloma, foreign body, defect)
- Finally, complications related to reconstruction morphology (disproportion, deformity).

Reference tables for grouping intervention and complication codes figure in Appendix 9.

### 3.2.9 Investigating complications in administrative hospital data

When it comes to rating of complications in the NHDB, we have to address some particular methodological issues.

#### 3.2.9.1 Caveats in dealing with hospital registrations of complications

Indeed, coding of complications in MCD registrations entails some thorny aspects:

- ICD-9-CM complication codes vary considerably from highly specific to notoriously unspecific ('other', 'NOS' & 'NEC' codes<sup>9</sup>). RIZIV-INAMI codes for billing complication treatments show similar findings.
- Some ICD-9-CM codes reflect complication 'status' (= 'on admission' & V-codes) as opposed to complication 'occurrence' (= 'in-hospital').
- Matching ICD-9-CM with RIZIV-INAMI codes for complications is often cumbersome.
- ICD-9-CM diagnoses are registered per specialism-per stay and ICD-9-CM procedures registrations sometimes show a dummy code for the related diagnosis (6% of codes for operations on the integumentary system for all extracted stays).
- 'Per stay-per code' frequencies are very likely to result in overestimation ('coding redundancy' – see also Appendix 2).

- However – without 'over stays' longitudinally – subsequent complications (ensuing stays) are missed.

To deal with all those issues, and certainly prevent as much as possible erroneous assessments, we need to:

- Carefully group target interventions in patients groups as 'homogeneous' as possible for complications (e.g. breast implants vs. flap reconstructions)
- Judiciously group ICD-9-CM complication codes, extracted from both procedures and diagnoses data sets, in clinically relevant complication groups
- Quantify complications per patient-intervention (=longitudinal) by 'binary counting' (0/1), without actually adding up single code registration frequencies ( $\Sigma n$ )

Nevertheless, we always must be very cautious with interpretations of obtained results: reliability of the underlying MCD registration should always be kept in mind.

#### 3.2.9.2 Rating complications

Since complications not only occur early post-operative, but also delayed, up to many months after interventions, we need to:

- Examine, for each target intervention, its follow-up duration (FU) in the data. In other words, and since our data window ends at 2011-12-31, we have to calculate the number of days between intervention date and 'end of data observation date'.
- Next we calculate, for each target intervention, the mean FU and its standard deviation (SD).
- Finally we discard all cases with short FU periods, the lower limit being set at Mean minus SD.

The resulting sample confinements are listed in Table 4:

<sup>9</sup> NOS = Not Otherwise Specified; NEC = Not Elsewhere Classified

**Table 4 – Sample confinements for complications rating**

Intervention group	FU in days			Residual sample size
	Average FU	St_dev	Lower FU limit	
Breast implants <sup>(1)</sup>	744	422	322	4 031
Flap reconstructions <sup>(2)</sup>	602	367	235	2 494
Heterolateral remodelling (w. or wo. prosthesis)	722	421	301	3 354
Nipple reconstruction	659	417	243	3 461

<sup>(1)</sup> all reconstructions involving a prosthesis implant; <sup>(2)</sup> any flap, unless prosthesis involved

Another concern is our window of observation: since our data are limited to a 'bandwidth' of overall four years and delayed complications of targeted interventions certainly can occur up to many years later, we must resign ourselves to those limits which unfortunately we cannot remedy. Consequently, resulting complication rates should be interpreted with extreme caution.

### 3.2.10 Investigating intervention lead times

Measuring interval periods usually implies combining data from a same patient, yet from different stays. Not necessarily however, since target interventions can occur simultaneously. Some mammary resections, for instance, are immediately followed by a reconstruction (same operation room session). The same can be the case for hetero-lateral remodelling and/or nipple reconstruction. In such cases lead times are zero.

Anyhow, to investigate interval periods between index interventions, we need longitudinal patient data and lead times are calculated by subtracting date of first intervention from that of next intervention. Classical descriptive statistics follow.

However, we do need to emphasize that lead times only can be measured for interventions that already took place: a fortiori interventions that took place after 2011 are missed (right censored). Issues concerning censored data with lead time statistics are addressed in Appendix 10.

### 3.2.11 Calculating fractions and ratios

Fractions and ratios, by definition, imply valuation of numerators and denominators.

#### 3.2.11.1 Numerators

For each index intervention we calculate from the corresponding focus table the number of interventions performed (in our time window). Since exhaustiveness of primary data extraction was excellent (see Appendix 7.1 and 7.2), these estimations are sufficiently robust.

There is however a serious constraint: we cannot count interventions that took place after 2011. So our numerators will suffer from some degree of underestimation.

#### 3.2.11.2 Denominators

Denominators present similar difficulties in valuation. Indeed, if for instance we are to calculate fractions of women having had a hetero-lateral breast remodelling after breast reconstruction, we also need to know how many women did not. Breast reconstruction is here the denominator intervention, yet we can only identify those having had one in our time slot 2008-2011. So, we miss those that took place before 2008 (left censored).

There is, however, another way to estimate our denominator from an external data source. RIZIV-INAMI accountancy department keeps annual records per intervention code of cases performed and cases booked (Doc N). If we look at sufficiently numerous years' series and assume that over





the years missing numbers (of related cases) per year compensate each other, we can estimate ratios on those data.

Analytical issues concerning censored data with valuation of numerators and denominators are also addressed in Appendix 10.

### 3.2.12 Health insurance costs calculations

From the point of view of health care budgetary planning it would be useful to have overall estimation data at hand, i.e. stay cost data per type of core intervention, expressed as reference costs for a corresponding entire hospital stay.

The concept of reference costs is not new in the context of Belgian hospital financing. In 2002 a system of reference amounts was introduced to detect and control large variability in hospital practices (Paragraphs 1-10 of Article 56ter of the Law regarding compulsory insurance for health care and indemnities, coordinated on July 14, 1994).

It was intended for harmonizing medical hospital practice (unjustified variability) by imposing fines retro-actively, be it restricted to homogeneous, frequent and less severe pathologies (selected APR-DRG and SOI 1 to 2). The reference amount is a standard by which the hospital is benchmarked and is calculated as the national average expenditure raised with 10%. The reference amounts contain the expenditures of clinical biology (with exception of the lump sum payments), medical imaging (with exception of the lump sum payments and MRI services) and other technical services (internal medicine, physiotherapy and various medico-technical services). Outliers Type II ( $Q3 + 2 \cdot IQR$ ) are excluded from the total expenditures. If the expenditures of a hospital exceed the reference amount, the surplus of expenditures can be reclaimed by the NIHDI. More details can be found in KCE Reports 121C, Feasibility study of the introduction of an all-inclusive case-based hospital financing system in Belgium, section 3.4.3.3. Full implementation of the system took many years with several regulatory modifications.

Since the publication of KCE Report 121, however, minds gradually turned to a broader approach to the concept of reference costs. In that spirit we calculated reference costs including all components of hospital refunding for major categories of breast reconstructions and secondary interventions.

The resulting reference costs, however, are not intended for benchmarking hospitals but to provide overall estimation data, useful for health care budgetary planning.

#### 3.2.12.1 Components of in-hospital health insurance costs

Refunding of costs incurred with hospitals stays covers different groups of services (see also Appendix 2):

- Hospital stay day remunerations extrapolated to 100% to include BFM financing. Indeed, hospital refunding for daily nursing care, main component of the biannually fixed Budget Financial Means (BFM), travels through a dual financing pathway: one (about 20% of the BFM) by means of per stay invoicing of 'per admission' and 'per diem' lump sums, different for each hospital, and the remaining 80% via directly transmitted monthly allowances, independent of hospital admissions. To account for these considerable hospital allowances (not registered in the HBD) per admission and per diem lump sum amounts are substituted by 100% extrapolated per diem amounts.
- Medical & paramedical fees
- Lab tests
- Pharmaceuticals: all totally or partially reimbursed pharmaceuticals. Most of them fall under a (partial) lump sum system (see KCE Report 121C).
- Implants, implantable medical devices & disposables
- Costs for blood & derivatives, radio-isotopes, etc.

#### 3.2.12.2 Sample confinements to reduce confounding effects of severe co-morbidity

A major drawback of such 'inclusive' per stay cost calculation is that costs related to co-morbidity are also included and the latter are responsible for quite a lot of cost variability (justified variability). To remedy this, a number of restraints can be set:

- Restriction to principal APR-DRG 363 (Appendix 3), since finding a mammary reconstruction or a secondary intervention in other APR-DRG ipso facto indicates other significant surgical pathology



- Exclusion of severity of illness (SOI) 4, containing the highest co-morbidity cases
- Exclusion of multiple intervention stays (simultaneous or metachronous)
- Exclusion of simultaneous combinations of different types: resection-reconstruction / reconstruction - completion
- Excluding type II outliers with outlier definition =  $Q3 + 2 \times (Q3 - Q1)$ , same definition as used in the system of reference amounts.

### 3.3 Results

In this section we will report and comment answers to the 4 sets of questions formulated in section 3.2.1.

#### 3.3.1 General results for index interventions

##### 3.3.1.1 Mammary resections

Table 5 presents annual numbers for interventions, hospital stays and patients. Figures refer to all mammary resections, tumorectomies for breast cancer included. The prominent higher numbers for 2008 are entirely attributable to a profound reform of related RIZIV-INAMI nomenclature as we discussed in Appendix 4. Numbers are given for 'all' (including males and ages < 15 yr<sup>h</sup>, as well as non linked stays) versus those for females ≥ 15 yr. Exhaustiveness (in %) gives the fraction of the latter.

<sup>h</sup> It should be noted that below 15 years, all reasons were related to malformations or benign disorders of the breast

**Table 5 – Mammary resections 2008-2011**

Registration years					
N_interventions	2008	2009	2010	2011	2008-2011
N_all	17 085	13 360	13 531	14 601	58 577
N_fem. ≥ 15 yr.	15 413	11 830	11 934	12 883	52 060
Exhaustiveness (%)	90.2%	88.5%	88.2%	88.2%	88.9%
N_stays	2008	2009	2010	2011	2008-2011
N_all	16 154	12 677	12 774	13 665	55 270
N_fem. ≥ 15 yr.	14 843	11 493	11 548	12 415	50 299
N_patients	2008	2009	2010	2011	2008-2011
N_all	14 646	11 632	11 775	12 530	50 583
N_fem. ≥ 15 yr.	13 722	10 748	10 845	11 616	46 931

Mammary resections are mainly performed for breast cancer related indications, curative as well as prophylactic (Table 6). Non breast cancer related mastectomies are remarkably less frequent (6.6% for females ≥ 15 yr.) and a lot of them are under private insurance covering (50.9%) indicating aesthetic indications that are not accepted for reimbursement, e.g. subcutaneous mastectomy combined with prosthesis implant.

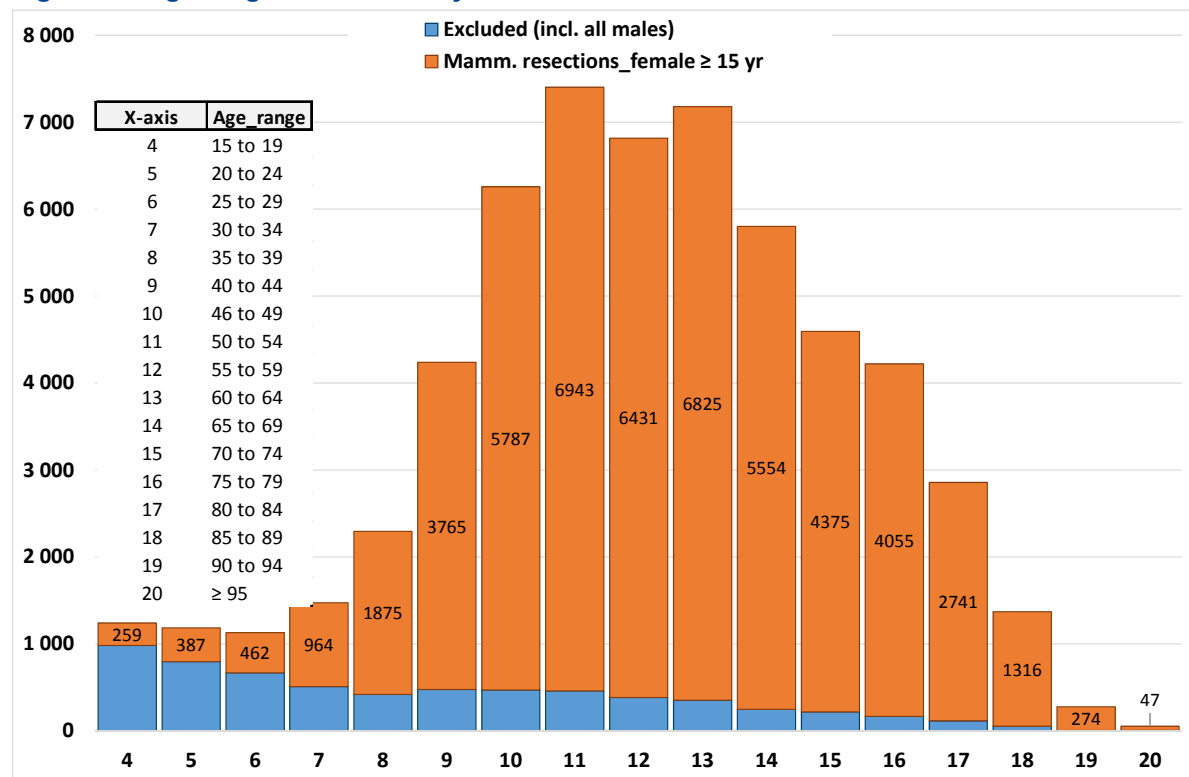
**Table 6 – Mammary resection and breast cancer**

Breast cancer related (*)	All	Fem ≥ 15 yr.	Exhaustiveness (%)
Yes	50 132	48 605	97.0%
No	8 445	3 455	40.9%
Total	58 577	52 060	
Fraction Breast CA (%)	85.6%	93.4%	

(\*) curative - partial, total or extended - as well as prophylactic mastectomies

Age ranges at intervention are presented in Figure 3. Remarkably breast resections can occur at ages under age 40, which usually reflects hereditary, familial predispositions. Mammary resections also occur at ages > 90, be it rarely.



**Figure 3 – Age ranges for mammary resections 2008-2011**



Finally follow up times for mammary resections are calculated, i.e. time between intervention and end of data observation period (31/12/2011). Statistics are presented in Table 7.

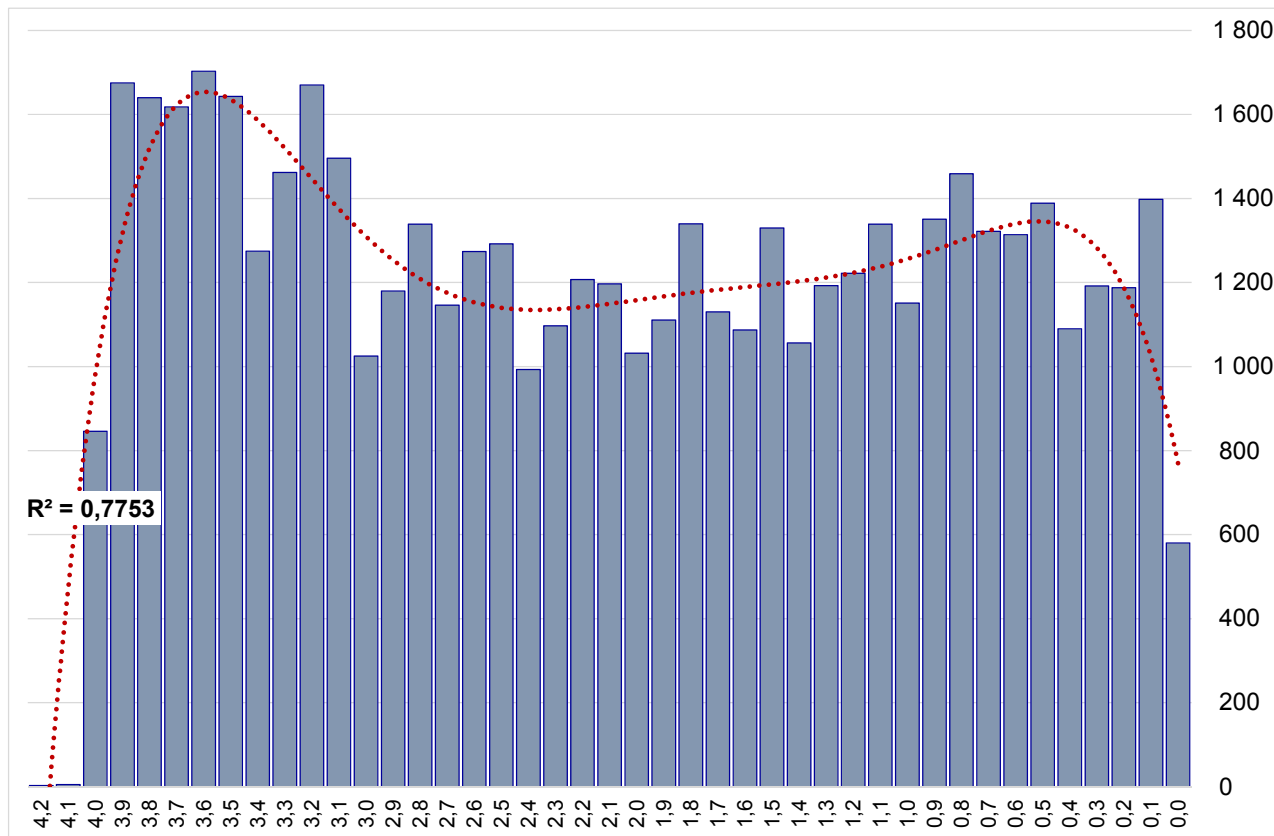
Figure 4 gives a distribution per tenths of years plotted in reverse order, i.e. from older (2008 - left) to recent (2011- right). Consequently, the drop in the trend line at the right of the histogram *only reflects absence of data after 2011 (end of observation period, no prediction value)*.

**Table 7 – Post-mammary resection follow up periods**

Mastectomies in 2008-2011 (N = 52 060)			
	FU in days	FU in months	FU in years
Min	1	-	-
Max	1 536	51.2	4.2
Mean	760.5	25.3	2.1
Median	771.0	25.7	2.1
IQR	786.0	26.2	2.2
SD	436.6377	-	-
Variance	190652.5334	-	-
CV	0.57	-	-
Lo 95% CI	756.7	25.2	2.1
Up 95% CI	764.2	25.5	2.1



Figure 4 – Frequency histogram for FU periods post mammary resection





In the histogram above we find – at the left side - some mammary resections having a FU period greater than 4 years (4.1 & 4.2): indeed, since registration of hospital stays is based on date of discharge, the 2008 data contain some, be it few mammary resections dating from last 2 months of 2007.

### 3.3.1.2 Mammary reconstructions

Based on main surgical characteristics we can group breast reconstructions in three main types:

- Reconstructions by means of a mammary implant, i.e. an implantable silicone prosthesis.
- Reconstructions by means of an autologous myo-cutaneous flap with a vascular pedicle that is preserved; such flaps are called transposition flaps or tunnelled flaps. Standard TRAM as well as LDF belong to this category. Yet other variants exist.

- Reconstructions by means of an autologous myo-cutaneous flap with a vascular pedicle that is carefully prepared, next cut and then re-implanted on a new axillo-pectoral or intercostal vascular pedicle by means of a micro-surgical vascular anastomosis (MSVA) involving an OR microscope. Such flaps are called free flaps. Examples are DIEP, SIEA and GAP, but other variants exist.
- The latter two groups have indeed different subtypes, depending on the donor site of the flap.

Table 8 shows numbers for different types of breast reconstruction interventions. Prosthesis implants are clearly in majority (48.8%), followed by DIEP (30.8%) and LDF 12.0%). All other variants are quite occasional.

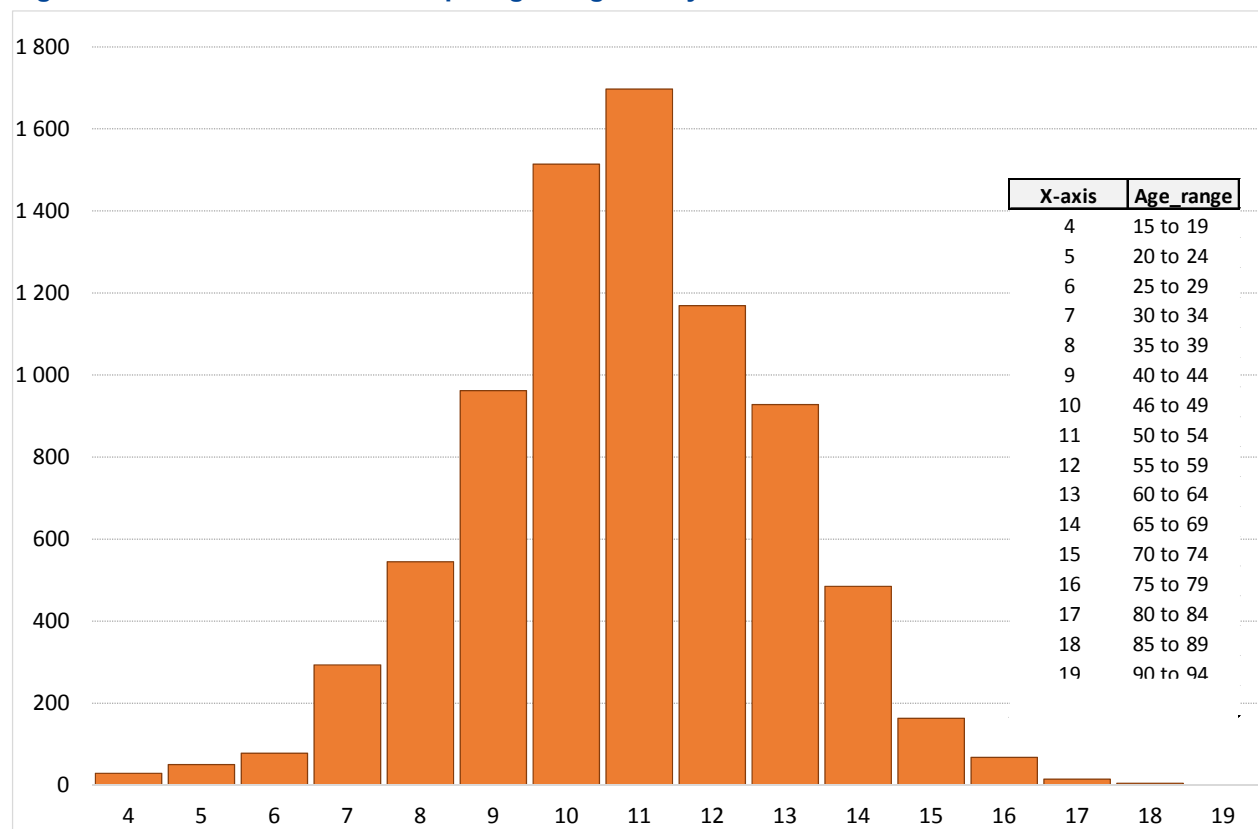
**Table 8 – Number of breast reconstructions interventions (females ≥ 15 yr.) - 2008-2011**

Subgroup	2008	2009	2010	2011	2008-2011	Col %
Rec_prosthesis	1 028	1 027	912	940	3 907	48.8%
Rec_free DIEP	39	774	773	877	2 463	30.8%
Rec_pedicled LDF	297	216	232	216	961	12.0%
Rec_other pedicled flap	80	88	123	135	426	5.3%
Rec_pedicled TRAM	5	39	46	38	128	1.6%
Rec_free GAP	0	15	17	31	63	0.8%
Rec_other free flap	3	11	10	13	37	0.5%
Rec_free SIEA	0	4	6	7	17	0.2%
<b>Grand Total</b>	<b>1 452</b>	<b>2 174</b>	<b>2 119</b>	<b>2 257</b>	<b>8 002</b>	



Figure 5 represents age distribution in 5 years ranges. Apparently reconstructions can occur at ages 75 and older.

**Figure 5 – Breast reconstructions per age range ≥ 15 year - 2008-2011**





### 3.3.1.3 Secondary mammary interventions

Figures for secondary 'completion' interventions are presented in Table 9. Incidences and fractions are calculated on total prior reconstructions, including those without completion intervention (N = 8 002).

**Table 9 – Secondary completion interventions with females ≥ 15 yr. - 2008-2011**

Subgroup	Prior recon <sup>(1)</sup>	No prior recon <sup>(2)</sup>	Total	Incidence <sup>(3)</sup>	Fraction <sup>(3)</sup>
Hetero-lateral remodelling mammoplasty	3 091	1 823	4 914	38.6%	2/5
Reconstruction nipple	2 818	3 441	6 259	35.2%	1/3
Lipofilling breast	280	182	462	3.7%	-
Tattoo (areola)	263	278	541	3.5%	-
<b>All breast reconstructions 2008-2011</b>	<b>8 002</b>				

<sup>(1)</sup> prior mammary reconstruction traced in time slot 2008-2011

<sup>(2)</sup> no prior reconstruction found in time slot 2008-2011

<sup>(3)</sup> left censored data, reconstructions before 2008 missing

Lipofilling of the breast, although not reimbursed, nevertheless is registered in MCD and sometimes they occur in conjunction with a reimbursed intervention (very few cases as shown in table). As for tattooing of the areola, this is often done ex-hospital, on ambulatory base. It even tends to be left to non-medical settings (private tattooists).

### 3.3.2 Complication rates

Methodological warnings concerning rating of complications in administrative hospital data are addressed in section 3.2.9. Complications of mammary resections are considered out of scope. First we address in-hospital mortality for reconstructions. Next, complications of reconstructions are bundled in 2 main groups, breast implants versus flap reconstructions. Complications of the two main completion interventions follow.

If we look at breast reconstructions, we see cases where a flap reconstruction or remodelling was combined with a mammary implant. Considering that mammary implants share a set of prosthesis-specific complications, we choose to assign them to the group of mammary implants.

Consequently the group flap reconstructions is restricted to 'flap only' interventions.

For hetero-lateral remodelling such subgroup division - implant versus no implant - was not applied.

Somewhat related to complications are concerns about the long term aftermath of the reconstructed breast; this issue is addressed in section 3.3.2.6.



### 3.3.2.1 In-hospital mortality

Since HBD data refer to hospital stays, we only can assess in-hospital mortality. Table 10 shows the latter is highly incidental and mostly concerns older patients.

**Table 10 – In-hospital mortality for mammary reconstructions**

Type of reconstruction	Age reconstr	N
Rec_DIEP	51	1
Rec_LDF	64	1
Rec_LDF	67	1
Rec_Ped	80	1
Rec_TRAM	80	1
Total:		5 (0.06%)

In-hospital mortality, however, is not a fixed period observation; indeed, it depends on length of hospital stay (LOS) which can vary (Table 11).

**Table 11 – Statistics concerning length of hospital stays**

Type_recon	N_stays	Mean LOS	Min	Max	SD	Variance	CV	Lo 95% CI	Up 95% CI
Rec_proth	3 587	3.7	0	49	4.029151322	16.23406038	1.09	3.6	3.8
Rec_DIEP	2 194	7.5	0	78	3.559381116	12.66919393	0.48	7.3	7.6
Rec_LDF	989	7.5	0	107	6.040167988	36.48362933	0.81	7.1	7.8
Rec_Ped	412	3.1	0	49	3.666307731	13.44181238	1.19	2.7	3.4
Rec_TRAM	126	10.3	0	131	13.56885012	184.1136936	1.31	8.0	12.7
Rec_GAP	61	7.8	4	40	4.859266381	23.61246977	0.62	6.6	9.1
Rec_Free	36	10.6	2	48	9.313802316	86.74691358	0.88	7.5	13.6
Rec_SIEA	14	8.4	3	20	3.639354058	13.24489796	0.43	6.5	10.3





Overall hospital stays for mammary reconstructions tend to be short to average: mean LOS (rounded) varies from 3 (pedicled flaps) to 11 days (free flaps). Numbers are per stay, not per intervention, which explains difference with the total 8 002 in Table 3.

Concerning the highly improbable zero LOS in the above table (column with minima), we can confirm that they concern very few stays,: 1 case for DIEP, 3 for TRAM, 6 for LDF, 57 for other pedicled flaps. An exception is to be made for reconstructions by prosthesis (N = 439), where a 'one day' stay seems perfectly plausible. Missing data or transfers to other hospital for complications' treatment are plausible explanations, but we did not verify this.

### 3.3.2.2 Complications of mammary implants

As stated higher the breast implant group includes flap reconstructions with added prosthesis. Statistics (Table 12) concern only mammary implants or reconstructions in 2008-2011 (left-censored data) and short FU cases were excluded for reasons explained in section 3.2.9.2. Incidences were calculated on the remainder total of 4 031 cases. Denominator for revisions of pedicle flap is 494.

**Table 12 – Complications of mammary implants**

Complication subgroup	N 2008-2011	Incidence
Removal of breast implant	638	15.8%
Mechanical complication due to breast prosthesis	348	8.6%
Revision of breast implant	338	8.4%
Capsular contracture of breast implant	68	1.7%
<b>All implant complications taken together</b>	<b>926</b>	<b>23.0%</b>
Surgical site skin/subcutis (scar, granuloma, foreign body, defect)	135	3.3%
Surgical site infection	25	0.6%
Surgical site hematoma/hemorrhage	21	0.5%
Surgical wound disruption	20	0.5%
Post surgery fat necrosis of breast	20	0.5%
<b>All surgical site complications</b>	<b>207</b>	<b>5.1%</b>
<b>Revision of pedicle flap</b>	<b>12</b>	<b>2.4%</b>
<b>Disproportion/deformity of reconstructed breast</b>	<b>206</b>	<b>5.1%</b>
Other specified complications, NEC	10	0.2%

### 3.3.2.3 Complications of mammary flap reconstructions

All flap reconstructions, with exclusion of combined mammary implant cases, amount to 2 494 cases. As with implants statistics concern only mammary reconstructions in 2008-2011 (left-censored data) and short FU cases were excluded for reasons explained in section 3.2.9.2. Incidences were calculated on the remainder total of 2 494 cases (Table 13).

**Table 13 – Complications of flap reconstructions (pedicled or free)**

Complication subgroup	N 2008-2011	Incidence
Surgical site skin/subcutis (scar, granuloma, foreign body, defect) <sup>(2)</sup>	299	12.0%
Surgical site infection	67	2.7%
Post surgery fat necrosis of breast	53	2.1%
Surgical site hematoma/hemorrhage	47	1.9%
Surgical wound disruption	26	1.0%
<b>All surgical site complications</b>	<b>444</b>	<b>17.8%</b>
<b>Disproportion/deformity of reconstructed breast</b>	<b>522</b>	<b>20.9%</b>
<b>Revision of pedicle flap</b>	<b>83</b>	<b>3.3%</b>
Other specified complications, not elsewhere classified (NEC)	14	0.6%

Pure flap reconstructions as a whole (pedicled as well as free) are free of prosthesis related complications. Yet, they seem to have more surgical site related complications than mammary implants (17.8% versus 5.1% for implants OR = 7/2). Flap surgery, indeed, is more invasive than a simple breast implant and surgery duration often is considerably longer.

### 3.3.2.4 Complications of hetero-lateral remodelling

As in previous sections short FU cases were excluded for reasons explained in section 3.2.9.2. Incidences were calculated on the remainder total of 3 340 cases (Table 14).


**Table 14 – Complications of hetero-lateral remodelling**

Main complication group	N 2008-2011	Incidence
Surgical site skin/subcutis (scar, granuloma, foreign body, defect) <sup>(1)</sup>	492	14.7%
Surgical site infection	85	2.5%
Post surgery fat necrosis of breast	74	2.2%
Surgical site hematoma/hemorrhage	50	1.5%
Surgical wound disruption	33	1.0%
<b>All surgical site complications</b>	<b>665</b>	<b>19.9%</b>
Other specified complications, NEC	29	0.9%

<sup>(1)</sup> delayed complications

The high overall percentage of 19.9% (1 out of 5!) is largely explained by the high incidence for delayed skin complications (14.7%).

### 3.3.2.5 Complications of nipple reconstruction

As in previous sections short FU cases were excluded for reasons explained in section 3.2.9.2. Incidences were calculated on the remainder total of 4 027 cases (Table 15).

**Table 15 – Complications of nipple reconstructions**

Main complication group	N 2008-2011	Incidence
Surgical site skin/subcutis (scar, granuloma, foreign body, defect) <sup>(1)</sup>	439	10.9%
Surgical site infection	60	1.5%
Surgical site hematoma/hemorrhage	42	1.0%
Surgical wound disruption	26	0.6%
<b>All surgical site complications</b>	<b>579</b>	<b>14.4%</b>
Other specified complications, NEC	39	1.0%

<sup>(1)</sup> delayed complications

Early surgical site complications are scarce and – again - delayed tegumental complications predominate.

### 3.3.2.6 Aftermath of the reconstructed breast

A last issue to address concerns the question what happens to the reconstructed breast beyond (registered) complications? In other words, which later interventions (RIZIV-INAMI billing codes) do we find? Table 16 gives us some clues.

**Table 16 – Corrections for nipple retraction & additional skin grafting in post-reconstruction stays**

Type of intervention <sup>(1)</sup>	Incidences (%)	
	Breast implants	Autologous reconstructions
Nipple retraction	1%	1%
Additional skin grafting	53%	33%
<b>Denominators (patients)</b>	<b>3 155</b>	<b>2 403</b>

<sup>(1)</sup> Interventions counted per patient, irrespective multiplicity

Interventions involving nipple retraction or additional skin grafting are looked for in post-reconstruction stays (excluding reconstruction stay itself). Counting is done per patient, irrespective multiplicity of interventions. However, since anatomical site information is lacking with RIZIV-INAMI billings for skin grafts (except for facial region) we must realize that over rating is quite possible (non breast site related skin grafting?).

Notwithstanding such caveat, it seems very likely that getting a complete, satisfactory breast reconstruction is not a 'few interventions project'. On the contrary, need for further 'maintenance' surgery seems foreseeable. However, more in depth research on actual patient records would be necessary to elaborate this topic.



### 3.3.3 Intervention lead times

Lead time estimations require longitudinal data series, which limits us to linked stays. Moreover, our lead time estimations are impaired by considerable missing data, left- as well as right-censored (see Appendix 10). Left-censored data concern e.g. all mammary reconstructions for which a preceding mammary resection cannot be found in the 2008-2011 data window, which means they were performed before 2008. Such left-censored data are considerably numerous; 73.6% of breast reconstructions missed their resection counterpart in our data.

Right-censored data concern interventions that were not yet done in 2008-2011, i.e. interventions done after 2011. Their fraction is hard to estimate (from assumption extrapolations on available 2008-2011 data) since this category covers 2 distinct subpopulations:

- reconstructions after mammary resections too close to end date of data observations, i.e. short follow up resections (in particular those in 2011 – see also Table 7, page 36);
- late to very late reconstructions. Indeed, breast reconstructions may be performed even years after mastectomy; hence these are impossible to estimate from available 2008-2011 data. Moreover, no related data were found in the scientific literature.

Similar considerations apply to secondary interventions. However, since such interventions are the logical consequence of a decision to get a breast reconstruction, we would expect very late secondary interventions to be less frequent.

Consequently, lead time statistics presented in this section are highly biased. Yet, we will present them for documentary reasons: first for initial mammary reconstruction interventions (Table 17), next for secondary, completion interventions (Tables 18-19).

**Table 17 – Lead time statistics for mammary reconstructions 2008-2011**

Subgroup	N	Interval_range	Average_interval	Overall average interval
A Immediate reconstructions	2 084	0 days	0 days	<b>126 days (4.2 months)</b>
B Early reconstructions	25	1 to 7 days	4 days	
C Delayed reconstructions <sup>(1)</sup>	297	75 days to 3.8 yr	548 days (1.5 yr)	
D Mastectomy prior to 2008	<b>5 596</b>	no mastectomy date found prior to reconstruction date		
TOTAL mammary reconstructions	8 002			

<sup>(1)</sup> average post-mastectomy FU period 3.4 yr, range 2.5 to 4.0



Early reconstructions concern interventions billed on a different day than that of the mastectomy, be it during same hospital stays. Lead times go from 1 to 7 days. Reasons for such short delays can be various but going in to this matter would be speculating.

**Table 18 – Lead time statistics for hetero-lateral breast remodelling**

Subgroup	Heterolateral remodelling	N	Interval_range	Average_interval	Overall average interval
A	Immediate HERM <sup>(1)</sup>	1 376	0 days - (7 days)	0 days	171 days (6 months)
B	Delayed HERM	2 198	14 to 1391	277 days	
C	Reconstruction prior to 2008 <sup>(2)</sup>	388	no reconstruction date found prior to HERM (intervals unknown)		
D	Missing 'priors' (based on Doc N)	883			

<sup>(1)</sup> including 1 case 7 days after reconstruction, same hospital stay

<sup>(2)</sup> in few cases we found a HERM prior to a mammary reconstruction, so the related reconstruction had to be performed before 2008

**Table 19 – Lead time statistics for nipple reconstruction**

Subgroup Nipple reconstructions	N	Interval_range	Average_interval	Overall average interval	
A Early nipple reconstruction <sup>(1)</sup>	407	0 days - 7 days	0 days	<b>256 days (9 months)</b>	
B Delayed nipple reconstructions	2 921	13 to 1396	292 days		
C Mammary reconstruction prior to 2008 <sup>(2)</sup>	245	no reconstruction date found prior to nipple reconstruction (intervals unknown)			
D Missing 'priors' (based on Doc N)	1 832				

<sup>(1)</sup> only 12 immediate, 395 early

<sup>(2)</sup> in few cases we found a nipple reconstruction prior to a mammary reconstruction, so the related mammary reconstruction had to be performed before 2008

### 3.3.4 Fractions & ratios

Fractions and ratios suffer similar limitations as with lead time estimations: missing data for both numerators and denominators. Nevertheless, results based on available data are shown in Table 20.

**Table 20 – Ratios from 2008-2011 research database**

Intervention	Early		Delayed		Overall		
	N	Fraction	N	Fraction	Total	Denominator	Fraction of index
Mammary resections	-	-	-	-	<b>52 060</b>	-	-
Mammary reconstructions	2 109	1/4	5 893	3/4	<b>8 002</b>	<b>50 060</b>	<b>1/7</b>
HERM	1 376	2/5	2 198	3/5	3 574	<b>8 002</b>	<b>4/9</b>
Nipple reconstructions	407	1/8	2 921	7/8	3 328	<b>8 002</b>	<b>2/5</b>

However, missing data can be roughly extracted from RIZIV-INAMI accountancy database (Doc N) as explained in Appendix 10. In doing so we even can extrapolate our estimations beyond 2011.

**Table 21 – Fractions and ratios for mammary reconstructions estimated from Doc N**

Year	Reconstructions	Mastectomies	Fractions	Ratios
2000	1 184	9 955	12%	1/8
2001	1 407	10 615	13%	1/8
2002	1 313	10 672	12%	1/8
2003	1 479	11 200	13%	1/8
2004	1 534	11 072	14%	1/7
2005	1 483	11 101	13%	1/7
2006	1 495	11 313	13%	1/8
2007	1 515	11 337	13%	1/7
<b>2008</b>	<b>1 626</b>	<b>11 844</b>	<b>14%</b>	<b>1/7</b>
<b>2009</b>	<b>2 392</b>	<b>13 338</b>	<b>18%</b>	<b>1/6</b>
<b>2010</b>	<b>2 314</b>	<b>13 555</b>	<b>17%</b>	<b>1/6</b>
<b>2011</b>	<b>2 427</b>	<b>14 535</b>	<b>17%</b>	<b>1/6</b>
2012	2 834	14 388	20%	<b>1/5</b>
2013	2 957	14 769	20%	<b>1/5</b>

Doc N ratios for 2008-2011 (in blue) coincide well with our estimations on NHDB (previous table). Ratios in red (2012-2013) suggest a rising trend.

**Table 22 – Fractions and ratios for secondary interventions estimated from Doc N**

Year	Reconstructions	HERM	Fractions & ratios HERM	Nipple	Fractions & ratios Nipple
2000	1 184	549	46%	4/8	926 78% 6/8
2001	1 407	662	47%	4/8	914 65% 5/8
2002	1 313	674	51%	4/8	1 080 82% 7/8
2003	1 479	702	47%	4/8	1 290 87% 7/8
2004	1 534	882	57%	5/8	1 201 78% 6/8
2005	1 483	924	62%	5/8	1 183 80% 6/8
2006	1 495	892	60%	5/8	1 157 77% 6/8
2007	1 515	937	62%	5/8	1 340 88% 7/8
<b>2008</b>	<b>1 626</b>	<b>1 142</b>	<b>70%</b>	<b>6/8</b>	<b>1 395 86% 7/8</b>
<b>2009</b>	<b>2 392</b>	<b>1 180</b>	<b>49%</b>	<b>4/8</b>	<b>1 386 58% 5/8</b>
<b>2010</b>	<b>2 314</b>	<b>1 231</b>	<b>53%</b>	<b>4/8</b>	<b>1 311 57% 5/8</b>
<b>2011</b>	<b>2 427</b>	<b>1 292</b>	<b>53%</b>	<b>4/8</b>	<b>1 313 54% 4/8</b>
2012	2 834	1 388	49%	<b>4/8</b>	1 383 49% <b>4/8</b>
<b>2013</b>	<b>2 957</b>	<b>1 637</b>	<b>55%</b>	<b>4/8</b>	<b>1 340 45% 4/8</b>



### 3.3.5 Health insurance costs

Health insurance costs only concern reimbursable interventions: either reconstructions, either secondary 'completion' interventions. For the latter only three categories of interventions are reimbursed: (1) hetero-lateral breast remodelling, (2) reconstruction of areola and nipple and (3) tattooing of the areola, which is a really minor intervention done on outpatient base and frequently even in non-health care settings. All other additional interventions (e.g. lipofilling or fat graft to the breast) are considered as cosmetic interventions and hence excluded from reimbursement.

#### 3.3.5.1 Costs for mammary reconstructions

Table 23 synthesizes costs statistics for the 3 main reconstruction groups. Sample confinements were applied as discussed in section 3.2.12.2. Figure 6 represents corresponding box plots.

As expected mammary implants are less costly than pedicled flaps and free flaps with microsurgical vascular anastomosis (MSVA). The latter largely exceed the two previous groups. Main parameters (means and confidence intervals) are quite distinct. Yet, we must not forget that RIZIV-INAMI fees for corresponding interventions differ congruously: 235.10 € for a mammary reconstruction by prosthesis; 772.83 € for a mammary reconstruction by pedicled transposition flap (TRAM) and 1449.06 € for a mammary reconstruction with DIEP or SGAP free perforator flap, 1255.85 € for other free flaps (tariffs valid 2010).

Mammary implants show remarkable homogeneity: no outliers and narrow 95% confidence interval. This can be explained by the fact that a mammary implant is a highly standardized procedure, similar for all patients. Moreover, bilateral implants were excluded, as well as all cases of simultaneous mammary resection-reconstruction and combined reconstructions, i.e. flap with implant. The effect of such sample confinement shows in the lower residual sample size for implants (N = 654 as opposed to 3 907 total implants = 16.7%).

Cost variability clearly is higher with flap reconstructions, both pedicled and free. Both groups have outliers: 5% and 8% respectively. Such variability

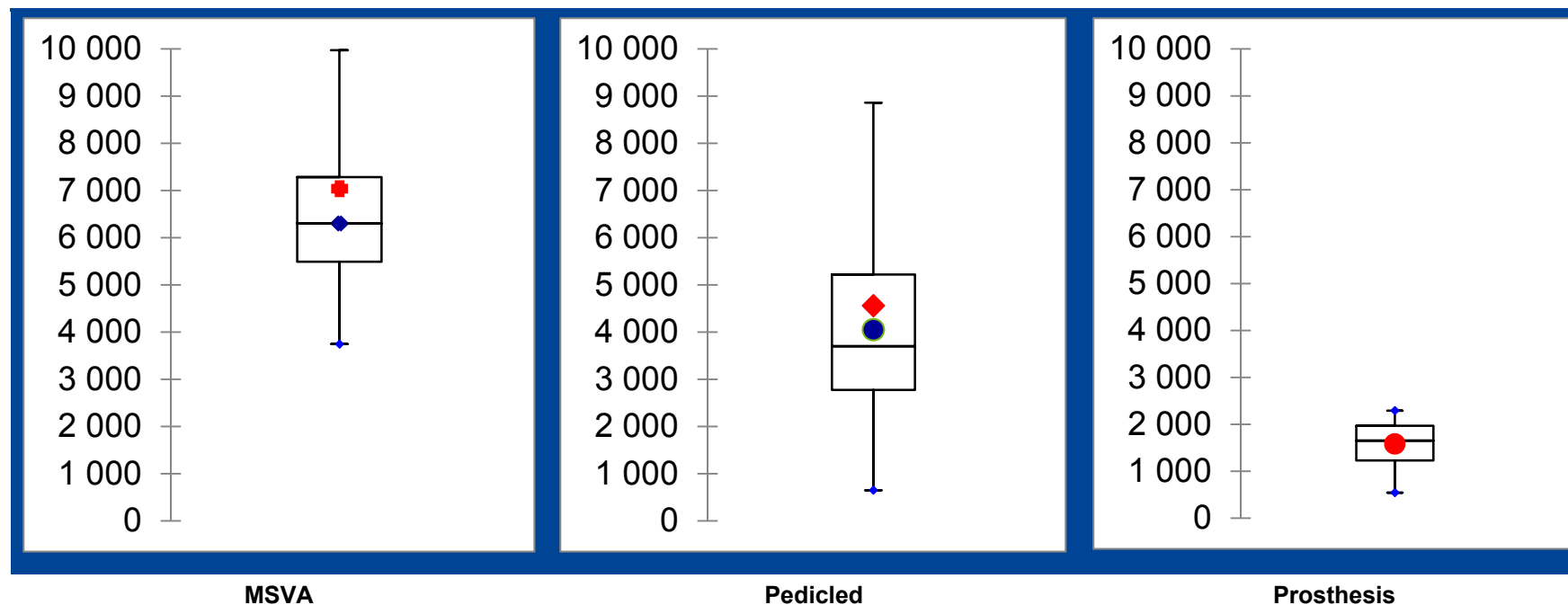
can of course be explained, at least partially, by the fact that both groups bundle different surgical techniques (see section 3.3.1.2) and some of them are more complex to carry out. Moreover, specific indications differ, resulting in different patient (sub)populations.

Anyhow, the fact that mammary reconstructions by prosthesis excel as 'low cost' intervention for health insurance, does not mean this should be the recommended reconstruction. Other, clinical as well as psychosocial factors play an important and legitimate role, not in the least individual patient choices.

**Table 23 – Health insurance cost parameters for mammary reconstructions**

Statistic <sup>(1)</sup>	MSVA	Pedicled	Prosthesis
No. of observations	1 018	1 713	654
Minimum	€ 3 746	€ 649	€ 543
Maximum	€ 46 825	€ 35 286	€ 2 291
1st Quartile	€ 5 491	€ 2 776	€ 1 230
Median	€ 6 306	€ 3 700	€ 1 653
3rd Quartile	€ 7 284	€ 5 219	€ 1 968
Mean	<b>€ 7 038</b>	<b>€ 4 561</b>	<b>€ 1 581</b>
Lower 95% CI	<b>€ 6 850</b>	<b>€ 4 453</b>	<b>€ 1 545</b>
Upper 95% CI	<b>€ 7 226</b>	<b>€ 4 704</b>	<b>€ 1 617</b>
Variance (n)	9382622,912	9173515,009	221226,997
Standard deviation (n)	3063,107	3028,781	470,348
Variation coefficient	<b>0,435</b>	<b>0,664</b>	<b>0,297</b>
Outlier limit	€ 10 869	€ 10 104	€ 3 445
No. of outliers	<b>81</b>	<b>91</b>	<b>0</b>
% outliers	<b>8%</b>	<b>5%</b>	<b>0%</b>
Right trimmed mean	<b>€ 6 304</b>	<b>€ 4 051</b>	<b>€ 1 581</b>

<sup>(1)</sup> only APRDRG 363, SOI 1-3

**Figure 6 – Box plots for total costs in 3 main groups of breast reconstructions**

*(Outliers not shown, red bullets represent mean, blue bullets right trimmed mean, no outliers for prosthesis)*





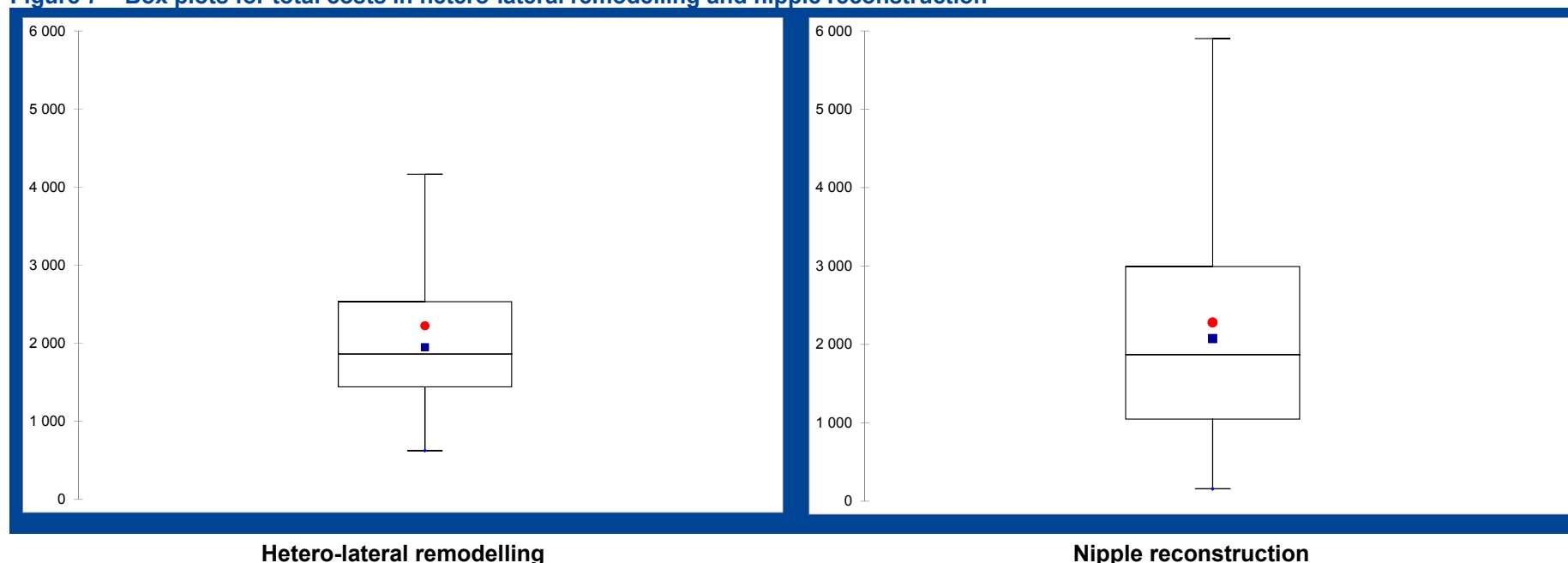
### 3.3.5.2 Costs for secondary 'completion' interventions

Table 24 summarizes costs statistics for the 2 main completion intervention groups: hetero-lateral breast remodelling (HERM) and areola-nipple reconstruction. Figure 7 represents corresponding box plots.

**Table 24 – Health insurance cost parameters for completion interventions**

Statistic <sup>(1)</sup>	HERM	Nipple
No. of observations	1655	5158
Minimum	€ 624	€ 157
Maximum	€ 22.334	€ 27.406
1st Quartile	€ 1.442	€ 1.047
Median	€ 1.860	€ 1.870
3rd Quartile	€ 2.531	€ 2.994
Mean	<b>€ 2.224</b>	<b>€ 2.278</b>
Lower 95% CI	<b>€ 2.153</b>	<b>€ 2.229</b>
Upper 95% CI	<b>€ 2.296</b>	<b>€ 2.328</b>
Variance (n)	2205351,272	3286623,528
Standard deviation (n)	1485,043	1812,905
Variation coefficient	0,668	0,796
Outlier limit	€ 4 711	€ 7 134
Outliers	<b>92</b>	<b>323</b>
Outliers %	<b>6%</b>	<b>6%</b>
Trimmed mean	<b>€ 1 950</b>	<b>€ 2 075</b>

<sup>(1)</sup> only APRDRG 363, SOI 1-3

**Figure 7 – Box plots for total costs in hetero-lateral remodelling and nipple reconstruction**

(Outliers not shown, red bullets represent mean, blue bullets right trimmed mean)

For both groups cost variability is higher than with primary breast reconstructions and nipple reconstructions show the highest variation coefficient and a wider box plot, which can be explained by the great variability in applied surgical techniques. Furthermore, both groups are closely related. So, it doesn't surprise that mean cost values differ not so much.

#### **Hetero-lateral remodelling (HERM)**

Hetero-lateral remodelling, indeed, covers different modalities. In cases of unilateral breast reconstruction, for instance, it may be difficult to attain symmetry, i.e. the same size and shape on both sides. For instance, the reconstructed breast may not droop like the natural breast; so, where

appropriate the surgeon can do a breast lift (mastopexy) on the natural breast to make it better match the reconstructed breast. In other cases the natural breast is bigger and therefore a breast reduction is needed removing unwanted skin and fat from the breast. If, on the contrary, the natural breast is small compared to the reconstructed side, a breast enlargement (augmentation mammoplasty) may be considered. Here the surgeon inserts an implant into the smaller breast to make it larger.



## Nipple reconstruction

Numerous techniques have been developed to reconstruct the nipple following mammary reconstruction. These include variations of local tissue flaps, skin grafts, cartilage grafts, tissue-engineered structures and nipple-sharing techniques, most of which are complicated and may leave residual scarring at the donor site. The nipple may be reconstructed from the surrounding skin at the site desired for nipple placement. The surgeon makes small incisions and then elevates the tissue into position, forming and shaping it into a living tissue projection that mimics the natural nipple. Older techniques, which used donor tissue from the genital region or elsewhere, have become less favoured over time.

An alternative to surgical nipple reconstruction is intradermal tattooing.

The most common problem following nipple reconstruction is a decrease in projection, or nipple flattening. Thus, methods of secondary nipple reconstruction as well as restoration of nipple projection have been reported.

Full details can be found at:  
<http://www.breastcancer.org/treatment/surgery/reconstruction/types/nipple>

## 3.4 Limitations and main figures

This chapter has the following limitation:

- Investigating administrative data from a clinical perspective always remains challenging. Indeed, deriving (co-)morbidity data from administrative databases is often criticized for lacking sufficient accuracy when used for clinical research. Granularity of the used coding systems (in this instance ICD-9-CM) is variable, with hyper granularity for some diseases (typical for TBC related codes in ICD-9-CM) and insufficient precision for other diagnosis codes. The same applies to procedure codes as well as RIZIV-INAMI billing codes. In addition, questions about the completeness of administrative data abound, certainly where it concerns registration of diagnoses, and even more for complications, as we pointed in section 3.2.9. On the other hand, it certainly is in the interest of hospitals to carefully register any relevant co-morbidity as well as complications in view of getting correct APR-DRG and SOI assignment for their stays and, overall, an accurate case-mix weighing, important determinant for their financing.
- Administrative data result from monitoring health care delivery and reimbursing for services.<sup>30-34</sup> Their operational rules ('business rules') and their objectives are quite specific and their primary accuracy is assessed for this context. Nevertheless these data are often used to evaluate the quality of health care, for health services research (HSR) and even for health technology assessment (HTA). Indeed, administrative data are readily available, are inexpensive to acquire, are computer readable, and typically encompass large populations. They have identified staggering practice variations across small geographic areas and underpinned research about outcomes of care. Many hospital benchmarking reports (comparing patient complication and mortality rates) and physician profiles (comparing resource consumption) are derived from administrative data. However, gaps in clinical information and the billing context can compromise the ability to derive valid outcome appraisals from administrative data.
- Consequently we had to be very cautious with data analyses in present study, always bearing in mind Bertrand Russell's adage 'Do not feel absolutely certain of anything'.<sup>35</sup> Checking unlikely results, proceeding with subgroup analyses for particular subpopulations, reconsidering selection criteria for querying and, if needed, starting all over again is the fate for every researcher engaging in such data. Checking exhaustiveness of extractions after inclusion-exclusion exercises is of paramount importance: what data did we keep and how many data did we exclude from the study? And do we have acceptable explanations for their exclusion? (see Appendix 8)
- In this respect, a principal factor for success is the painstaking process of assembling, evaluating and tagging code lists deemed relevant for data extraction as we amply discussed in appendices 2 to 6. This work was extra complicated by the fact that we had to study multiple target interventions (section 3.2.2). Hence we chose to check all theoretical ('deductive') code lists by a complementary 'inductive' approach, i.e. by verifying the former for their frequencies in the entire hospital stays database. Based on those frequencies and pre-assessment queries to assess 'what was behind' we could either eliminate, either include 'unexpected' codes, especially where it concerned complications as well as some peculiarly or vaguely labelled RIZIV-INAMI interventions. However, we never lost sight of B. Russell's adage.



- Another major limitation of present study is its 'narrow bandwidth': only four years is precious short if we consider that in the domain of mammary reconstructions times between initial mammary resection and subsequent reconstruction as well as secondary completion interventions can vary considerably. Various psychosocial and highly individual factors interfere: balancing post-mastectomy mourning period, infringed body image, fear for subsequent invasive surgery and worries about ultimate survival as well as need for adjuvant cancer treatment. Consequently lead times can rise to several years, invoking problems with censored data (see Appendix 10). Since we considered that the fraction of 'outlying' lead times could not reliably be estimated from available data we saw no advantage in using classical statistical techniques (Kaplan-Meier estimations). This is the main reason why we expressed caution for complication statistics and certainly for assessed lead times, the latter being seriously flawed.
- A last word about our health insurance costs calculations. As we emphasized in section 3.2.12 the resulting reference costs are not intended for benchmarking hospitals but to provide overall estimation data, useful for health care budgetary planning.

### Main figures

#### Mammary reconstructions:

- 1 out of 7 women  $\geq 15$  yr. had a post-mastectomy reconstruction (2008-2011)
- Trend is rising to an estimated 1/5 (Doc N 2012-2013)
- 1/2 had reconstruction by prosthesis; 1/3 DIEP and 1/8 LDF
- 1/4 early reconstructions, overwhelming majority was immediate
- 3/4 delayed reconstructions

#### Secondary 'completion' interventions

- 4 out of 9 post reconstruction women had hetero-lateral remodelling; 2/5 immediate and 3/5 delayed
- 2 out of 5 post-breast reconstruction women had nipple reconstruction; 1/8 early and 7/8 delayed
- Trends for both are rising to estimated 1/2 (Doc N 2012-2013)

#### Complications of mammary reconstructions

- **Observational window – only 2008-2011 – is limited, hence rates should be interpreted with caution**
- **Breast implant related: overall 23% implant related complications, early as well as - predominantly – delayed; 16% implant removals; 8% implant revisions**
- **Surgical site related complications, early as well as delayed: Overall 18% for flap reconstructions; 5% for breast implants; 20% for hetero-lateral remodelling; 17% for nipple reconstruction / Predominantly delayed scar problems, which explains high rates**
- **In-hospital mortality highly 'incidental' (6/10 000).**
- **13% of post-reconstruction stays reported deformity of reconstructed breast (any type)**
- **High rates of post-reconstruction skin grafting suggest need for long term 'surgical maintenance'**

#### Referential all-inclusive health insurance costs (per stay)

- **Reconstruction by implant: € 1 653**
- **Free flap with MSVA: € 6 306**
- **Pedicled transposition flap: € 3 700**
- **Hetero-lateral mammary remodelling & nipple reconstruction: € 2 000 each**

Missing data – left- as well as right-censored – cause lead time statistics to be flawed



## 4 TIME MEASUREMENTS AND VALUATION SCENARIOS FOR THE “SURGEON COST”

### 4.1 Introduction

The aim of the study is to provide objective data on autologous breast reconstructions to serve as basis of discussion for a potential revision of the current reimbursement tariff (also called the RIZIV-INAMI fee). Consequently, the study only focus on resources covered by the surgeon RIZIV-INAMI fee, i.e. what we called the “surgeon cost”. This means that resources covered by other financing sources (e.g. equipment, nurses, overhead, etc.) are not included. Results presented here therefore cannot be used to estimate the total cost of an autologous breast reconstruction technique.

### 4.2 Scope of the study

#### 4.2.1 Perspective

This study takes the provider perspective into account. This means that only actual costs in the operating room are calculated and not actual prices billed to patients. For your information, a study on current prices billed to patients, including supplements, was recently performed by the Vlaamse Liga tegen Kanker.<sup>36</sup> According to this study, women who underwent a bilateral reconstruction (n=52) paid on average €4 057 out-of-pocket. Women who underwent a unilateral reconstruction (n=93) paid on average €2 620 out-of-pocket.

#### 4.2.2 Treatment considered: the full autologous breast reconstruction episode with flap

Treatments included in this study comprise all autologous breast reconstruction techniques with flap. Reconstruction with implants and autologous breast reconstructions without flap are out of the scope of this study, as the tariffs for these techniques are not part of current discussions (see Table 25).

The full treatment episode is considered, i.e. the primary breast reconstruction (i.e. what we called the “flap transfer”) but also subsequent secondary interventions (e.g. lipofilling see section 4.5) as patients’ out-of-pocket payments for these secondary interventions are largely at the source of current discussions. Short term re-interventions in case of complication (such as implant rejection or surgical site infections) are also considered but long-term subsequent intervention episodes (e.g. because the reconstructed breast does not evolve in the same way as the natural breast) are out of scope for this study as the long term treatment trajectories may vary strongly from one patient to another.

**Table 25 – Treatment within and out of scope of this study**

In scope	Out of scope
<ul style="list-style-type: none"><li>• Autologous breast reconstruction with flap</li><li>• Autologous breast reconstruction with flap in combination with breast prosthesis</li><li>• Secondary interventions following autologous breast reconstruction with flap</li><li>• Short term re-intervention for complication following autologous breast reconstruction with flap</li></ul>	<ul style="list-style-type: none"><li>• Non-autologous breast reconstructions (i.e. with prosthesis)</li><li>• Autologous reconstructions without flap (e.g. with lipofilling only)</li></ul>



### 4.3 Time driven costing methodology

As this study aims at providing information for a potential revision of the current reimbursement tariff, the focus lies on the costs borne by the tariff: essentially the surgeon work time. Therefore, the cost evaluation was performed on the basis of time measurements (see also section 4.8.5). The current study also followed the KCE “Manual for Cost-Based Pricing for Hospital Interventions”.<sup>37</sup> This manual provides input data concerning personnel costs as well as guidelines on how to perform cost calculations.

The costing approach applied was historical costing. This means that the cost evaluation was based on the historical or current cost observed in the field, from an analysis of a sample of Belgian surgeon teams (see section 4.4). It is different from standard costing, which is based on standards defined for efficient care.

In order to perform the cost analysis, four elements needed to be defined:

1. The list of treatment components, i.e. interventions performed in Belgium (see section 4.5).
2. The list of the activities composing the intervention process (see section 4.6).
3. The resources used for these activities and cost information for these resources (cost objects and unit costs) (see sections 1.1 and 4.8).
4. The cost drivers which were used to allocate the costs to the treatments (see section 4.8).

## 4.4 Recruitment and selection of the surgeon teams

### 4.4.1 Recruitment

For the recruitment of the surgeon teams, a mail was sent by the Royal Belgian Society for Plastic Surgery - Beroepsvereniging van Belgische Plastische Chirurgen (VBS) / Association Professionnelle des Chirurgiens Plasticiens Belges (GBS) - to all members. The mail was sent on September 13th 2014 and interested teams were requested to pose their candidature to the KCE at the latest on September 29th 2014, together with the number of DIEP and SGAP interventions performed in 2013 by their centre.

### 4.4.2 Candidates

11 teams applied to participate:

- 3 teams (fully or partly) operating in a Flemish university centre,
- 1 team operating in a Walloon university centre,
- 3 teams operating in one or more Flemish general centres,
- 2 teams operating in a Walloon general centre,
- 2 teams operating in a Brussels general centre.

### 4.4.3 Selection

Ten out of eleven teams were selected. To maintain a balance between the regions and between university and general teams, it was decided to drop one team operating in a Flemish university hospital. During the course of the study, 1 of the 10 selected teams stopped its registrations because the person dedicated to the data collection was not available anymore, with the effect that the number of registrations for that team are very limited. This stop in registrations was not linked to the quality of the data received, but purely an internal reason of that team.

The list of participating teams is shown in Table 26. The team that ended its participation during the course of the study is indicated in *italic*.

**Table 26 – List of participating teams**

	Flemish region	Walloon region	Brussels
<b>University</b>	UZ Leuven UZ Gent	CHU Liège	CHU Saint-Pierre
<b>Non-University</b>	AZ Delta Roeselare-Menen AZ Klina Brasschaat AZ St Jan Brugge, Jan Yperman Ziekenhuis Ieper en AZ Sint-Augustinus Veurne*	CHC Liège Cliniques et Maternités Sainte-Elisabeth Namur	Clinique Edith Cavell (Chirec)

AZ = Algemeen Ziekenhuis; CHC: Centre Hospitalier Chrétien; CHU: Centre Hospitalier Universitaire; UZ = Universitair Ziekenhuis \*Results for these hospitals were grouped because interventions were performed by the same team. This is why we use the term “team” and not “hospital”

#### 4.4.4 Pilot teams

Among the 10 teams, 3 teams were selected as pilot. The pilot teams participated actively in the definition of the activities composing the autologous breast reconstruction process. These activities form the building blocks of each intervention and are the channel through which the costs of each intervention was calculated. Next to the activities, the pilot teams also participated in preparing the list of techniques used in Belgium and in the development of time measurement templates.

The cost model was developed and tested in close collaboration with the pilot teams. After the test phase, the methodology was adopted by all teams.

#### 4.4.5 Presentation of results

The “surgeon cost” of each technique is presented per team, not per centre because one of the selected surgeon teams operates in three different centres. When output data per team are reported in this report, the names of the teams were replaced by a letter code (A, B, C...) and the code was randomly changed for each output presented (therefore, team A in Figure 14 is not the same team as team A in Figure 19). It should be noted that the objective of this report is not to evaluate the efficiency of the participating teams but to observe current practices and compute the average actual “surgeon cost” of autologous breast reconstructions in Belgium.

## 4.5 Considered interventions

As stated in the scope of the study, all interventions related to the full autologous breast reconstruction episode were considered, i.e. primary breast reconstruction (mentioned hereafter as the flap transfer), secondary interventions, and short term re-interventions for complications.

The full list of interventions was established with the help of the pilot teams and through discussions with medical specialists. These interventions are categorized in terms of techniques (e.g. DIEP, S-GAP, LDF...) and in terms of variants (i.e. unilateral vs. bilateral; immediately performed vs. delayed, etc.). A description of these interventions can be found in the section 1.3 of this report. The full list and the number of interventions considered is presented in Table 27 and Table 28. Costs of secondary interventions were calculated separately as most are currently not included in the RIZIV-INAMI fee for autologous reconstruction (see section 1.3). For short term re-interventions, data for 13 re-interventions were collected.





Table 27 – List of interventions considered for the flap transfer

Techniques	Variants
<b>DIEP / SIEA</b> DIEP: Deep Inferior Epigastric Perforators SIEA: Superficial Inferior Epigastric Artery	Unilateral, mono-pedicled flap, immediately performed Unilateral, mono-pedicled flap, delayed Unilateral, bi-pedicled flap, immediately performed Unilateral, bi-pedicled flap, delayed Unilateral, tertiary reconstruction (redo) Bilateral, bi-pedicled flap, immediately performed Bilateral, bi-pedicled flap, delayed Bilateral, tertiary reconstruction (redo)
<b>S-GAP/ I-GAP / PAP / TUG (=TMG) / LAP (lumber)</b> S-GAP: Superior Gluteal Artery Perforator I-GAP: Inferior Gluteal Artery perforator PAP: Profunda Artery Perforator TUG: Transverse Upper Gracilis (= TMG: Transverse Myocutaneous Gracillis) LAP: Lumbar Artery Perforator	Unilateral, immediately performed Unilateral, delayed Unilateral, tertiary reconstruction (redo) Bilateral, immediately performed Bilateral, delayed, Bilateral, tertiary reconstruction (redo)
<b>Free TRAM flap</b> TRAM: Transverse Rectus Abdominis Myocutaneous	Unilateral, immediately performed Unilateral, delayed Unilateral, tertiary reconstruction (redo) Bilateral, immediately performed Bilateral, delayed, Bilateral, tertiary reconstruction (redo)
<b>Pedicled myocutaneous flaps: LDF</b> <b>LDF: (Latissimus dorsi flap)</b>	Unilateral, immediately performed Unilateral, delayed, without prosthesis Unilateral, delayed, with prosthesis Unilateral, tertiary reconstruction (redo) Bilateral, immediately performed Bilateral, delayed, without prosthesis Bilateral, delayed, with prosthesis Bilateral, tertiary reconstruction (redo)
<b>Pedicled myocutaneous flaps: Conventional TRAM</b>	Unilateral, immediately performed Unilateral, delayed Unilateral, tertiary reconstruction (redo) Bilateral, immediately performed



	Bilateral, delayed,
	Bilateral, tertiary reconstruction (redo)
<b>TAP / intercostal perforator</b>	Unilateral, immediately performed
TAP: Thoracodorsal Artery Perforator	Unilateral, delayed

**Table 28 – List of interventions considered: Secondary interventions**

Techniques	Variants
<b>Symmetrization with prosthesis</b>	Immediate
	Delayed with general anaesthesia
<b>Symmetrization without prosthesis</b>	Immediate
	Delayed with general anaesthesia
<b>Correct flap: prosthesis</b>	Delayed with general anaesthesia
<b>Correct flap: Lipofilling</b>	Immediate
	Delayed with general anaesthesia
<b>Correct flap: reduction or lift</b>	Immediate
	Delayed with general anaesthesia
<b>Donor site corrections</b>	Immediate
	Delayed with general anaesthesia
	Delayed with local anaesthesia
<b>Nipple (and areola) reconstruction</b>	Immediate (rare)
	Delayed with general anaesthesia
	Delayed with local anaesthesia
<b>Tattoo of the areola area</b>	Delayed, local anaesthesia



It should be noted that not for all interventions sufficient data were obtained. An aggregation of some interventions was therefore performed for the presentation of results as shown in Table 29 and Table 30.

For the flap transfer, following variants were merged:

- Uni-pedicled and bi-pedicled: this aggregation was made to reach a higher statistical confidence on the data. Data did not show an important difference in intervention time between these 2 variants.
- Immediately performed and delayed interventions: This aggregation was also made to reach a higher confidence in the data, without a high impact on the medical soundness of the aggregated category.

Due to the absence of data, some reconstruction techniques were also excluded from the analysis:

- Free TRAM flap
- Pedicled TRAM flap
- TAP flap

For the secondary interventions, aggregation was done on the technique (with difference between unilateral and bilateral when relevant), independently from the area where the technique was used (e.g. adjustment on donor or on acceptor area). For example, liposuction on donor site and on acceptor site are aggregated in the same technique "liposuction". Only techniques with more than 5 measures are analysed in this study. It is important to note that this is not a guarantee for statistical significance.

**Table 29 – List of “flap transfer” interventions (aggregated)**

Techniques	Variants	#
DIEP / SIEA	Unilateral	103
	Bilateral	44
S-GAP/ I-GAP / PAP / TUG (=TMG) / LAP (lumber)	Unilateral	12
Pedicled myocutaneous flaps: LDF (Latissimus dorsi flap)	Unilateral	9

**Table 30 – List of secondary interventions and related side activities (markings & wound dressing) (aggregated)**

Secondary intervention techniques	Variants	#
Markings (side activity)		110
Lipofilling	Unilateral	52
	Bilateral	17
Liposuction		37
Scar correction		26
Nipple reconstruction	Unilateral	36
	Bilateral	18
Prosthesis	Unilateral	7
	Bilateral	2
Reduction		15
Tattoo of the areola area		5
Wound dressing (side activity)		137

#### 4.6 The list of activities related to the interventions

Activities considered in this report concern all activities related to the interventions defined in the previous section, i.e.:

- the flap transfer,
- secondary interventions, and
- short term re-interventions for complications

The list of activities constituting these interventions was established with the help of the pilot teams and through discussions with medical specialists (see Figure 8 to Figure 10).



#### 4.6.1 Activities for the flap transfer

Because the objective of this report is to provide information helping to readjust the current RIZIV-INAMI fee for the autologous breast reconstruction, only activities covered by this fee are taken into account (summary in Table 31).

Pre- and post-operative activities (in grey in Figure 8) are not included in the scope of the study, as these activities have their own RIZIV-INAMI code. This includes the surveillance after the 5 days following the intervention. However, the surveillance for the first 5 days after the intervention is in scope as it is supposed to be covered by the RIZIV-INAMI fee of the intervention.

Therefore, this cost was also added to the intervention cost based on the current RIZIV-INAMI fee for surveillance (see also section 4.8.1).

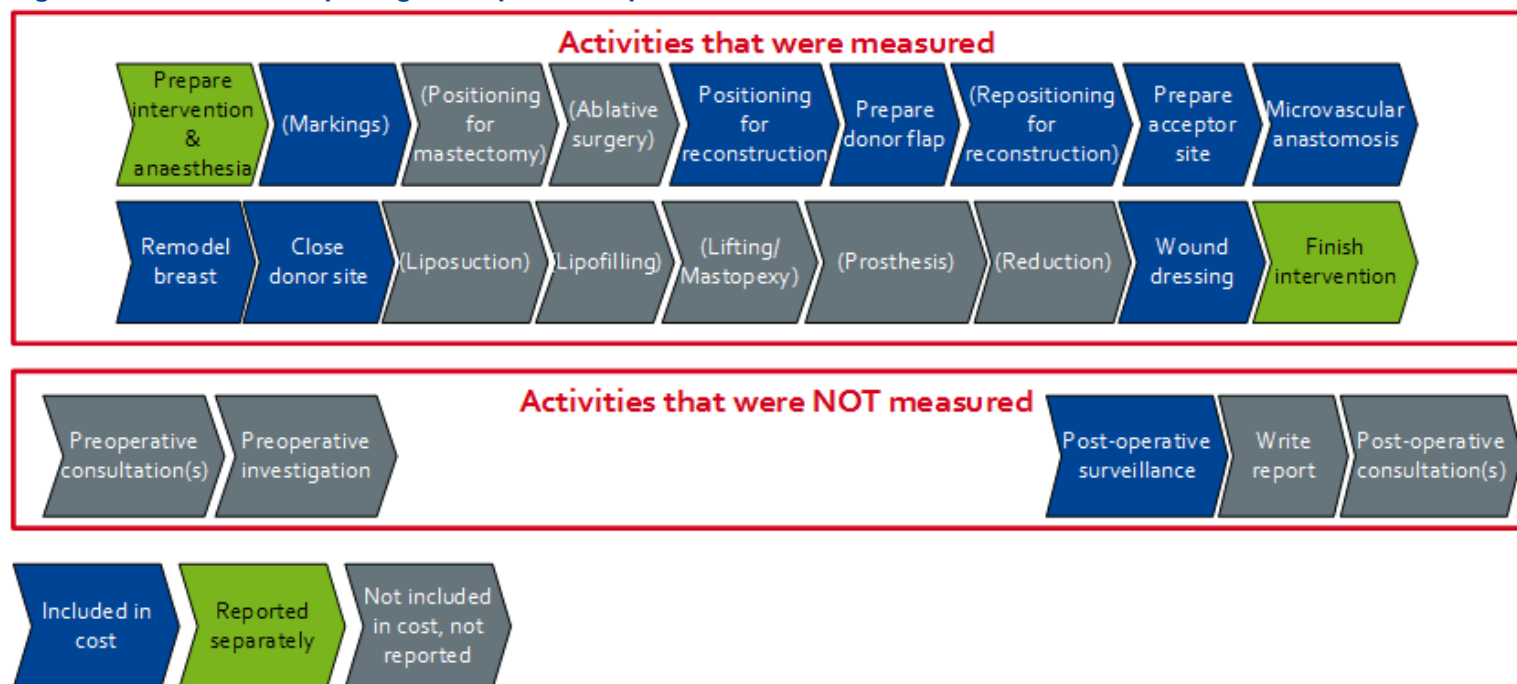
The “Prepare intervention and anaesthesia” and the “Finish intervention” activities (in green in Figure 8) are usually performed in the absence of the surgeon. Therefore, they are also not included in the costs. However, given that anaesthetists currently also claim part of the aesthetic supplements and that preparing and finishing the intervention are sometimes performed in the presence of the plastic surgeon, time spent on those activities and the subsequent costs will be reported separately in section 4.11.

The ablative breast surgery (mastectomy) is also out of scope as this surgery is reimbursed by another RIZIV-INAMI fee.

**Table 31 – Activities within the scope of this study**

	IN scope	OUT of scope
<b>Activities</b>	<ul style="list-style-type: none"><li>• Activities covered by the current RIZIV-INAMI reconstruction reimbursement codes (including surveillance for the first 5 days)</li><li>• Activities related to the preparation and the finishing of the intervention are presented separately</li></ul>	<ul style="list-style-type: none"><li>• Pre- and post-operative activities ( including surveillance after 5 days following the intervention)</li><li>• Anaesthesia</li><li>• Ablative surgery</li></ul>

More details about the full list of activities composing the flap transfer process is presented in Figure 8. The brackets indicate that the activity was not performed during each intervention. These are optional activities that may or may not be performed.

**Figure 8 – Activities composing the flap transfer process**

Note that the immediate secondary interventions are not included and only the costs of the flap transfer activities are considered here because the costs of secondary interventions are presented separately (see the next section).

#### 4.6.2 Secondary interventions

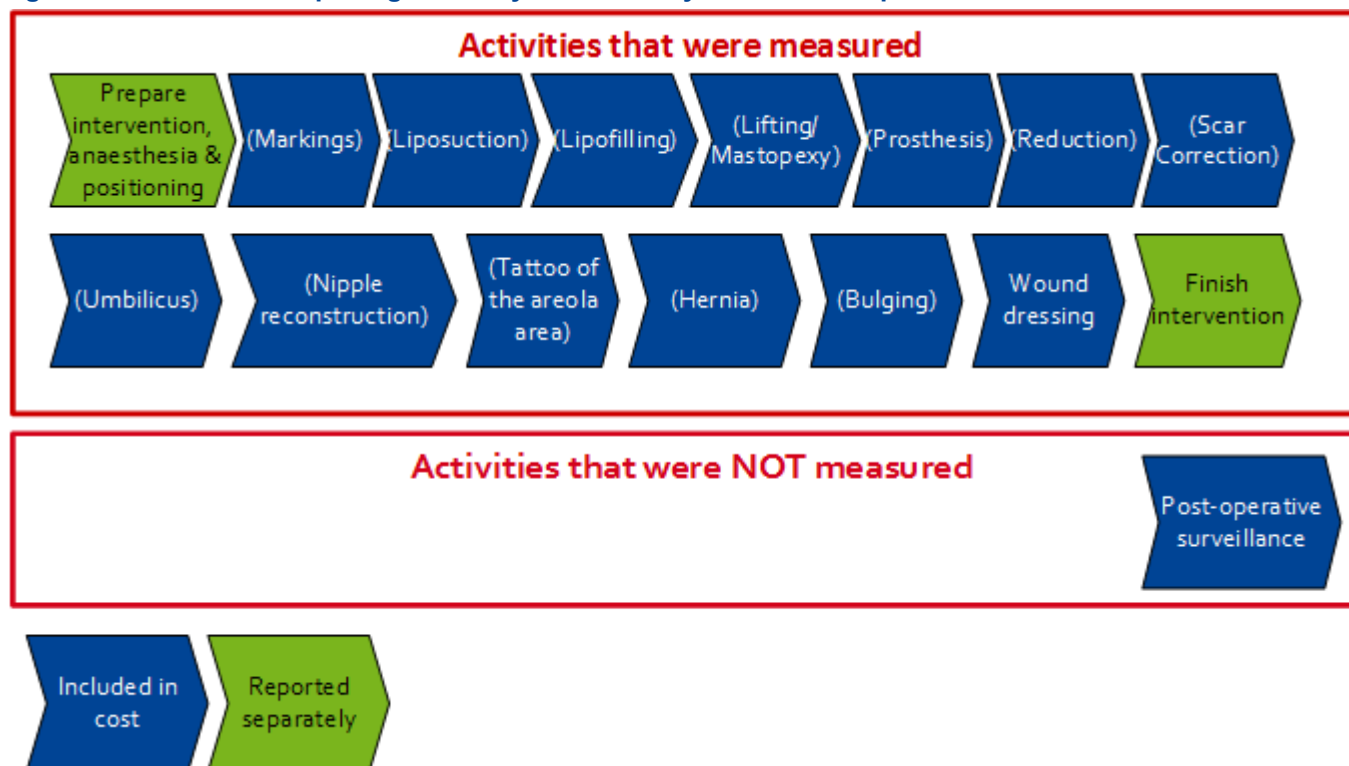
Immediate secondary interventions (i.e. adjustments performed at the same time of the breast reconstruction) have not been included in the results, due to a low number of valid measures. Only delayed secondary interventions are presented hereafter.

The process for these secondary interventions is presented in Figure 9. Note that some “side activities” have to be performed no matter how many adjustments are done. These “side activities” are comprised of: “Prepare intervention, anaesthesia and positioning”, “Markings”, “Wound dressing”, “Finish intervention” and “Post-operative surveillance”.

The order of this process can change, depending on the surgeon.



Figure 9 – Activities composing the delayed secondary interventions process

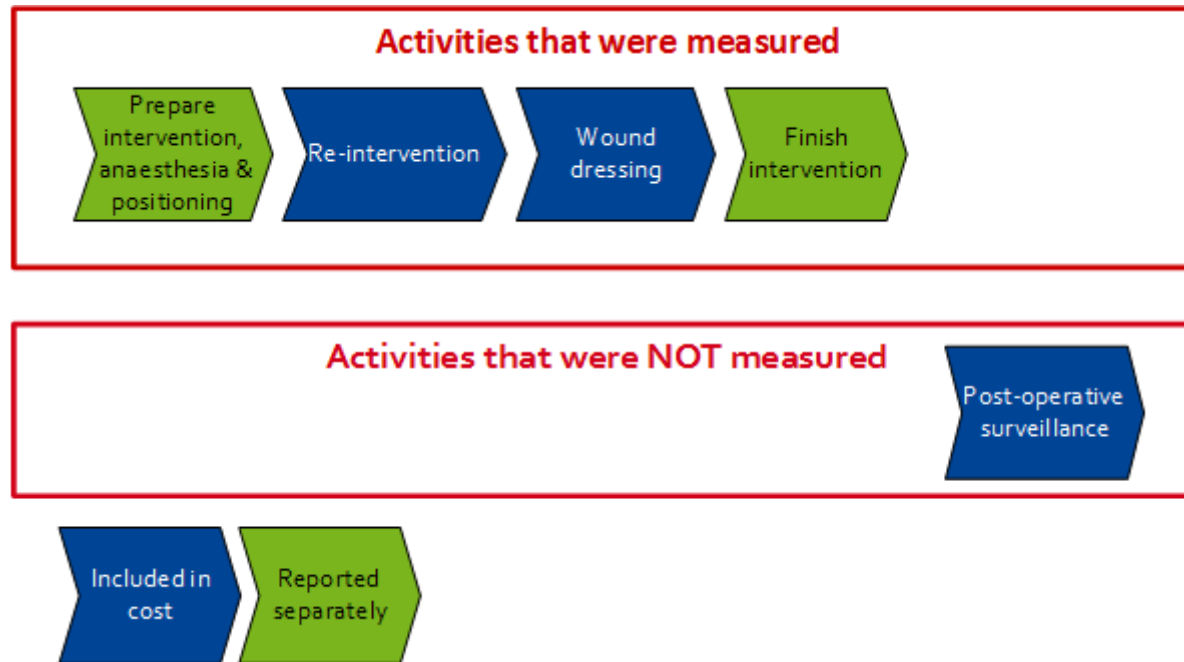




#### 4.6.3 *Re-interventions for complications*

Finally, a specific simplified process was defined for re-interventions for complications (see Figure 10).

**Figure 10 – Activities composing the process of re-intervention for complications**





## 4.7 Considered resources

This section elaborates on the resources that were used to perform the activities listed in the previous section. Again, as the primary goal of this analysis is to provide objective data to support the revision of RIZIV-INAMI fees, only the resources covered by these fees are taken into account. Resources covered by other hospital revenue sources (e.g. payments for pharmaceutical products and the hospital budget) are not considered (see Box 1 and next section for more details).

### Box 1 – The dual payment system in Belgium

There are two main sources of payment for the interventions of breast reconstruction in Belgium, i.e. the hospital budget of financial means and the RIZIV-INAMI fees:

**The hospital budget of financial means ('Budget van Financiële Middelen' (BFM) / 'Budget des Moyens Financiers' (BMF))**

The first payment channel is the hospital budget (BFM/BMF), which intends to cover infrastructure investments (through the A1 part of the BFM/BMF), overhead costs such as administration, maintenance, cleaning (through the B1 part) and nursing staff and medical costs (through the B2 part) for hospital services in general, including the operating theatre.

**The RIZIV-INAMI fees**

The second payment channel consists of the RIZIV-INAMI fees as physicians' work is paid on a fee-for-service basis.

## Which resources are taken into account?

In terms of human resources, activities listed in section 4.6 can include the presence of surgeons (plastic surgeons or other surgeons), physicians in training,<sup>i</sup> nurses or other staff. Because nurses or other staff are covered by the BMF-BFM, they are not taken into account in this analysis. The same rationale is followed for other resources covered by the BMF-BFM (i.e. OR building and equipment, material, overhead).

However, as stipulated in the Hospital Act, physician fees have to cover the costs incurred by the performance of medical services that are not covered by the BMF-BFM. Because such a contribution is not regulated by law, there is a lot of variability in the type of financial agreements across hospitals and within hospitals. As a consequence, what is covered by this contribution is unknown and vary between hospitals. Nevertheless, this means that a part of what should normally be covered by BMF-BFM is financed by the physician fee and is therefore indirectly taken into account in this analysis (but not measured, see section 4.8.1). In addition, in some hospitals some resources (e.g. the "instrumentalist") are also directly covered/paid by the physicians themselves. These resources are therefore also indirectly included in the analysis (but not measured, see section 4.8.1).

Moreover, as stated above, nurses are not taken into account but an exception is done for the "tattoo nurse" as, for tattoos done within the hospital, the surgeon generally fully delegates the work to a tattoo nurse who performs the procedure in the outpatient setting. The work of the tattoo nurse is therefore not covered by the BFM-BMF and thus needs to be taken into account in the cost analysis.

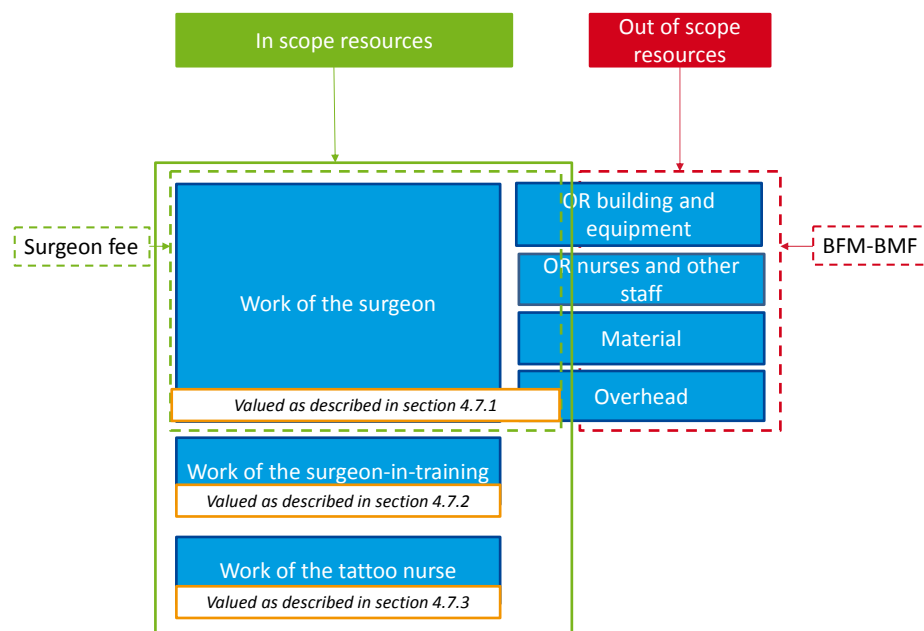
Resources taken into account in this study are summarized in Figure 11 and Table 32. In the following sections, the term "profile" is used to speak about these different specialties (plastic surgeon, other surgeon, surgeon in training, tattoo nurse).

<sup>i</sup> In a limited number of cases, some medical students also actively participated in a part of the intervention. In such a case, his time was measured and valorized as a surgeon in training.





Figure 11– Resources taken into account in this study



More details on the way these resources are valued can be found in the following sections (4.8.1 to 4.8.3). Resources covered by other hospital revenue sources than RIZIV-INAMI fees and the hospital budget (BFM-BMF), such as for example payments for pharmaceuticals, are not included in the figure but are also out-of-scope.

Table 32 – Summary of resources within scope of this study

IN scope	OUT of scope
<ul style="list-style-type: none"><li>• Work of the surgeons</li><li>• Other resources to the extent they are borne by the surgeons (through contributions or through direct payment):<ul style="list-style-type: none"><li>○ Part of the staff (including the instrumentalist)</li><li>○ Part of the infrastructure and equipment</li><li>○ Part of material</li><li>○ Part of overhead</li></ul></li><li>• Work of the physician in training</li><li>• Work of the tattoo nurse</li></ul>	<ul style="list-style-type: none"><li>• Resources covered by the Budget of Financial Means:<ul style="list-style-type: none"><li>○ Part of the staff</li><li>○ Part of the infrastructure and equipment</li><li>○ Part of the material</li><li>○ Part of overhead</li></ul></li></ul>

## 4.8 Unit costs for each resource and cost drivers

### 4.8.1 Unit cost for the work done by plastic surgeons and other resources borne by plastic surgeons

The work of the plastic surgeons as well as other resources borne by the plastic surgeons (see Table 32) are valued using a cost per hour and are allocated to activities and to interventions using the working time of the surgeon (see also section 4.8.5 for more details). Time measurements were thus done for each activity performed by the plastic surgeons. This was not possible for the surveillance performed by the plastic surgeon during the first five days following the intervention, which was therefore valued using the current RIZIV-INAMI fee (i.e. code 598006, with a tariff of €12.16 per day) multiplied by 5 (i.e. €60.80).



### Several scenarios

To estimate the cost per hour, several scenarios were considered:

- Scenario A is based on the gross cost of plastic surgeons excluding supplements, which is provided by the KCE manual for cost studies (see Box 2).<sup>37</sup>
- Scenario B was added since plastic surgeons experience their remuneration as insufficient. It is based on the weighted average net cost of all medical specialists, to which the difference between the gross and net cost of plastic surgeons was added (to adjust for deductions and costs at charge of the plastic surgeon). This was also provided by the KCE manual for cost studies.<sup>37</sup>
- Scenario C was added based on the current reimbursement of reconstructions with breast implant ("prosthesis opportunity cost"). It tries to answer the question: what would the remuneration of a plastic surgeon be if (s)he spends his/her time on prosthesis breast reconstructions instead of autologous breast reconstructions. In order to calculate the cost per hour of prosthesis reconstructions, the duration of 14 prosthesis reconstruction interventions was extracted from the OR data of 3 centres. From this information and the RIZIV-INAMI fees for these interventions, the hourly remuneration of a plastic surgeon performing prosthesis reconstructions was calculated. Note that this hourly cost is only based on 14 interventions which limits the accuracy of the estimation.

### The yearly gross cost

As stated above, scenarios A and B are based on the yearly gross cost of medical specialists provided by the KCE manual for cost studies<sup>37</sup>. This gross cost is calculated per medical speciality, based on the average yearly remuneration of medical specialists for all activities that are billable to the RIZIV-INAMI<sup>j</sup> before deductions and subtraction of other costs at charge of the medical specialist, and with exclusion of supplements (see Box 2 for more details). In the manual, the average yearly gross cost was € 212 544 for plastic surgeons and € 259 812 for the weighted average of all medical specialists.<sup>37</sup>

<sup>j</sup> so also including consultations

### Box 2 – The yearly gross costs provided by the KCE manual for cost studies<sup>37</sup>

#### The yearly gross costs provided by the KCE manual for cost studies correspond to:

1° the remuneration of all activities performed within the hospital, i.e. not in private practices outside the hospital;

2° and with a RIZIV-INAMI reimbursement, i.e. billable activities: activities outside the RIZIV-INAMI reimbursement scheme such as pure aesthetic interventions are not included in the yearly cost.

For more data on this topic, we refer the reader to chapter 2 and appendix 18 of KCE manual for cost studies<sup>37</sup>

#### Indexation of this yearly gross cost

The yearly gross costs of the KCE manual for cost studies were based on the year 2010. The indexation to 2013 (latest year available for RIZIV-INAMI data) was done as follows:

- Stage 1: Determination of activity-mix of plastic surgeons in 2010:
  - with the 2010 expenditures based on the sum of RIZIV-INAMI reimbursement of all codes billed by plastic surgeons in 2010, and
  - the 2010 volume, i.e. the number of interventions in 2010, taking into account the way codes are billed.
- Stage 2: Determination of 2013 expenditures calibrated on 2010 volume:
  - with a 2013 tariff per intervention assessed by dividing the total 2013 expenditures for each code identified in stage 1 and billed in 2013 by the 2013 volume (i.e. the number of interventions in 2013),
  - 2013 expenditures calibrated on 2010 volume were then assessed by multiplying the 2013 calculated tariff per intervention by the 2010 volume.



- Stage 3: Determination of the indexation rate from 2010 to 2013, assessed by dividing 2013 expenditures calibrated on 2010 volume (stage 2) by 2010 expenditures (stage 1), resulting in an index of 1.0131.

### Conversion of the yearly gross cost in a cost per hour

The activity level of a full-time-equivalent (FTE) physician was estimated at 11 half-days per week (maximum of half-days that can be reported for the election of the Medical Board (for these elections a vote is assigned to each physician, weighted by its level of activity in the hospital in terms of half days). By taking into account holidays, attendance at congresses, illnesses, etc., it has been estimated that a FTE worked 482 half days per year (see Table 33).

**Table 33 – Number of half days worked per year for clinical services**

Number of half days	
Baseline number of half days per physician (52 weeks * 11 half days)	572
Holidays, attendance at conferences, illnesses, ...(35 days)	70
Public holidays (10 days)	20
Average number of half days per FTE per year	482

Source: KCE manual for cost studies<sup>37</sup>

This allowed to convert the yearly gross remuneration of a plastic surgeon (FTE) in a cost per half day. Based on this, the cost per hour can then be estimated by determining the number of hours physicians usually work per half day. Nevertheless, because the gross cost was only based on billable activities (i.e. consultations and interventions but not administrative work, etc.), it is the number of billable hours per half day that must be estimated, not the total number of hours worked per half day. Because no official data are available on this subject, estimations were based on a questionnaire filled out by the participating centres (see Table 34 and Table 35).

Note that the third line - "Surveillance" (post-operative consultations first 5 days) (3) – is not included in the number of billable hours as this activity is not billable but supposed to be covered by the remuneration of the intervention.


**Table 34 – Number of billable hours per week for a full time equivalent**

Activities	Billable or not billable hours	Average hours per week spent by 1 “full time equivalent”	Minimum hours per week spent by 1 “full time equivalent”
<b>Billable interventions, i.e. with RIZIV-INAMI code (1)</b>	Billable hours	24.99	10.00
<b>Consultations within the hospital (2)</b>	Billable hours	11.86	10.00
<b>“Surveillance” (post-operative consultations first 5 days) (3)</b>	Non billable hours	2.48	2.00
<b>Other activities (e.g. work time on non-reimbursed interventions, work time outside the hospital, administration, lunch breaks, training, and transport) (4)</b>	Non billable hours	18.86	32.00
<b>Total hours per week for a full time equivalent (5)=(1)+(2)+(3)+(4)</b>	Billable and non-billable hours	58.19	54.00
<b>Total billable hours per week for a full time equivalent (6) = (1)+(2)</b>	Billable hours	36.85	20.00
		Average hours per half day	Minimum hours per half day
<b>Total billable hours per half day (by taking into account 11 half days per week, as estimated in the KCE manual for cost studies, see above) (7) = (6) / 11</b>	Billable hours	3.35 (i.e. 3 hours 21 minutes)	1.82 (i.e. 1 hour 49 minutes)

**Table 35 – Conversion of the yearly gross cost in a cost per hour for surgeons**

	Scenario A		Scenario B		Scenario C	Source
<b>Reference cost</b>	Gross cost of a plastic surgeon, excluding supplements		Average gross cost of all medical specialists, excluding supplement		Prosthesis opportunity cost	
<b>Gross cost in € per year, for the year 2010 (8)</b>	€ 212 544		€ 259 812			KCE manual for cost studies
<b>Index to 2013 (9)</b>	1.01		1.01			
<b>Gross cost in € per year, for 2013 (10)</b>	€ 215 329.84		€ 263 216.96			
<b>Number of half day per year (11)</b>	482		482			KCE manual for cost studies
<b>Gross cost in € per half day (12)</b>	€ 446.74		€ 546.09			(10) / (11)
	Average	Upper bound	Average	Upper bound		
<b>Total billable hours per half day (13)</b>	3.35	1.82	3.35	1.82		(7) of Table 34
<b>Cost per hour</b>	<b>€133.35</b>	<b>€245.71</b>	<b>€163.01</b>	<b>€300.35</b>	<b>€228.02</b>	<b>(12) / (13)</b>

#### 4.8.2 The work of the surgeons-in-training

In order to estimate the cost of the surgeon in training, we used the minimum legal salary (€ 20 500\* 1.6084 (index)), increased by a factor to take into account the employer costs on top of the gross wage (35.4% based on the KCE manual for cost studies)<sup>37</sup>. With a maximum legal work time of 48 hours per week and the number of productive days reported in Table 33, the cost per hour is estimated to €21.23 (see Table 36).

**Table 36 – Cost per hour of surgeons-in-training**

Label (source)	Estimate
<b>Number of productive day per year (482/2, see Table 33)</b>	241
<b>Number of productive day per week (11/2, see Table 33)</b>	5.5
<b>Number of hours per week (i.e. the legal maximum)</b>	48
<b>Number of hours per years (241*48/5.5)</b>	2103.27
<b>Yearly cost (minimal legal salary of 20 500*1.6084*1.354)</b>	€44 644.36
<b>Cost per hour</b>	€21.23



### 4.8.3 The work of the tattoo nurse

Based on the KCE manual for cost studies, the cost per hour of a tattoo nurse was estimated to be € 40.96 (€ 40.16 per hour for a consultation nurse, index of 1.02 to 2013).

Because the nipple tattoo is often performed outside the hospital, i.e. by professionals outside the healthcare system, the number of time registrations for this activity is limited. This is why, in addition to the cost resulting from time registrations performed within the hospitals, the market price of a breast tattoo is also briefly presented.

### 4.8.4 The work of other medical profiles

In addition to plastic surgeons, surgeons-in-training and tattoo nurses, from time to time a gynaecologist also participated to the intervention. In these (rare) cases, the hourly cost of the gynaecologist was calculated in the same manner as the cost of the plastic surgeon in scenario A and B:

- Start from the gross cost of a gynaecologist (based on the KCE cost manual): € 213 417 per year (base year 2010)
- Index this yearly cost to 2013 using the same index as that of plastic surgeons: 1.01
- The resulting yearly gross cost of a gynaecologist amounts to € 216 214.28
- Based on 482 half days per year, the cost per half day amounts to: € 448.58
- Using the same number of billable hours per half day as for the plastic surgeons, the average cost per hour of a gynaecologist amounts to € 133.90 and the upper bound amounts to € 246.72

### 4.8.5 Cost drivers

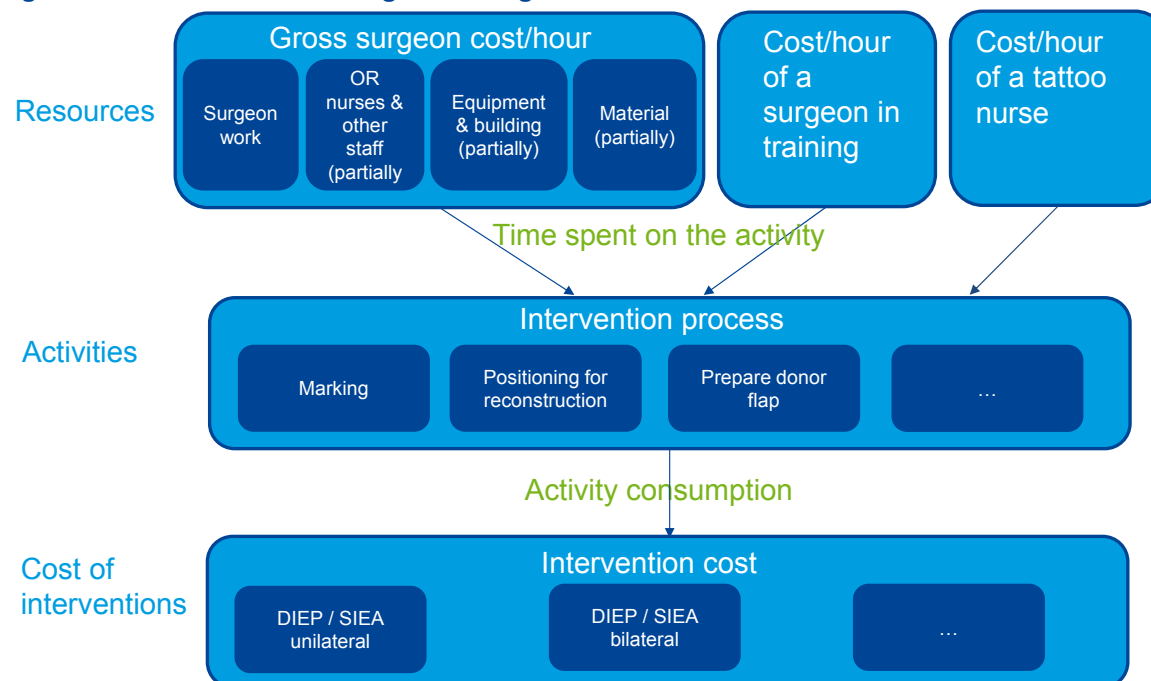
After having identified all resources and unit costs, the last step consisted of allocating the unit cost of each resource to the activities and then the activities to the interventions. This was done using cost drivers (see Figure 12 and Box 3) for an illustration of this method). In the topmost part of the figure, the different types of resource costs can be seen. The objective was then to allocate these costs amongst the different types of interventions (lowest part of the figure).

The green text represents the manner in which the allocation was performed:

1. First, the resource costs were allocated to each activity. This was done by:
  - Calculating the resource cost per hour (see sections 4.8.1 to 4.8.3)
  - Multiplying the resource cost per hour by the duration of the activity, for each activity performed by a surgeon, a physician in training or a tattoo nurse. The duration of the activities were measured by the participating teams: they registered the duration per intervention type during approximately 3 months (see section 4.9 for more information on the registrations).
  - This gives us a cost per activity.
2. The costs of the individual activities was then summed to obtain the cost of a complete intervention. In this step it was important to know which activities were performed for which type of treatment. This was also registered by the teams (see section 4.9 for more information on the registrations).

Since the activity consumption of each individual treatment was measured directly, there was no need to calculate an average activity consumption for a generic intervention. Instead, the activity consumption of each individual registration was used to calculate the total intervention cost. After doing this for all interventions, the average intervention cost was calculated.

In the case of secondary interventions, the cost is defined separately for each technique as defined in section 4.6.2.

**Figure 12 – Time driven costing of autologous breast reconstructions**



**Box 3 – Formula to determine the cost of an intervention****1° Duration per activity (calculation of man-hours per profile)**

(1) For the surgeons:  $\sum$  number of hours for each activity \* N° of surgeon present for the activity

(2) For the surgeons in training:  $\sum$  number of hours for each activity \* N° of surgeon in training present for the activity

(3) For the tattoo nurses:  $\sum$  number of hours for each activity \* N° of tattoo nurses present for the activity

**2° Cost per activity**

Cost / hour for a surgeon \* duration of the activity for the surgeons (1) + Cost / hour for a surgeon in training or a student \* duration of the activity for the surgeons in training (2) + Cost / hour for a tattoo nurse \* duration of the activity for the tattoo nurses (3)

**3° Cost of the intervention**

$\sum$  cost of each activity + **surveillance fees of €60.80** (as explained at the beginning of section 4.8.1)

- For this, all relevant medical profiles were included separately, including surgeons in training.

This template was created by the outsourced team “Möbius” between October and December 2014 and tested in the pilot teams in December 2014 with close supervision. During that testing phase, the template was updated with the remarks of the teams. End December 2014 and beginning of January 2015 the measurements started in the other teams. Each team received a training by Möbius to make sure the data was registered in the same and correct way.

In almost all teams, it was the main nursing staff that registered the times, with the help of the surgeons when needed. In one team, it was the anaesthetist that filled the template.

This time registration was spread over 3 months. During these 3 months, the registrations were sent to the team “Möbius” approximately every week. This allowed for close monitoring and fast correction if measurements were not performed in the correct way. Möbius also often visited the different teams to make sure that the registrations were correctly performed.

Re-interventions for complications, often occurring during the night after the flap transfer, were less easy to measure as the nursing staff available was not trained to use the template. To facilitate this measurement, the template for re-interventions was also simplified.

**4.9 Data collection plan and templates**

In order to analyse the data, it was essential that all teams delivered the same data in the same format. To this end, time-registration templates were provided to the teams. These templates were first tested in the pilot teams. Then, they were adapted based on the feedback of those teams and distributed to all teams.

Figure 13 shows the time registration template for a reconstruction. These tables were filled out for each intervention.

- First, some general information on the intervention was completed on top of the sheet.
- Then, for each activity (leftmost column) the start and stop times were filled in, as well as the number of people performing the activity and their specialization.



Figure 13 – Time registration template

<div>Encrypt, Save and Close</div>	Date	
	Planned intervention duration	
	Number of nurses	
	Number of instrumentists	
	Technique	
	Mono/Bi-pedicle? (only for DIEP/SIEA)	
	Unilateral/Bilateral	
	Immediate reconstruction (following mastectomy)/ Delayed reconstruction	
	Number of veins and arteries?	
Connecting sensitive nerves (Y/N)?		

Activities	Type	Start	Stop	Nb of plastic surgeons	Nb of surgeons in training	Nb of students	Nb of gynaecologists	Other	Remark
(Markings)									
Prepare intervention and anaesthesia									
(Positioning for mastectomy)									
(Mastectomy)									
Positioning for reconstruction									
Prepare donor flap									
(Re-positioning for reconstruction)									
Prepare acceptor site									
Microvascular anastomosis									
(Place prosthesis: only for LDF-flaps with prosthesis)									
Model breast									
Close donor site									
(Symmetrisation with prosthesis + Type?)									
(Symmetrisation without prosthesis + Type?)									
(Donor site corrections)	Liposuction								
Wound dressing									
Finish intervention									

#### 4.10 Data overview and data validation

All 9 teams performed time registrations during 3 months and registered primary interventions (flap transfer), secondary

Figure 14):

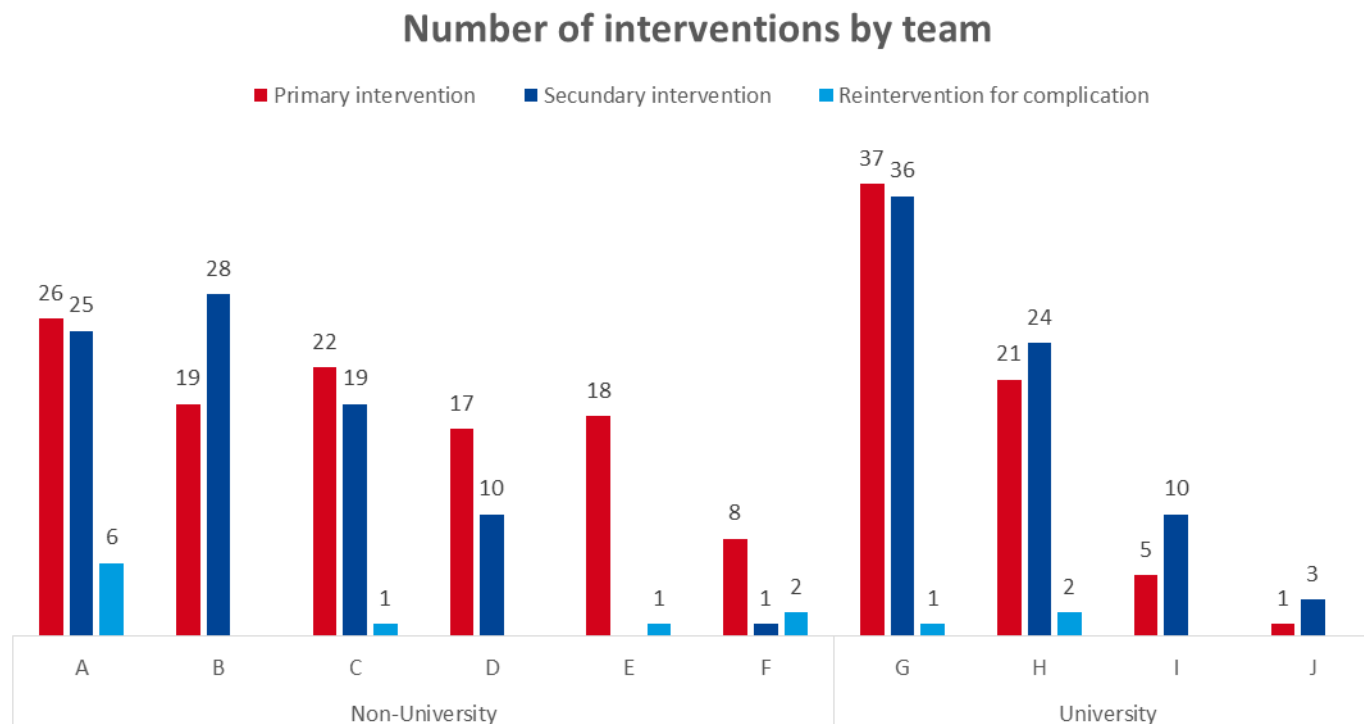
- 174 reconstruction interventions
- 156 procedures for delayed secondary interventions (with an average of 1.91 secondary intervention techniques per procedure)
- 13 re-interventions

interventions and re-interventions for complications. In total, the following number of registrations are used in this cost study (see

Note that the registrations included in the analysis come from both university and non-university teams. Team J is the team who stopped the time registrations after the start of the project.



Figure 14 – Data overview



Some faulty registrations (n=6) are excluded from the analyses (e.g. registration without number of medical profiles). Furthermore, while the objective was to register 100% of the interventions that occurred during those 3 months, for practical reasons, some interventions were not registered. These practical reasons include for example the absence of part of the nursing staff trained for registering the time, due to holiday, sick leave, etc. Other reasons include temporary technical problems to access the template on the operating room computer or negligence of the team, forgetting to measure sometimes.

In order to evaluate the risk of bias due to not including all interventions in the cost calculations, the time registrations used in the study were matched with the intervention data from the operating room IT systems (planned duration or real duration, depending on the available data). This allowed us to verify that, in the 9 teams who participated to the complete study (centres A to I in Figure 14), an average of 67% of the interventions in scope were included in the cost study. If we exclude 2 university teams, that registration rate even reaches 88%.



Next, in order to evaluate the measurement bias, the duration of the interventions according to the time registrations were compared with the duration reported in the centre's OR IT system. This analysis shows that, on average, the durations registered for this project vary between 96% and 107% of the duration that is reported in the centre's OR IT system.

Note however, that the data from the OR IT system was only available in 5 centres out of 9. In the remaining 4 centres, the average intervention duration of DIEP reconstructions was compared to the average duration of the DIEP reconstructions in other centres. The result of this comparison shows that, on average, the duration in these 4 centres is 11% shorter than in the other centres.

## 4.11 Results

The results shown below are based on data presented in section 1.1. Despite a high number of measures, not all techniques of reconstructions and secondary interventions are shown due to a lack of data in some less common techniques. Furthermore, some results are based on a limited set of data. To inform the reader on this, the number of measures will always be mentioned in following results.

As explained in Box 3, in order to calculate the intervention cost, 2 elements are needed:

1. First the duration of each activity and of the interventions
2. Next, the cost per minute of each profile

The unit costs per minute have been presented in section 4.8.

In this section, first the duration results are shown (paragraph 4.11.1), followed by the valuation of that duration, in the cost results (paragraph 4.11.2).

### 4.11.1 Time results

The time results below are shown in graphs and in tables. The graphs show the **intervention duration** for the reconstructions and the **activity duration** for the secondary interventions, while the tables show the **man-hours** per main profile.

Following sub-section explains these three important concepts in detail.

#### 4.11.1.1 Concepts: Intervention duration, activity duration, man-hours, profiles & error bars

##### Intervention duration

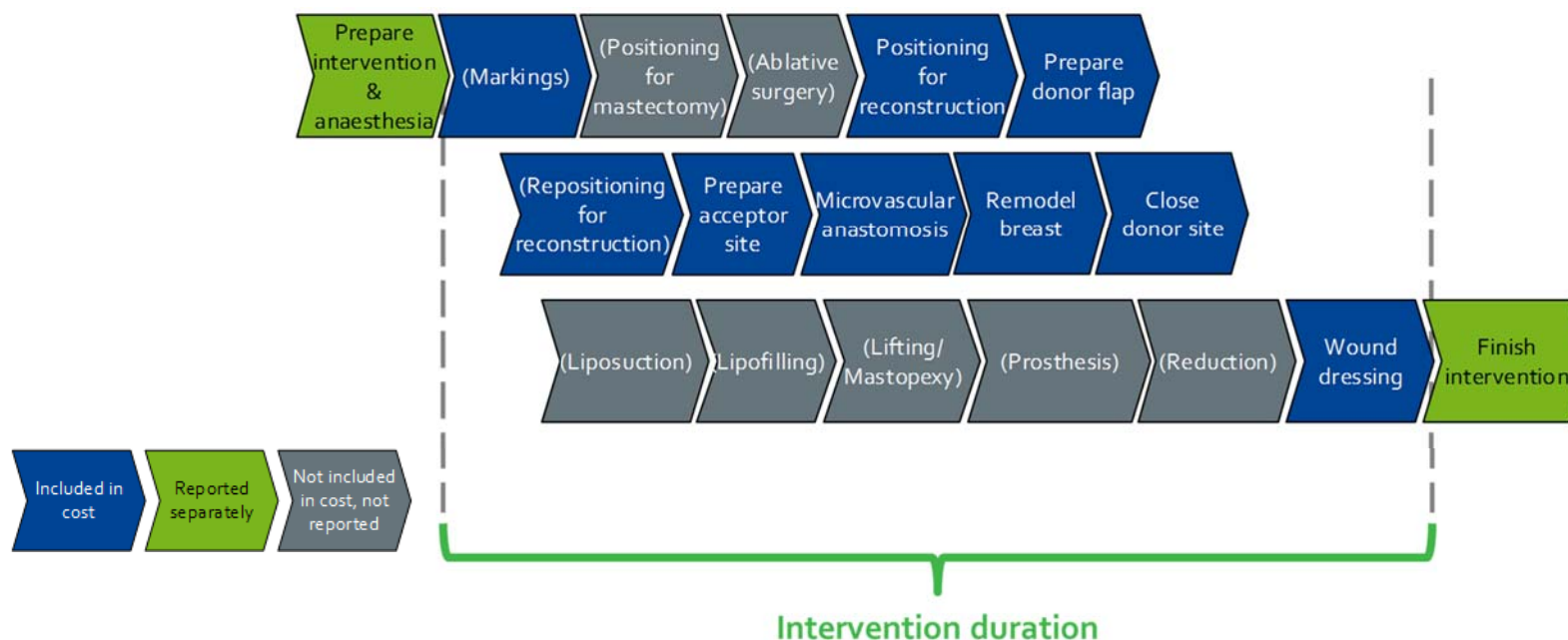
The intervention duration corresponds to the difference in time between the first and the last registered activity and subtracting the duration of "Prepare intervention & anaesthesia" and "Finish intervention" activities (cf. section 4.6), see Box 4 and Figure 15:

#### Box 4 – Formula to determine the average duration of a reconstruction intervention, including activities related to ablation and immediate secondary interventions (if performed)

**Intervention Duration** = [STOP time of the activity registered last] – [START time of the activity registered first]  
– [Duration of the activity "Prepare intervention & anaesthesia"]  
– [Duration of the activity "Finish intervention"]

Because some activities are performed in parallel, it was not possible to determine an intervention duration that excluded "out-of-scope activities" such as the ablative surgery.

For delayed secondary interventions graphs, the duration is presented per secondary intervention technique.

**Figure 15 – Duration of a reconstruction intervention, including activities related to ablation and immediate secondary interventions (if performed)**

### Activity duration

The activity duration, shown for the secondary interventions, is the difference between the start and end time of that specific activity.

Here too, the number of man-hours per profile is used because there can be more than one profile working on a specific intervention (cf. below)

### Man-hours per profile

To calculate the intervention cost, man-hours per profile are used (see also Box 3 of section 4.8.5) instead of the intervention duration. The man-hours per profile correspond to the time spent by each medical personnel present on in scope activities (see section 4.6), summed by profile. To calculate the

cost of each technique, the number of man-hours is multiplied by the unit cost per hour (see also Box 3 of section 4.8.5).

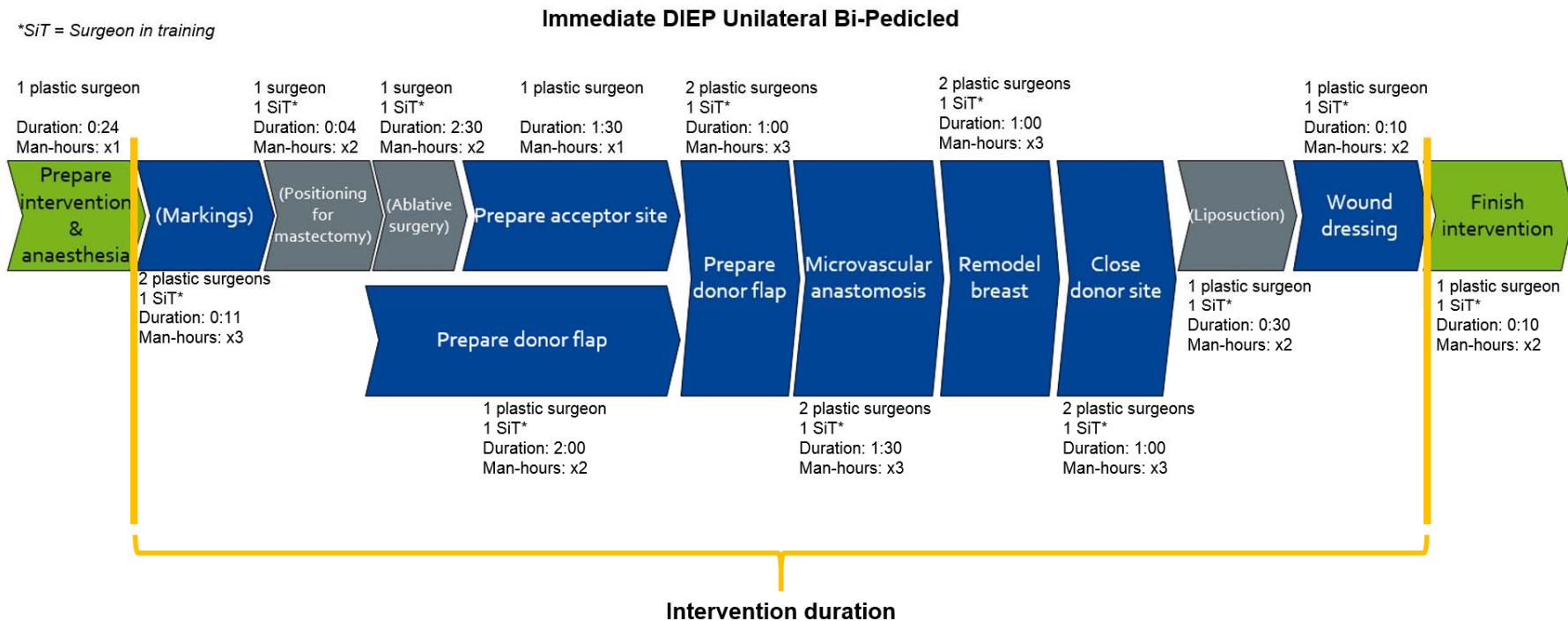
There are 3 reasons why we use the man-hours per profile instead of the intervention or activity duration for the cost calculations:

- During a reconstruction, the team working on the reconstruction activities can change (e.g. it is possible to switch from one surgeon to two surgeons for specific parts of the intervention).
- Several activities in scope might be performed in parallel.
- Out of scope activities such as ablative surgery activities or immediate secondary interventions, are included in the intervention duration but not in the cost of the flap transfer.



Figure 16 shows an example of an intervention, illustrating the difference between “intervention duration” and “man-hours”. The intervention duration is the time between the first in scope activity and the last in scope activity, regardless of the number of surgeons and the out-of-scope activities during that intervention. The man-hours, however, sums per medical profile the time spent by each team member on each in scope activity. For example, the micro anastomosis has been performed by 2 surgeons and 1 surgeon in training. Therefore, the man-hours of plastic surgeons for that activity is 2x the activity duration (= 2x2h = 4h).

**Figure 16 – Example of DIEP unilateral intervention duration and man-hours**



**Profiles presented**

To summarize the results, only man-hours of plastic surgeons and man-hours of surgeons-in training will be shown in underlying tables. Other profiles (gynaecologists) only very rarely participate to the intervention. Their work is included in the cost calculations but their average number of man-hours per intervention is too low to show in the underlying tables.

**Error bars**

To give the reader an idea of the spread between different measures, error bars, corresponding to  $\pm 1$  standard deviation, were added on the graphs.

**4.11.1.2 Active medical personnel during the interventions**

In the templates, it is the number of profiles active during the intervention that is measured, not the profiles that are callable. This means that when a surgeon leaves the operating room to do something else, his time out of the operating room is not measured. Similarly, a student that is not active in the intervention, but only watching is also not measured.

This means that the intervention cost calculated in this study includes only the active medical personnel during the intervention, without the potential callable profiles. For example, in a university environment, it is frequent that the surgeons in training<sup>k</sup> perform a big part of the intervention, while the plastic surgeon works on something else, but stays available for the intervention in case of problem or for the more decisive activities of the intervention (e.g. the microsurgery). In this study, only the active (= active on the patient) medical personnel has been included, omitting the potential callable personnel.

**4.11.1.3 Duration of a reconstruction****Duration per technique**

This paragraph provides an overview of the average duration of a reconstruction per technique (see Figure 17). Next, Table 37 shows on how many observations this average duration is based and the number of man-hours spent on in scope activities by plastic surgeons and surgeons-in-training.

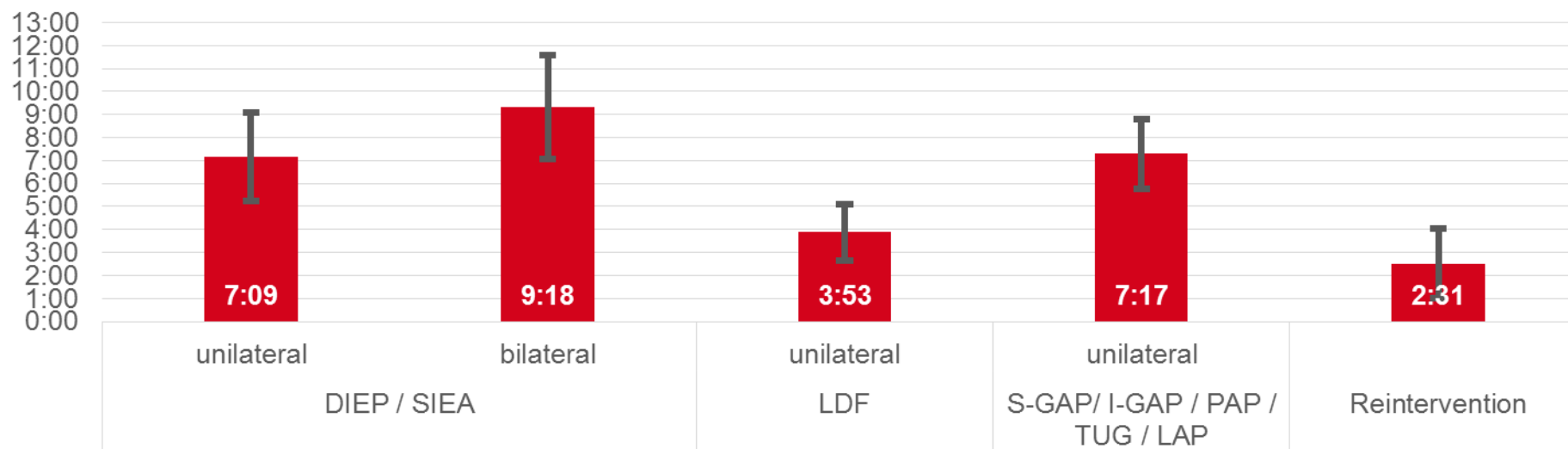
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<sup>k</sup> In a limited number of cases, some medical students also actively participated in a part of the intervention. In such a case, his time was measured and valorized as a surgeon in training.





**Figure 17 – Average duration of a reconstruction by technique, including activities related to ablation and immediate secondary interventions (if performed)**



**Table 37 – Number of registrations per technique and man-hours spent on in-scope activities by profile (i.e. excluding activities related to ablation and immediate secondary interventions)**

	DIEP / SIEA		LDF	S-GAP / I-GAP / PAP / TUG / LAP	Re-intervention
	Unilateral	Bilateral	Unilateral	Unilateral	
# of observations	103	44	9	12	13
Reconstruction man-hours of plastic surgeon	7:18	10:10	4:03	7:54	3:05
Reconstruction man-hours of surgeon in training	4:14	6:44	3:40	8:01	1:08

*As stated above, some activities can be performed in parallel or more than one surgeon can be present at the same time, which explain why the number of man hours can be higher than the intervention duration (see paragraph 4.11.1.1 for more information).*



The above graph shows that DIEP / SIEA is the most commonly encountered technique. The duration of DIEP / SIEA and S-GAP/I-GAP/PAP/TUG/LAP interventions also seems significantly longer than that of LDF reconstructions. This remains true when we look at the number of man-hours spent on in-scope activities. Note however, that this study only includes 9 LDF reconstructions and 12 S-GAP/I-GAP/PAP/TUG/LAP reconstructions.

Furthermore, the group S-GAP/I-GAP/PAP/TUG/LAP is composed of techniques with a high degree of heterogeneity on intervention duration. Therefore, the average has to be considered cautiously.

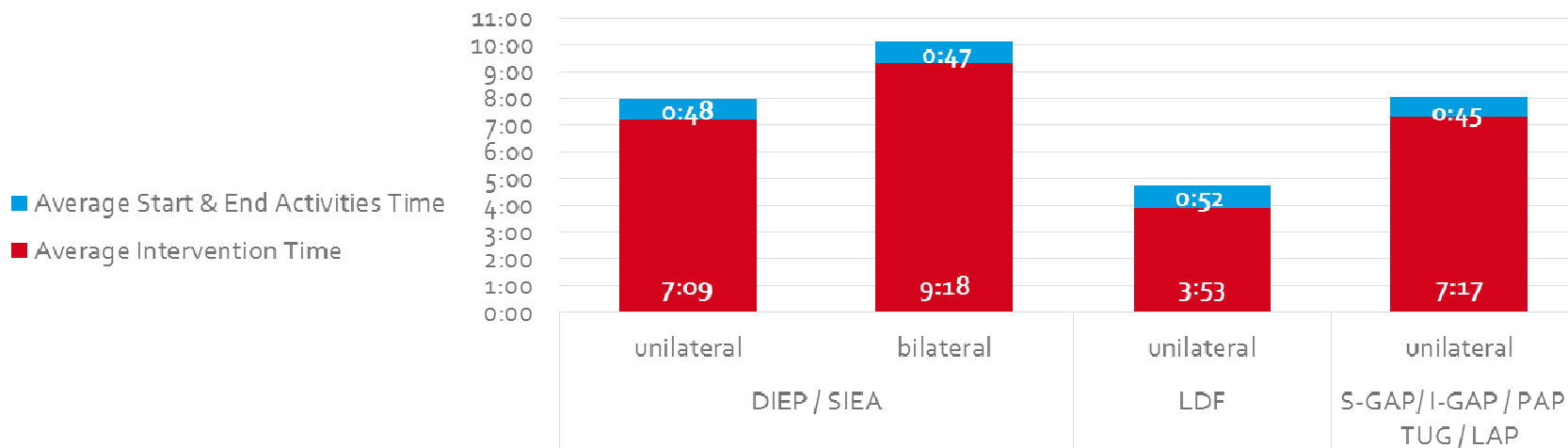
Next, we observe that the duration of bilateral DIEP / SIEA interventions is approximately 30% longer and takes approximately 50% more man-hours than a unilateral reconstruction.

Finally, re-interventions require an average of 4:13 man-hours (all medical profiles together). However, there is a high variation on these interventions, probably due to the wide variety of causes for re-intervention and activities performed during the intervention. Here too, the number of registrations is limited.

#### Start and end activities

Below, Figure 18, shows the duration of the start and end activities (“Prepare intervention & anaesthesia” and “Finish intervention” in light blue) on top of the total intervention duration already presented above. Note that the duration of the start and end activities does not vary much from one technique to another. Depending on the technique, the average duration of the start and end activities varies between 45’ and 55’.

**Figure 18 – Start and end activities by reconstruction technique**



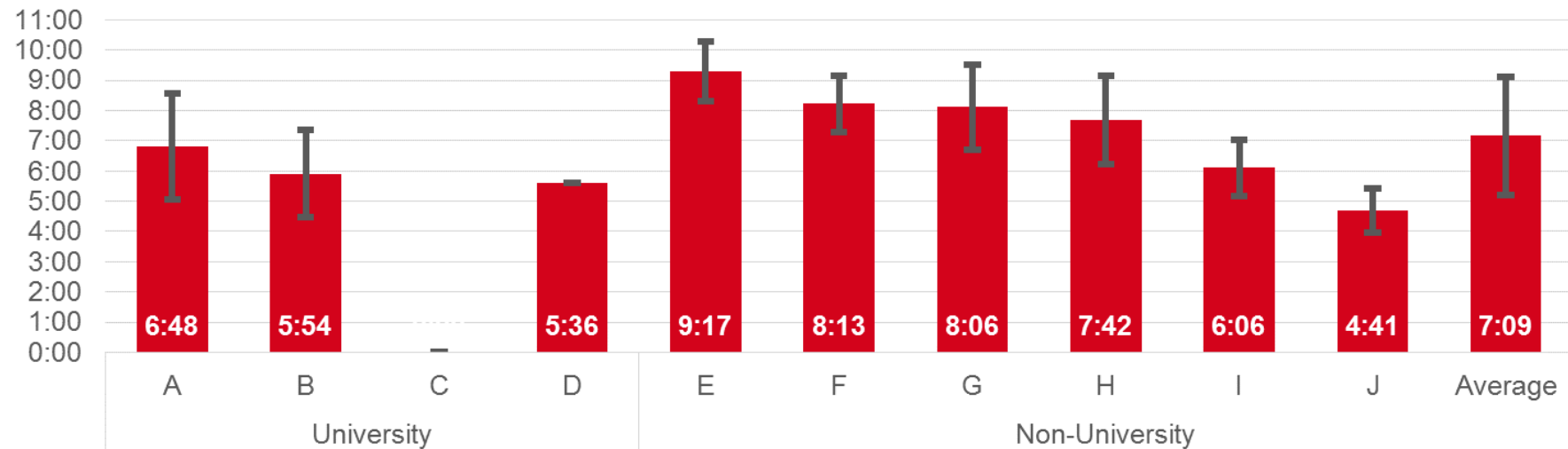


### A focus on unilateral DIEP/SIEA reconstruction

Figure 19 shows the average intervention duration of a unilateral DIEP/SIEA reconstruction for each team. Again, the underlying table (Table 38) shows on how many observations this average duration is based and the number of man-hours that plastic surgeons and surgeons-in-training spend on in scope activities.

Only this technique is presented in detail as it is the reconstruction technique with the most number of recorded measures in this study.

**Figure 19 – Average duration of a unilateral DIEP/SIEA reconstruction by team, including activities related to ablation and immediate secondary interventions (if performed)**





**Table 38 – Number of unilateral DIEP/SIEA registrations by team and man-hours spent on in-scope activities by profile (i.e. excluding activities related to ablation and immediate secondary interventions)**

	A	B	C	D	E	F	G	H	I	J	Average
# of observations	23	9	0	1	15	11	13	12	4	15	103
Reconstruction man-hours of surgeon	4:55	6:58		5:36	10:11	7:45	7:37	7:23	11:30	6:33	7:18
Reconstruction man-hours of medical student and surgeon in training	8:58	10:43		10:57	7:13	0:39	0:00	0:00	1:51	0:00	4:14

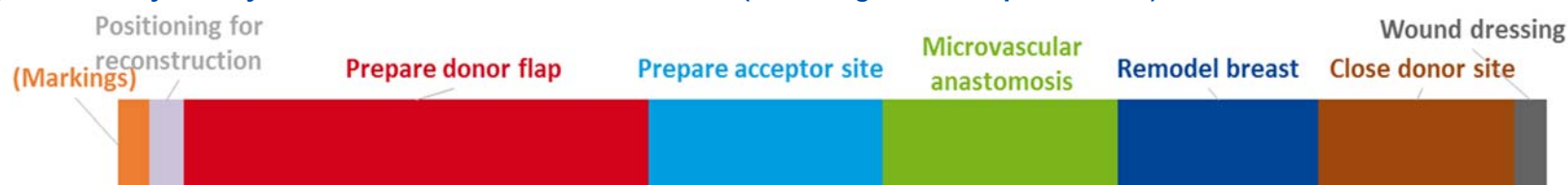
The average intervention duration varies between 4:41 to 9:17. This spread can be caused by various elements:

- size of the surgeon teams (working in parallel or not)
- ability of the surgeons
- materials used
- teaching time; etc.

When looking at the man-hours of surgeons-in-training, one can observe that some teams work a lot with surgeons-in-training while others never work with them. University teams seem to use a high number of surgeons in training, while the other team use less, except for team E.

Figure 20 and Figure 21 illustrate the duration and team size for each in-scope activity of a DIEP/SIEA unilateral reconstruction.

**Figure 20 – Average duration by activity of DIEP/SIEA unilateral reconstruction (excluding out-of-scope activities)**



**Figure 21 – Average duration and number of profiles by activity for a DIEP/SIEA unilateral reconstruction (excluding out-of-scope activities)**

	Markings	Positioning for reconstruction	Prepare donor flap	Prepare acceptor site	Microvascular anastomosis	Remodel breast	Close donor site	Wound dressing
Average activity duration	0:10	0:11	2:37	1:18	1:19	1:07	1:06	0:10
Average # of surgeons	1,0	0,8	1,0	0,7	1,1	1,0	0,7	0,7
Average # of surgeons-in-training	0,5	0,5	0,5	0,6	0,5	0,4	0,7	0,3



The longest activity is the “Prepare donor flap” activity which has an average duration of 2:37, followed by the 4 next activities with similar durations, between 1:19 and 1:06. At the other end of the spectrum, markings, positioning and wound dressing have a very short duration of approximately 0:10 each.

Note that “Wound dressing”, “Prepare acceptor site”, “Close donor site” and “Positioning for reconstruction” require 0.7-0.8 plastic surgeons on average, while the other activities require at least one plastic surgeon. This means that in some teams, the aforementioned activities are performed by either surgeons-in-training or specially trained nurses.

On average, between 0.3 and 0.7 surgeons-in-training are present during each reconstruction activity. This can be explained by the fact that some

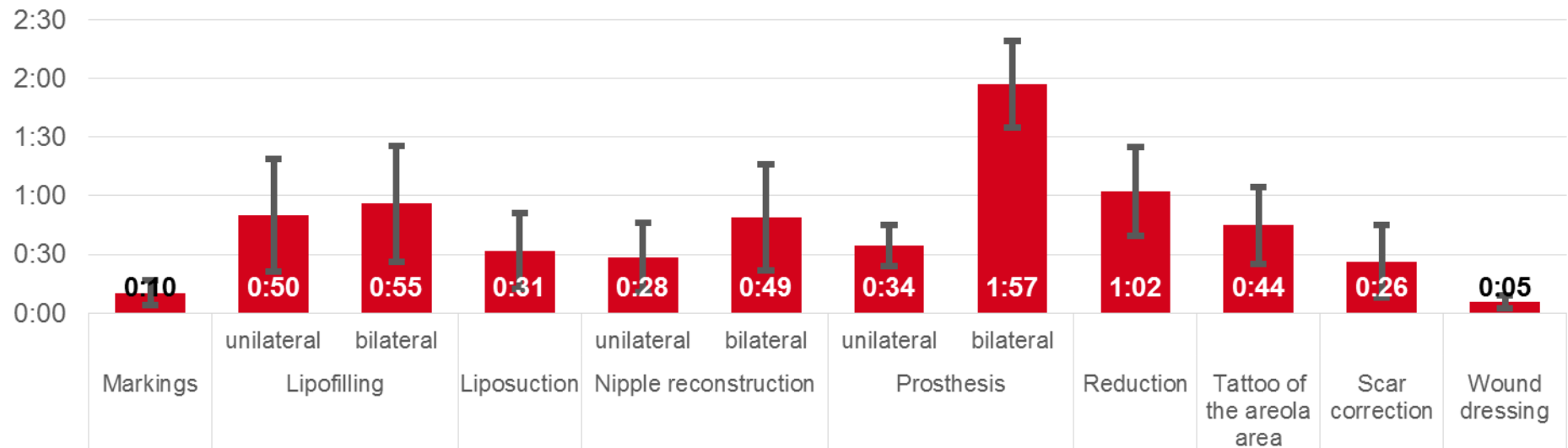
teams nearly always work with one or multiple surgeons-in-training, while others never work with surgeons-in-training.

#### 4.11.1.4 Duration of delayed secondary interventions

This paragraph presents the durations and the composition of the medical team in terms of man-hours for the most common secondary intervention techniques, that is, for those techniques for which a minimum number of registrations are available.

Figure 22 provides an overview of the average duration of delayed secondary intervention activities. Next, Table 39 shows on how many registrations these average durations are based and the number of man-hours spent on in-scope activities for plastic surgeons and for surgeons-in-training.

**Figure 22 – Average duration of secondary interventions**




**Table 39 – Number of secondary interventions registrations by type of activity and man-hours by profile**

	Markings	Lipofilling		Lipo-suction	Nipple reconstruction		Prosthesis		Reduction	Tattoo of the areola area	Scar correction	Wound dressing
		Unilateral	Bilateral		Unilateral	Bilateral	Unilateral	Bilateral				
# of observations	110	52	17	37	36	18	7	2	15	5	26	137
Man-hours of plastic surgeons	0:09	0:45	0:35	0:28	0:27	0:42	0:34	1:57	0:58	0:07	0:18	0:03
Man-hours of surgeons in training	0:06	0:30	0:47	0:25	0:17	0:50	0:13	3:06	0:45	0:00	0:22	0:03

Despite a high global number of measures, for many secondary intervention techniques, the number of registrations is very limited. This is due to the high diversity in techniques. Furthermore, the long error bars show a high variation in measures. For both these reasons, the results for secondary intervention techniques should be interpreted with care.

Note that bilateral lipofilling has a longer total duration than unilateral lipofilling but that the number of man-hours of plastic surgeons is lower in the case of bilateral lipofilling. The result of this will be a lower total cost for bilateral lipofilling than for unilateral lipofilling as the man-hours of surgeons-in-training are remunerated at a lower rate than the man-hours of a plastic surgeon. This further indicates the need for more registrations.

#### 4.11.2 Cost results

This section presents the cost results of the study which are based on the time results (cf. 4.11.1) and on the unit cost of the resources (cf. 4.8).

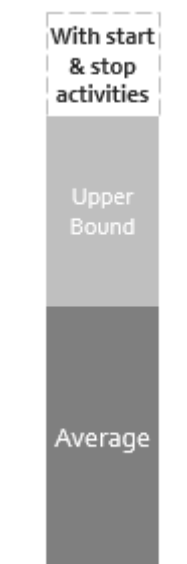
As explained in paragraph 4.8, three different scenarios are considered, each scenario being based on a different valuation of the surgeons' time

- Scenario A is based on the gross cost of plastic surgeons excluding supplements provided by the KCE manual for cost studies (see Box 2).<sup>37</sup>. The hourly remuneration of this scenario varies from € 131.63 to € 242.29.

- Scenario B is a gross cost based on all medical specialists. This was also provided by the KCE manual for cost studies.<sup>37</sup>. The hourly remuneration of this scenario varies from € 160.90 to € 296.17.
- Scenario C represents the "prosthesis opportunity cost" in that it calculates the income of a surgeon who would perform prosthesis breast reconstructions instead of autologous breast reconstructions. The hourly remuneration of this scenario amounts to € 228.02.

Figure 23 illustrates the format in which all cost results are presented:

- The average cost of each scenario (calculated based on the average number of hours per half day)
- is represented by a dark bar.
- The lighter bar whose value is higher represents the cost obtained when using the hourly remuneration
- that is based on the minimum number of billable hours per half day.
- Finally, the cost of the presence of one plastic surgeon during the start and end activities (Activities "Prepare intervention & anaesthesia" and "Finish intervention") is calculated separately. In the following graphs, it is represented by the dashed box.

**Figure 23 – Legend for cost results**

#### 4.11.2.1 “Surgeon cost” of the flap transfer

Figure 24 shows the average cost results of unilateral and bilateral DIEP/SIEA interventions. For each type of intervention, all the cost scenarios are presented. Note that the number of registrations is relatively high: there are 103 registrations of unilateral DIEP / SIEA reconstructions and 44 registrations of bilateral DIEP/SIEA interventions.

Note that the costs that are calculated on the basis of the average number of billable hours per half day (illustrated by the lower bars in darker colours) do not exceed the current RIZIV-INAMI fee for unilateral and bilateral DIEP/SIEA reconstructions. All other scenarios however, including scenario C show a cost that exceeds the current RIZIV-INAMI fee by +30% to +70%, depending on the considered scenario.



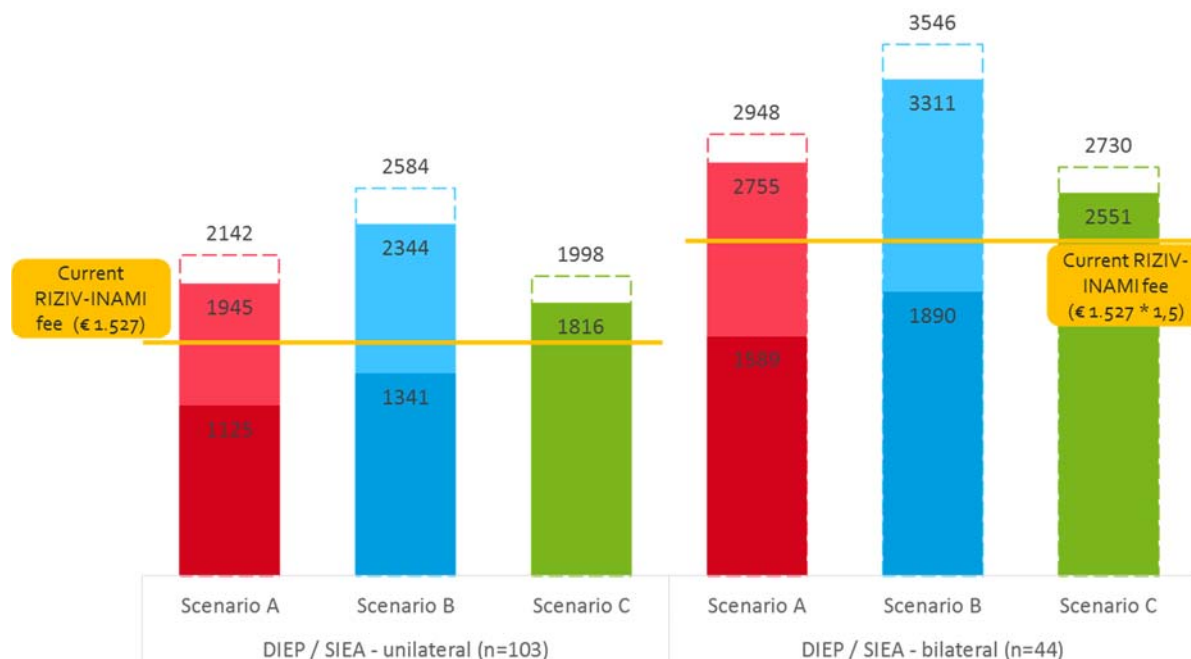
**Figure 24 – Average “surgeon cost” of unilateral and bilateral DIEP/SIEA interventions**

Figure 25 shows the average cost results of unilateral LDF reconstructions and of unilateral S-GAP/I-GAP/PAP/TUG/LAP reconstructions.

The number of registrations for these intervention techniques is more limited than for the unilateral and bilateral DIEP/SIEA reconstructions, as these techniques are less common. Therefore, these results must be considered more carefully.

For the unilateral LDF reconstruction, all cost scenarios result in a higher cost than the current RIZIV-INAMI fee, ranging from a 40% higher cost (in the case of scenario A calculated with the average number of hours per half day) up to a cost that is 230% higher than the current RIZIV-INAMI fee (in

the case of scenario B calculated with the minimum number of hours per half day and including the start and stop activities).

Although they are somewhat higher, the results for the unilateral S-GAP/I-GAP/PAP/TUG/LAP reconstructions are similar to the results of the unilateral DIEP/SIEA reconstructions: the costs calculated on the basis of the average number of billable hours per half day (illustrated by the lower bars in darker colours) do not exceed the current RIZIV-INAMI fee. All other scenarios however, including scenario C show a cost that exceeds the current RIZIV-INAMI fee by +30% to +85%, depending on the considered scenario.

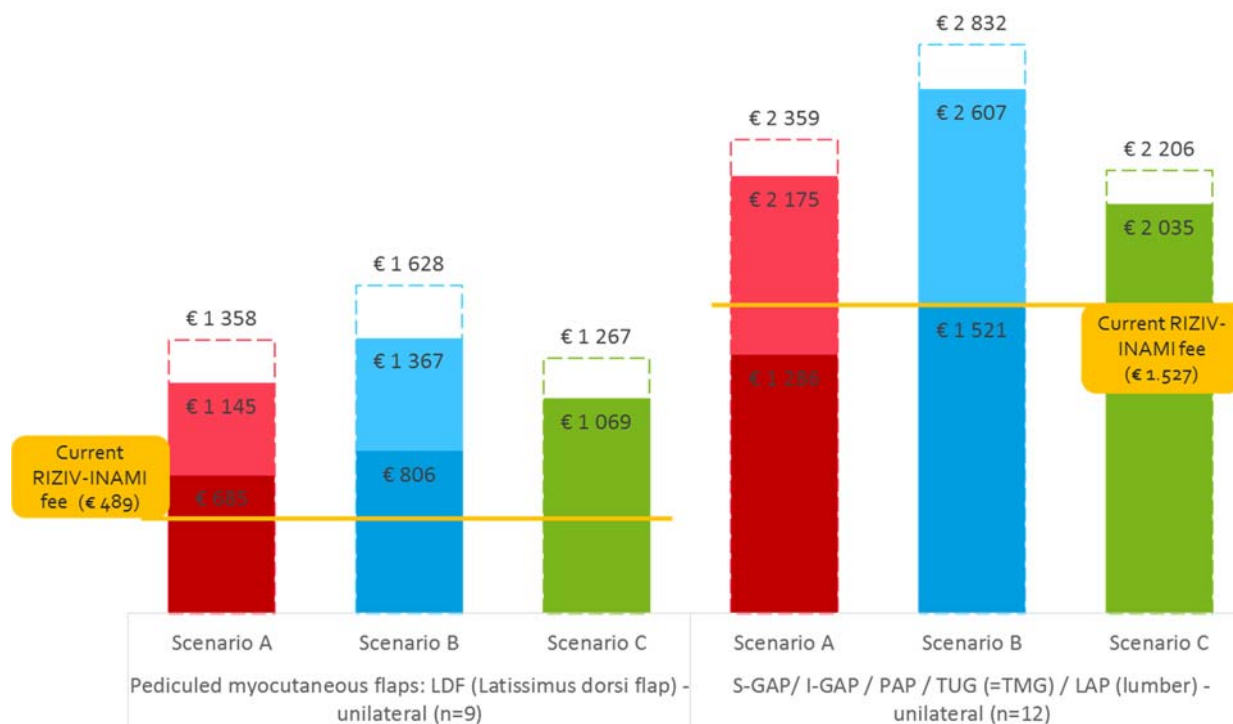
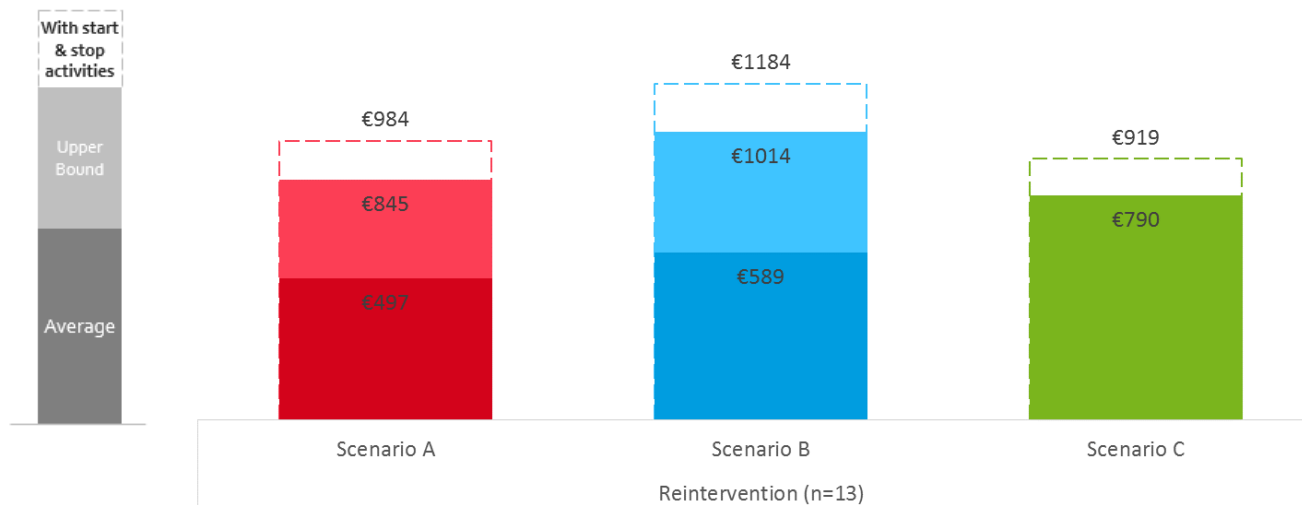
**Figure 25 – Average “surgeon cost” of unilateral LDF and S-GAP/I-GAP/PAP/TUG/LAP interventions**

Figure 26 shows the average cost results of re-interventions. Note that there are only 13 registrations of re-interventions and that the time results of re-interventions showed a great variability in the duration of these interventions. Depending on the type of complication and therefore, on the type of re-intervention, a different RIZIV-INAMI fee will be billed. This renders it impossible to compare the cost results shown below with current RIZIV-INAMI fees.

**Figure 26 – Average re-intervention cost by scenario**

#### 4.11.2.2 “Surgeon cost” of delayed secondary interventions

This section focuses on the cost results of the secondary intervention techniques defined in section 4.5.

- First, the individual average “surgeon cost” of each type of secondary intervention technique is presented.
- Next, given that some ‘side activities’ (markings, prepare intervention and anaesthesia...) are necessary in order to be able to perform the secondary interventions, the “surgeon cost” of these side activities is also presented.
- Finally, in order to allocate the cost of these side activities to each technique, the total cost of these side activities is divided by 1.9, i.e. the average number of techniques that are performed during the same intervention (average based on the collected time registrations).

There is a lot of diversity in the different types of secondary interventions. Therefore despite a high overall number of registrations, the number of measures by type of technique is relatively low and the results should be

taken with care. Some results with a very low number of measures are also partially transparent to underline this fact (e.g. tattoo cost in Figure 28).

In the case of secondary interventions, only the average and upper bound variants of the three scenarios is shown directly. The start and end activities will be shown at the end of this paragraph, when analysing the cost of the “side activities”.

Figure 27 shows the average “surgeon cost” of unilateral or bilateral lipofilling and liposuction. Despite a relatively high number of measures, one can observe a contra-intuitive relative cost when comparing unilateral and bilateral lipofilling: the cost of bilateral lipofilling should be higher than that of unilateral lipofilling. However, as explained in paragraph 4.11.1.4, even if the total activity duration of bilateral lipofilling is longer than that of unilateral lipofilling, the number of plastic surgeon man-hours is lower in the case of bilateral lipofilling. This is the reason for the lower cost and indicates the need for more registrations.

Note that there is currently no RIZIV-INAMI fee for liposuction and lipofilling.

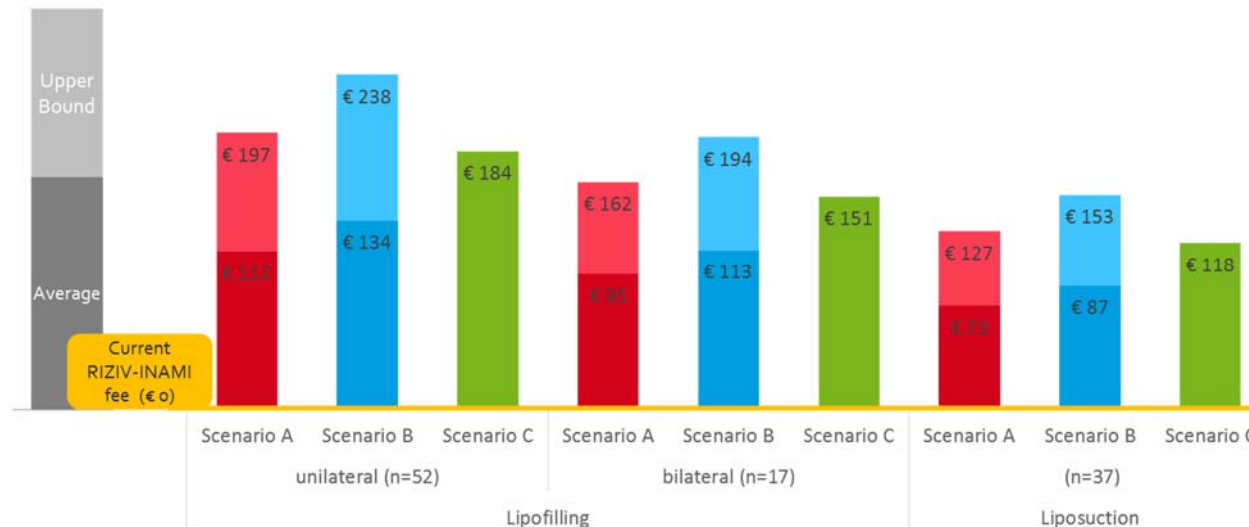
**Figure 27 – Average “surgeon cost” of lipofilling and liposuction**

Figure 28 shows the average “surgeon cost” of unilateral and bilateral nipple reconstructions, of tattoos of the areola area (unilateral or bilateral) and of scar corrections.

Note that the number of measures of tattoos of the areola area is very limited as most teams send patients to commercial tattoo centres outside of the hospital setting. The 5 registrations of tattoos of the areola area come from a single team.

For the nipple reconstruction, the cost results are almost always lower than current RIZIV-INAMI fees. However, it is important to note that the cost results shown here do not include the cost of side activities (see Figure 31)

The cost of tattoo of the areola in the private sector has been estimated between € 150 and € 300.



Figure 28 – Average “surgeon cost” of nipple reconstructions, tattoos of the areola area and of scar corrections

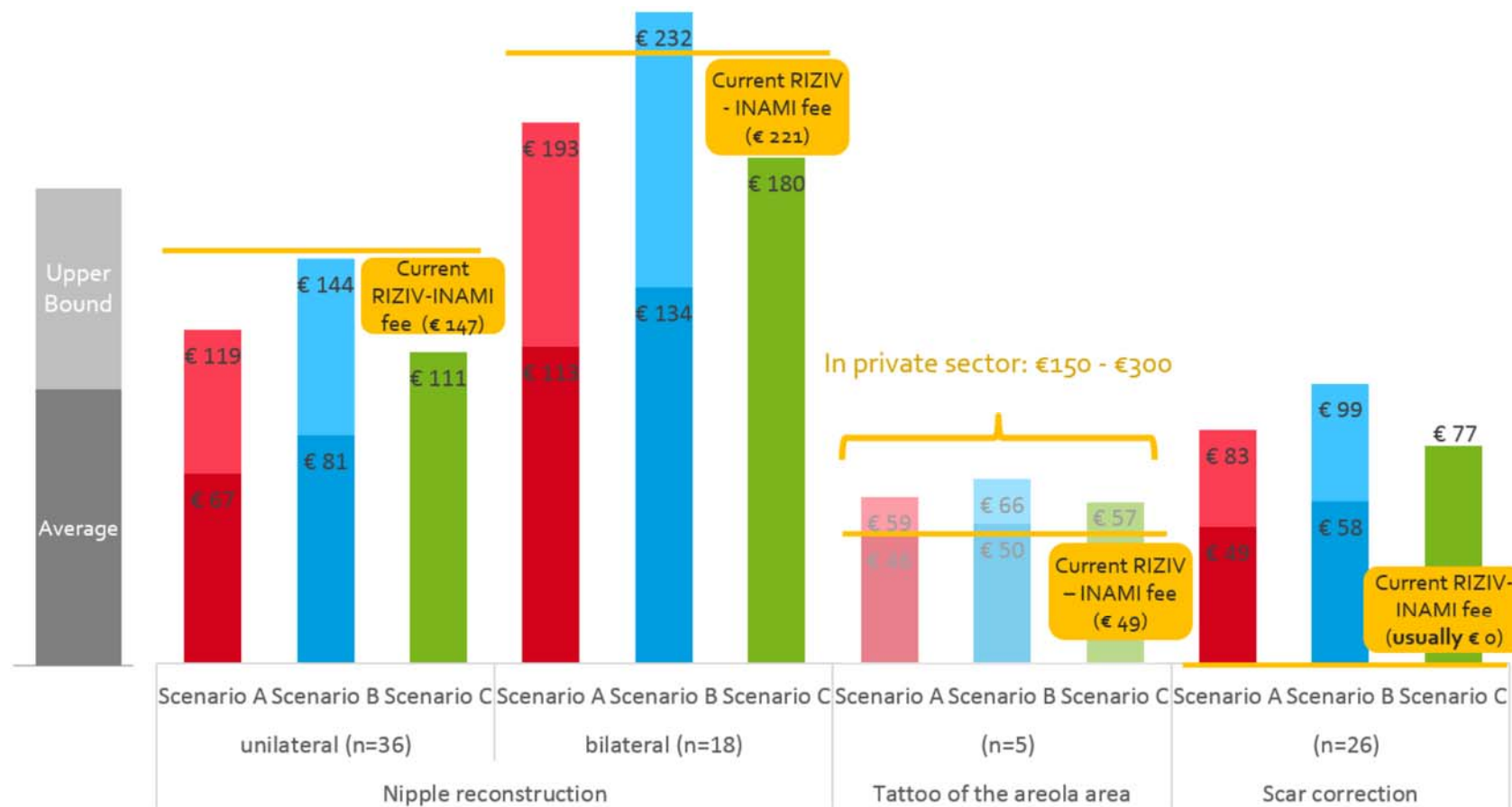


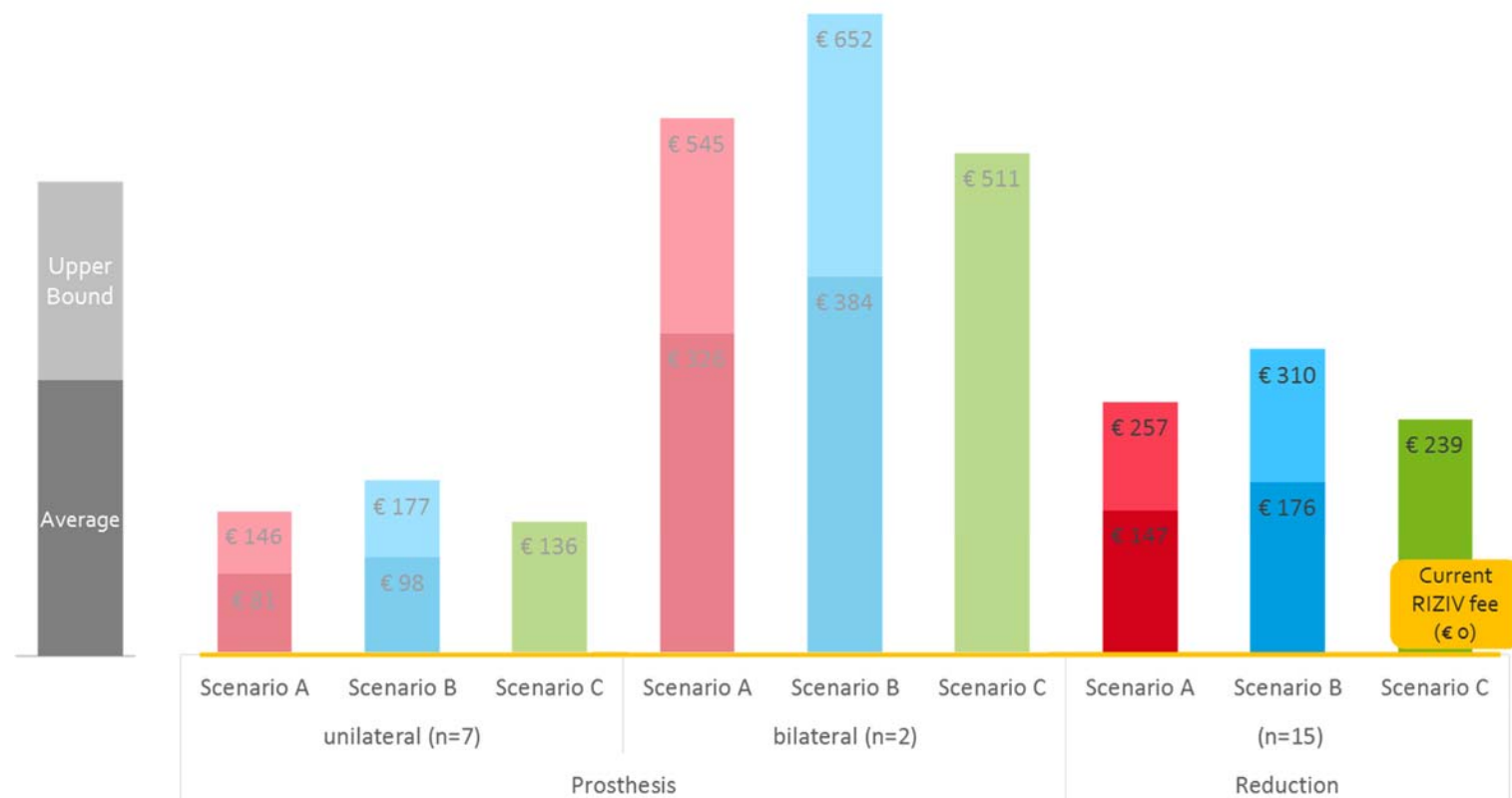
Figure 29 shows the average “surgeon cost” of secondary interventions using a prosthesis (unilateral and bilateral) and of adjustments by reduction. The number of measures is very low for prosthesis adjustments and the results should be taken with care. The cost of adjustments by way of

reduction are based on a slightly higher but still limited number of registrations.

Again, there is currently no RIZIV-INAMI fee for these secondary interventions today.

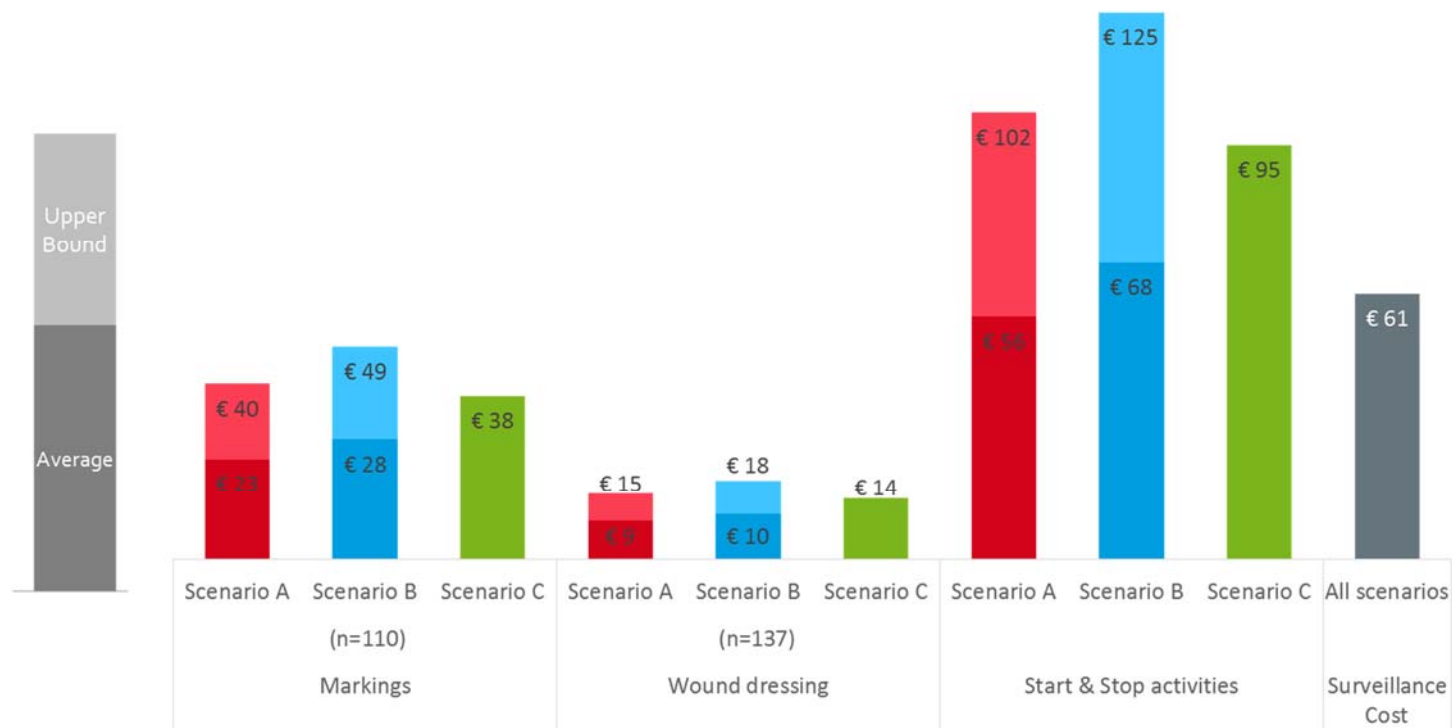


Figure 29 – Average “surgeon cost” of prosthesis adjustments and of reductions (graph 3/3)



The previous figures presented the average “surgeon costs” of each adjustment activity individually but without taking into account that some “side activities” are required in order to perform those adjustments. These activities are: “Markings”, “Wound dressing”, “Start & Stop activities” (the cost of which corresponds to the cost for the presence of 1 plastic surgeon during the activities “prepare intervention, positioning and anaesthesia” and “Finish intervention”) and “Surveillance cost” which is calculated based on the current RIZIV-INAMI fee for daily surveillance during 5 days (cf. 4.8.1).

Figure 30 shows the cost of these side activities.

**Figure 30 – Average “surgeon cost” of side activities of secondary interventions by scenario**

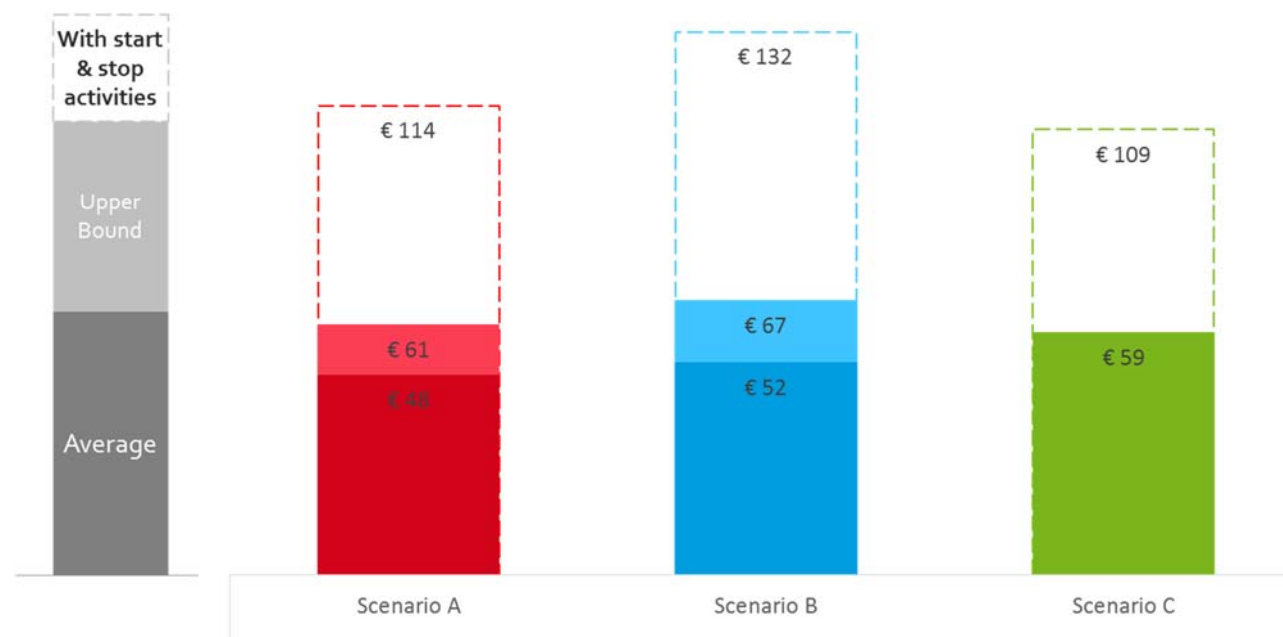
As stated above, the cost of these “side activities” must then be divided by 1.91 to be allocated to each secondary intervention activity (i.e. 1.91 techniques were on average performed during the same intervention). For example, for scenario B (average number of billable hours), the cost of the “side activities” (without start & stop activities) equals €99 (28+10+61), the cost of each technique should therefore increase by  $€99/1.91 = €52$  (see Figure 31).

The resulting costs per technique are illustrated in Figure 31. Note that the “side activities” included in the average and upper bound scenario are “Markings”, “Wound dressing” and “Surveillance cost”. Start and stop activities are added separately, just as in the graphs on flap transfer costs (cf. 4.11.2.1).

The average “surgeon cost” of side activities is relatively high when compared to the average “surgeon cost” of individual secondary intervention techniques and should therefore not be forgotten when studying the cost of secondary interventions.



Figure 31 – Average “surgeon cost” of side activities to be added to each individual secondary intervention technique







## 4.12 Summary of main figures and handling of uncertainty

Results presented in the previous section mainly depend on the cost per hour and the number of man hours:

- For the cost per hour, no objective data was available and a number of methodological choices were done. Uncertainty around these methodological choices was handled using scenario analyses. The description of the different scenarios can be found in section 4.8.
- Concerning the man-hours, because the cost is obtained by multiplying the number of man-hours per the cost per hour, variations in the total number of man-hours will impact linearly the cost of interventions.

To give an idea of variations around cost-estimates, Table 40 summarizes the average cost obtained +/- the standard deviation (sd) for each scenario and Table 41 the median and the interquartile range (IQR) for each scenario.

### 4.12.1 Constant duration per technique for start and stop activities

Standard deviations and IQR between costs with or without start and stop activities are systematically the same. This is because a constant time was taken for the start and stop activities of each technique (e.g. 0:48 for DIEP/SIEA unilateral, 0:25 for secondary interventions...). It was chosen to take a constant time by technique, because in some interventions, the start and stop activities were not measured. This is often due to the fact that the plastic surgeon, leading the measurement, sometimes arrives after the start activities and leaves before the end activities. For reconstruction techniques, about 95% of measures included start and stop measures, while for secondary interventions, this drops to about 75%. For reconstruction techniques, the standard deviation of start and stop activities is about 0:15 (with average duration = 0:48) while for secondary interventions, the standard deviation is about 0:10 (with average duration = 0:25).

### 4.12.2 Variability in intervention duration and man-hours

A relatively important variability can be observed in intervention duration and man-hours (see section 4.11.1), implying important variations in cost results. Several reasons were identified that could explain that variability:

1. Surgeon: The experience and skills of the surgeon and the level of quality desired by the surgeon could have an impact.
2. Team: The size, the experience and the skills of the team performing the intervention could also be determining. For example, some surgeons have extensively trained their operating room nurse for more efficient interventions, not needing a second surgeon.
3. Material: The use of specific material can also increase or decrease the time of certain activities during the intervention.
4. Patient: The size/weight/etc. of the patient could also be an explanation.



Table 40 – Average “surgeon cost” of each technique (+/- standard deviation) for each scenario

Table 4b - Average surgeon cost for each technique (+/- standard deviation) for each scenario											
	Current RIZIV-INAMI Fee	Scenario A  (Based on the gross remuneration of plastic surgeon)				Scenario B  (Based on the average net remuneration of medical specialists + the difference between the net and the gross remuneration of plastic surgeon)				Scenario C  Prosthesis opportunity cost	
		Average  (based on the average number of billable hour per half day)		Upper bound  (based on the min. number of billable hour per half day)		Average  (based on the average number of billable hour per half day)		Upper bound  (based on the min. number of billable hour per half day)		-	
		Without start and stop activities	With start and stop activities	Without start and stop activities	With start and stop activities	Without start and stop activities	With start and stop activities	Without start and stop activities	With start and stop activities	Without start and stop activities	With start and stop activities
RECONSTRUCTION TECHNIQUES											
DIEP/SIEA unilateral (n= 103)	€1527	€1125 σ=€356	€1231 σ=€356	€1945 σ=€646	€2142 σ=€646	€1341 σ=€432	€1472 σ=€432	€2344 σ=€789	€2584 σ=€789	€1816 σ=€600	€1998 σ=€600
DIEP/SIEA bilateral (n= 44)	€2291	€1589 σ=€595	€1693 σ=€595	€2755 σ=€1100	€2948 σ=€1100	€1890 σ=€724	€2018 σ=€724	€3311 σ=€1340	€3546 σ=€1340	€2551 σ=€1011	€2730 σ=€1011
LDF unilateral (n= 9)	€489	€685 σ=€271	€801 σ=€271	€1145 σ=€441	€1358 σ=€441	€806 σ=€314	€947 σ=€314	€1367 σ=€521	€1628 σ=€521	€1069 σ=€409	€1267 σ=€409
S-GAP/I-GAP/PAP/TUG/LAP unilateral (n= 12)	€1527	€1286 σ=€499	€1386 σ=€499	€2175 σ=€911	€2359 σ=€911	€1521 σ=€606	€1643 σ=€606	€2607 σ=€1114	€2832 σ=€1114	€2035 σ=€845	€2206 σ=€845
SECONDARY INTERVENTION TECHNIQUES (with “Side Activities” included)											
Lipofilling - unilateral (n=52)	€0	€160 σ=€68	€189 σ=€68	€258 σ=€123	€311 σ=€123	€186 σ=€83	€222 σ=€83	€305 σ=€150	€371 σ=€150	€242 σ=€115	€292 σ=€115
Lipofilling - bilateral (n=17)	€0	€144 σ=€75	€173 σ=€75	€222 σ=€139	€276 σ=€139	€165 σ=€91	€200 σ=€91	€261 σ=€170	€326 σ=€170	€210 σ=€129	€260 σ=€129
Liposuction (n=37)	€0	€121 σ=€82	€150 σ=€82	€187 σ=€142	€241 σ=€142	€139 σ=€98	€174 σ=€98	€220 σ=€172	€285 σ=€172	€177 σ=€133	€227 σ=€133
Nipple reconstruction - unilateral (n=36)	€147	€116 σ=€43	€145 σ=€43	€180 σ=€77	€233 σ=€77	€133 σ=€52	€168 σ=€52	€211 σ=€94	€276 σ=€94	€170 σ=€72	€219 σ=€72



Nipple reconstruction - bilateral (n=18)	€221	€161 σ=€73	€190 σ=€73	€254 σ=€128	€307 σ=€128	€186 σ=€87	€221 σ=€87	€298 σ=€155	€364 σ=€155	€239 σ=€119	€289 σ=€119
prosthesis - unilateral (n=7)	€0	€130 σ=€30	€159 σ=€30	€207 σ=€49	€260 σ=€49	€150 σ=€35	€186 σ=€35	€244 σ=€59	€309 σ=€59	€195 σ=€46	€244 σ=€46
prosthesis - bilateral (n=2)	€0	€375 σ=€81	€404 σ=€81	€606 σ=€122	€660 σ=€122	€436 σ=€92	€471 σ=€92	€718 σ=€142	€784 σ=€142	€569 σ=€116	€619 σ=€116
Reduction - unilateral (n=15)	€0	€195 σ=€65	€224 σ=€65	€318 σ=€115	€371 σ=€115	€228 σ=€78	€263 σ=€78	€377 σ=€140	€443 σ=€140	€298 σ=€107	€348 σ=€107
Tattoo of the areola area (n=5)	€49	€95 σ=€31	€124 σ=€31	€120 σ=€56	€174 σ=€56	€101 σ=€37	€137 σ=€37	€132 σ=€68	€198 σ=€68	€116 σ=€52	€166 σ=€52
Scar correction (n=26)	€0 (usually)	€97 σ=€25	€126 σ=€25	€144 σ=€46	€197 σ=€46	€109 σ=€30	€145 σ=€30	€166 σ=€58	€232 σ=€58	€136 σ=€43	€186 σ=€43

Table 41 – Median “surgeon cost” of each technique and IQR for each scenario

	Current RIZIV-INAMI Fee	Scenario A				Scenario B				Scenario C	
		(Based on the gross remuneration of plastic surgeon)				(Based on the average net remuneration of medical specialists + the difference between the net and the gross remuneration of plastic surgeon)				Prosthesis opportunity cost	
		Average		Upper bound		Average		Upper bound		-	
		(based on the average number of billable hour per half day)		(based on the min. number of billable hour per half day)		(based on the average number of billable hour per half day)		(based on the min. number of billable hour per half day)			
		Without start and stop activities	With start and stop activities	Without start and stop activities	With start and stop activities	Without start and stop activities	With start and stop activities	Without start and stop activities	With start and stop activities	Without start and stop activities	With start and stop activities
RECONSTRUCTION TECHNIQUES											
DIEP/SIEA unilateral (n= 103)	€1527	€1040 IQR=€399	€1147 IQR=€399	€1822 IQR=€708	€2018 IQR=€708	€1234 IQR=€481	€1365 IQR=€481	€2178 IQR=€847	€2419 IQR=€847	€1695 IQR=€657	€1877 IQR=€657
DIEP/SIEA bilateral (n= 44)	€2291	€1529 IQR=€712	€1633 IQR=€712	€2622 IQR=€1346	€2815 IQR=€1346	€1822 IQR=€861	€1949 IQR=€861	€3180 IQR=€1662	€3415 IQR=€1662	€2442 IQR=€1250	€2620 IQR=€1250



<b>LDF unilateral (n= 9)</b>	€489	€785 IQR=€526	€900 IQR=€526	€1247 IQR=€870	€1460 IQR=€870	€907 IQR=€617	€1048 IQR=€617	€1472 IQR=€1037	€1732 IQR=€1037	€1174 IQR=€816	€1372 IQR=€816
<b>S-GAP/I-GAP/PAP/TUG/LAP unilateral (n= 12)</b>	€1527	€1202 IQR=€557	€1302 IQR=€557	€1956 IQR=€1017	€2140 IQR=€1017	€1401 IQR=€689	€1523 IQR=€689	€2322 IQR=€1222	€2547 IQR=€1222	€1837 IQR=€950	€2008 IQR=€950
<b>SECONDARY INTERVENTION TECHNIQUES (with “Side Activities” included)</b>											
<b>Lipofilling - unilateral (n=52)</b>	€0	€150 IQR=€101	€179 IQR=€101	€239 IQR=€196	€293 IQR=€196	€174 IQR=€126	€209 IQR=€126	€283 IQR=€241	€348 IQR=€241	€225 IQR=€181	€275 IQR=€181
<b>Lipofilling - bilateral (n=17)</b>	€0	€105 IQR=€144	€134 IQR=€144	€143 IQR=€291	€196 IQR=€291	€108 IQR=€183	€144 IQR=€183	€167 IQR=€360	€232 IQR=€360	€135 IQR=€268	€185 IQR=€268
<b>Liposuction (n=37)</b>	€0	€97 IQR=€62	€127 IQR=€62	€145 IQR=€111	€199 IQR=€111	€110 IQR=€76	€146 IQR=€76	€169 IQR=€133	€234 IQR=€133	€138 IQR=€104	€188 IQR=€104
<b>Nipple reconstruction - unilateral (n=36)</b>	€147	€114 IQR=€60	€143 IQR=€60	€180 IQR=€105	€233 IQR=€105	€131 IQR=€71	€166 IQR=€71	€211 IQR=€128	€277 IQR=€128	€169 IQR=€98	€219 IQR=€98
<b>Nipple reconstruction - bilateral (n=18)</b>	€221	€138 IQR=€103	€167 IQR=€103	€218 IQR=€190	€272 IQR=€190	€159 IQR=€123	€195 IQR=€123	€260 IQR=€228	€325 IQR=€228	€205 IQR=€178	€255 IQR=€178
<b>prosthesis - unilateral (n=7)</b>	€0	€120 IQR=€63	€149 IQR=€63	€192 IQR=€103	€245 IQR=€103	€139 IQR=€74	€174 IQR=€74	€227 IQR=€122	€293 IQR=€122	€180 IQR=€96	€230 IQR=€96
<b>prosthesis - bilateral (n=2)</b>	€0	€375 IQR=N/A	€404 IQR=N/A	€606 IQR=N/A	€660 IQR=N/A	€436 IQR= N/A	€471 IQR=N/A	€718 IQR=N/A	€784 IQR= N/A	€569 IQR=N/A	€619 IQR=N/A
<b>Reduction - unilateral (n=15)</b>	€0	€219 IQR=€113	€248 IQR=€113	€359 IQR=€191	€412 IQR=€191	€257 IQR=€136	€293 IQR=€136	€426 IQR=€227	€491 IQR=€227	€337 IQR=€179	€387 IQR=€179
<b>Tattoo of the areola area (n=5)</b>	€49	€85 IQR=€57	€114 IQR=€57	€98 IQR=€89	€151 IQR=€89	€89 IQR=€65	€124 IQR=€65	€104 IQR=€105	€169 IQR=€105	€96 IQR=€84	€145 IQR=€84
<b>Scar correction (n=26)</b>	€0 (usually)	€103 IQR=€41	€132 IQR=€41	€135 IQR=€70	€188 IQR=€70	€112 IQR=€48	€148 IQR=€48	€155 IQR=€89	€221 IQR=€89	€128 IQR=€65	€178 IQR=€65



### 4.13 Study limitations

Results presented in this chapter 4 “Time measurements and valuation scenarios of the surgeon cost” must be used with caution due to a number of limitations. These limitations are discussed here:

- The only objective data in the study is the duration of activities and the associated man-hours per profile. Nevertheless, the validity of these data is limited by the low number of observations for some interventions (see Table 40 for the number of observations per intervention). Indeed, only the unilateral DIEP-SIEA intervention had a number of observations superior to 100; and only bilateral DIEP-SIEA, unilateral nipple reconstruction, unilateral lipofilling and liposuction interventions had a number of observations superior to 30.
- To value the work of the surgeon, a cost per hour was needed. Nevertheless, no methodological flawless data was available for this parameter and a number of methodological choices had to be made. As shown in the scenario analyses presented in the previous section, these methodological choices had a significant impact on results. In a first scenario, resources were valued using a cost per hour based on the current yearly gross remuneration of plastic surgeons (i.e. taking into account official tariffs for all activities performed in the hospital and covered by the national health insurance, excluding supplements). The fact that the current reimbursement levels were used as basis for the analysis and that these levels were considered as too low by plastic surgeons (at least for autologous breast reconstructions) led to a vicious circle. Unsurprisingly, the first scenario did not result in (much) higher costs compared to current reimbursement levels. In order to avoid the vicious circle, other scenarios were explored: a second scenario based on the average remuneration of all medical specialists and a third scenario based on a prosthesis opportunity cost. Nevertheless, these scenarios are also based on the current reimbursement levels that could also not be appropriated.
- It should also be noted that the yearly remunerations used in this study are based on a previous KCE report (“the manual for cost study”, KCE report 178), with the limits described in this previous report. More especially, estimations in this previous report were based on a small number of observations (13 hospitals) and did not take into account salaried physicians. Important variations in data were also highlighted. Nevertheless, these are the best estimates currently available for Belgium. It should also be noted that for surgeons-in-training, no estimation was provided in the KCE report 178. Ideally, a survey should therefore have been done to estimate the average remuneration of surgeons-in-training in the teams that participated in the study. This was however not performed for practical reasons and estimations in this study are based on the minimal salary (given a cost per hour of €21.23). Because of the usual low remuneration of surgeon-in-training, such a choice does nevertheless not really impact results. Moreover, the same amount was used for the few students who participated actively in some activities, which in this case is an overestimation of their remuneration.
- Besides the yearly remuneration of medical specialists (converted in a remuneration per half day according to the manual for cost study), the cost per hour also depended on the number of billable hours per half day (i.e. the time spent on activities reimbursed by the national health insurance, and who must implicitly cover non remunerated activities such as administrative tasks). No data was nevertheless available for the number of billable hours. This parameter was therefore estimated based on a questionnaire sent to the participating teams and important variations in the responses were found. For the first two scenarios, two sub-scenarios were therefore done, i.e. an average scenario based on the average number of billable hours per half day given by the teams and an upper-bound scenario (i.e. a maximum cost per hour) based on the minimum number of billable hours per half day found. As a result, the cost per hour varied from € 131.63 to € 296.17 according to the scenario. It should also be noted that this number of billable hours per half day, provided by plastic surgeons, was also used for the scenario B (based on the average remuneration of all medical specialists). Because the number of billable hours per half day is expected to be different for other medical specialists, this means that the scenario B is purely hypothetical and does not really reflect an average cost per hour for all medical specialists.
- The studied scenarios also did not include evaluations based on intensity, stress, skill-level, etc. of the performed intervention. This approach could nevertheless only be performed on a global level (see also the discussion of this report).



- Finally, surveillance costs for the first five days were included in this analysis because the fee is expected to cover them. Ideally, this should have been done by assessing the time of surveillance, multiplied by a cost per hour. Assessing the time of surveillance was nevertheless not possible for practical reasons. Because such a parameter had only a limited impact on the cost (i.e. €60 on an average cost of minimum € 1125 for a DIEP (scenario A)) it was decided to use the current RIZIV-INAMI tariff for surveillance per day, multiplied by 5 (according to the tariffication rules). This choice nevertheless induces a confusion between costs and prices and depends on tariffication rules that could not be appropriate.

It is crucial that these limitations are well understood by the users of this report. As cost scenarios have important limitations, the usage of one of these scenarios without careful reflexion should not be done.

## 5 DISCUSSION AND CONCLUSION

The main objective of this study was to provide objective data to serve as a basis of discussion for a possible re-evaluation of the RIZIV-INAMI fee for autologous breast reconstruction with flap. Even if this study has a lot of limitations implying that results must be used with cautions, this study allows us to identify important points of attention for policy makers:

### **Important variations in the remuneration of medical specialists and the need for a base cost per hour**

Variations in the cost per hour obtained in the different scenarios reflect the differences in remunerations between medical specialists (with an average cost per hour of € 131.63 for plastic surgeons and an average cost per hour of € 160.90 for all medical specialists confounded) and within the same specialty (an average cost per hour of € 131.63 for all activities performed by a plastic surgeon and of € 228.02 for a reconstruction with a prosthesis). This difference would yet be higher if we had taken into account a cost per hour only based on the remuneration of other medical specialists known as being high. A previous KCE report has already highlighted the important variations in the remuneration of medical specialists, obviously not linked to a corresponding tenfold in workload, risk or expertise.<sup>37</sup> An agreement on what is a reasonable cost per hour for a base intervention is needed, that can then be adjusted according to other characteristics such as additional stress and expertise (see also below).

### **A global re-evaluation of the remuneration of all medical specialists is required, based on additional factors than only time**

Although initially fees for surgery were based on rude estimates of time and complexity of interventions compared to a number of base interventions (appendectomy e.g. served as base intervention for abdominal surgery fees), the link between the tariff and objective criteria such as time and complexity blurred over time. Some fee (re)negotiations but also the lack of adaptation of some other fees (e.g. when the complexity / time of an intervention was reduced because of technological progress) have led to unjustifiable imbalances in remuneration between different medical specialists.

In a recent KCE report proposing a framework for an improved hospital payment system (KCE report 229), a re-evaluation of the remuneration of





medical specialists was put forward as one of the pillars of the recommended reform.<sup>38</sup>

Imbalances should be redressed not only by taking into account the time spent by the medical specialist (as done in this study) but also by using a number of factors such as the level of required expertise and experience, risks (including litigation risk) and stress, required intellectual effort, physical effort and discomfort. The resource-based relative value scale, developed by Hsiao<sup>39</sup> and used by Medicare in the U.S. is an example of a relative fee-setting model, where the physician work component is based on the physician's time, mental effort, technical skill, judgment, stress and training. Official tariffs were also reviewed in France where a common classification of medical procedures ('classification commune des actes médicaux', CCAM) for technical procedures was established based on this model.<sup>40</sup> Such a fee-setting process nevertheless requires a valuation of activities relative to the value of other activities across all medical specialists, to ensure coherency and to allow estimating and controlling the impact on aggregate expenditures. It encompasses a simultaneous approach and cannot be done separately and consecutively for different medical specialists, and certainly not for one single activity within one specialty.

The currently presented cost analysis on autologous breast reconstruction therefore does not provide a solid answer to the question of what can be considered a fair remuneration, i.e. based on objective criteria. It could only be used for a temporary fee revision, awaiting a more global re-evaluation across but also within medical specialties.

#### **Toward a professional fee without current deductions**

In its framework for reform, the KCE furthermore proposes to abandon the system of deductions and to move towards a system where fees only cover the physician's cognitive and physical labour and related risks. The presented analysis on breast reconstruction still follows the lines of the current fee-for-service system, along the general principle that fees are meant to cover more than just the physician's cognitive and intellectual labour. They are also meant to cover the costs incurred by the performance of medical services that are not covered by the hospital budget. Details on such contributions are not regulated by law and agreements between physicians and hospitals on the costs to be covered vary widely. This posed a difficulty to calculate the real cost to be covered by the RIZIV-INAMI fees. In order to circumvent this problem, current gross remuneration data were

used, i.e. remuneration of plastic surgeons before making any subtractions either for deductions to the hospital, or for direct expenses made by the plastic surgeon e.g. for an instrumentalist at own charge. This allowed us to focus efforts on time measurements, which should anyhow be one of the important building blocks for any future – global - fee re-evaluation.

#### **Beyond a simple re-evaluation of specialists' remuneration tariffs: A global revision of the nomenclature...**

Besides the tariffs, a global revision of the structure of the nomenclature was also highlighted, e.g. a revision of the descriptions as well as of the number of codes (removal or adding of specific codes). There is currently almost 9000 different codes and in many domains the list is for example considered too detailed by stakeholders interviewed in the KCE report 229 (proposing a framework for an improved hospital payment system). The current study also shows that some specific rules / mechanisms should be revised. For example, fees for anaesthesia are currently linked to the remuneration of the surgeon fee (% of the surgeon fee). Thus, by increasing the remuneration of plastic surgeons, the remuneration for anaesthesia will also increase, without change in the level of complexity of anaesthesia.

It should nevertheless be noted that the identification of problems linked to the current nomenclature was out of scope of this report. The aim of this discussion is not to provide an exhaustive list of problems linked to the current nomenclature but rather to insist on the need for a global revision through examples.

#### **...and an extension of the hospital budget, more based on real resources consumptions**

The current study only focus on the "surgeon cost" to re-evaluate his/her remuneration. Nevertheless, the KCE report 229 also underline a chronic issue of underpayment for the Budget of Financial Means (BFM). The so-called BFM is less and less sufficient to pay for nursing and other (non-medical) care personnel or general expenses. The framework for reform in the KCE report 229 therefore also propose to **extend the existing DRG-based payment per admission**, and to determine the **DRG tariffs much more on the basis of actual costs** than is the case today, requiring the collection of average costs derived from a sample of hospitals. This mean that in the future, an enlargement of this study to a total cost based on all resources will be needed.

**The question of aesthetic adjustments**

The RIZIV-INAMI fee is expected to cover the full reconstruction process including adjustments. Aesthetic interventions are not reimbursed but in the case of breast reconstruction after mastectomy, the borderline between aesthetic and not aesthetic adjustments is situated in a twilight zone. In order to avoid to determine by ourselves which adjustments must be taken into account to determine the total fee for an autologous breast reconstruction intervention, the costs of secondary interventions are presented separately from the cost of the flap transfer.

**Not a classical HTA**

Finally, it should be noted that the aim of this study was not to analyze the effectiveness and cost-effectiveness of autologous breast reconstruction interventions compared to alternatives as it is usually done in classical health technology assessments (HTA). The clinical part on the effectiveness and safety of these procedures compared to alternatives as well as the description of the current practice in Belgium (including some cost data) were rather presented to set the frame of the medical context around autologous breast reconstruction.

As stated above, the scope of this report was not to put in question the reimbursement decision of autologous breast reconstruction techniques but rather to provide objective data for potential re-evaluations of the current reimbursement tariffs. This is also why the cost study was limited to the “surgeon cost” for the initial breast reconstruction episode, also without taking into account long-term complications.

**In conclusion**

Important variations were found in the results, also depending of methodological choices. For unilateral DIEP interventions for example, results ranged from € 1125 (which is below the current RIZIV-INAMI fee of € 1527) to € 2344 depending on the scenario. This amount further increases when taking into account start and stop activities (up to € 2584) or by adding secondary interventions (i.e. immediate or delayed adjustments). Due to the long list of limitations described above, the current analysis must be used with caution and can only serve for a temporary revision of the fees for autologous breast reconstruction techniques with flap, awaiting a more global re-evaluation across and within medical specialties.

The big challenge in the future will be to define what would be a fair and reasonable base hourly income for a physician.





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