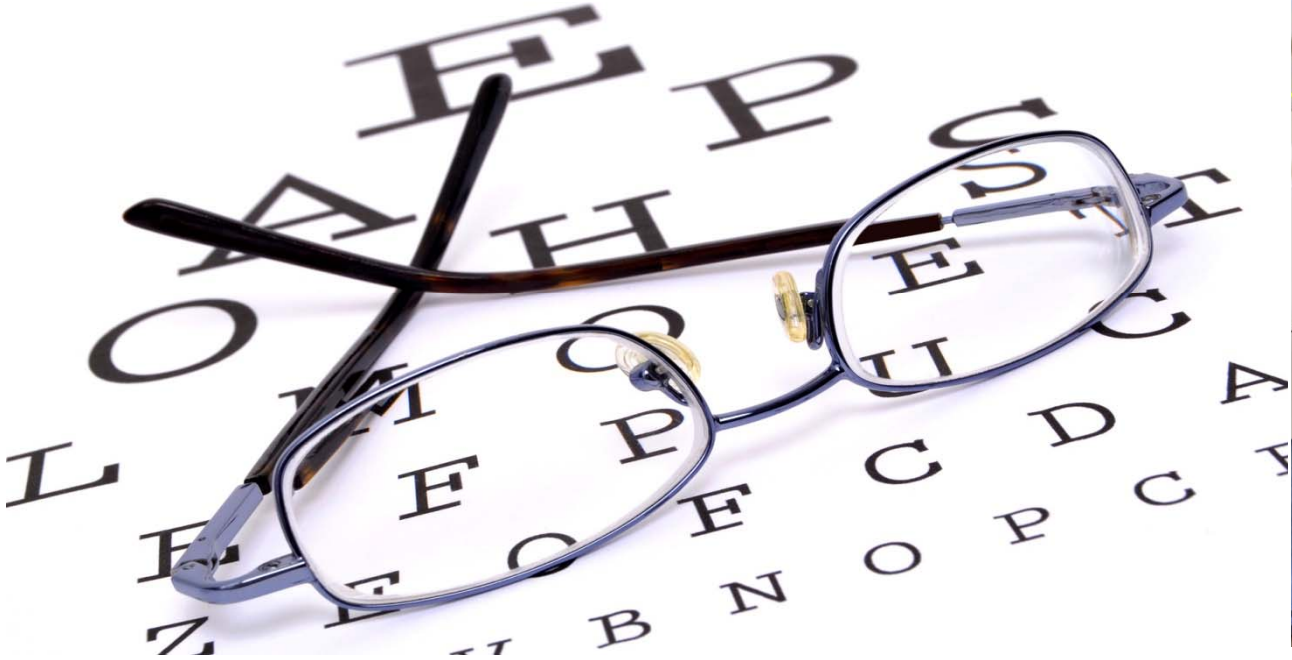
KCE REPORT 215Cs

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

## SYNTHESIS

# CORRECTION OF REFRACTIVE ERRORS OF THE EYE IN ADULTS – PART 2: LASER SURGERY AND INTRAOCULAR LENSES



# Belgian Health Care Knowledge Centre

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KCE REPORT 215Cs
HEALTH TECHNOLOGY ASSESSMENT

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# FOREWORD

This is the second part of our study on methods used to correct refractive error of the eye. This time, we look in greater detail at the advantages and disadvantages of new treatments including laser surgery and artificial lens implants. As discussed previously in the first part of the study, this field is situated at the limits of regular healthcare – and more and more completely outside of hospitals. And yet, are the results of these techniques really as promising as we imagine? Lastly, these are surgical treatments for a problem to which there are enough safe alternative solutions. Therefore, a critical examination is more than justified.

In the first study, we learned that there is certainly no general call for reimbursement by compulsory health insurance, except perhaps for highly specific target groups that can only be properly helped by these techniques. The corollary of this is naturally that people can operate outside the system and thus away from any possible government control of quality and safety. It is still not entirely clear how our healthcare system should deal with this. This will require further reflection that nowadays would only be meaningful in a European context. We will tackle this issue in a later study.

Until then, the concern is to provide citizens with complete, objective information about the benefits and risks of refractive eye surgery so that anyone who makes the significant investment to get the treatment has no later regrets because they were not sufficiently informed.

What today, based on the results of our first study, is still considered as a luxury surgery and has perhaps not yet grown out of the experimental stage, may tomorrow be the ultimate solution for a highly common 'manufacturing defect' of the human race. It is time to get a clearer view!

Christian LÉONARD
Deputy general director

Raf MERTENS
General director

# ABSTRACT

Someone who suffers from myopia, hyperopia or astigmatism can choose between wearing glasses, contact lenses or undergoing “refractive surgery”. Unlike the first two alternatives, this operation has an invasive character whose consequences may be irreversible. In view of the fact that these techniques are applied to eyes which usually do not have other problems, they are sometimes controversial. However, refractive surgery is gaining popularity among physicians and patients alike.

This study is the second part of a trilogy on the correction of refractive errors. This "health technology assessment" analyses, step by step, the effectiveness of the techniques, the risks incurred, the costs aspects and the patients' perspective. The third part of this trilogy will consider organisational and legal aspects of surgical practice in a non-hospital environment.

The techniques taken into consideration here are the laser techniques (PRK, LASEK and LASIK) and phakic intraocular lens implantation. Success rates reported in the clinical literature does not allow a clear-cut interpretation: patient groups are heterogeneous (age, condition), long-term follow-up is often lacking and the success rate varies from one study to another. It is estimated to be around 70% for myopic patients while the results are slightly worse in hyperopic patients (50-60 %). These figures do not tell the whole story: patients with good results in some cases still need correction and conversely, some patients may not require correction even if their clinical results are not perfect. Success rates published in the literature are lower than those reported by ophthalmologists.

Choosing a technique adapted to the patient is a key factor when it comes to reducing the incidence of complications, but the risks inherent to surgery remain. Serious side effects are rare but can lead to irreversible loss of vision, partial or total. As the phakic intraocular lens technique is more invasive, it is more risky than laser surgery. The consequences of laser surgery are, for their part, less serious but can be unpleasant and include dry eyes, halos and glare. Long-term stability after laser treatment seems better for myopia than for hyperopia.

Compulsory health insurance does not reimburse refractive surgery. The complementary insurance of sickness funds frequently covers the procedure, at least partially. For the patient, surgery can be a source of potential savings or an expensive option, depending on age, the corrective method used, the personal investment (glasses and/or contact lenses), taking into account the price of surgery and the time horizon. Younger patients and users of expensive contact lenses are those with most to gain.

For most people, surgery is optional. There is however a specific group of patients for whom it is not a luxury but a necessity, such as patients who are already eligible for reimbursement of their optical correction (particularly severe myopia or hyperopia).

Safety and quality standards in surgery centres in a non-hospital environment currently rely on voluntary initiatives of the profession. In other countries, clinical practice guidelines clarify the indications and contraindications for each surgical technique but in Belgium, such guidelines have not yet been developed.

# SYNTHESIS
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# 1. CONTEXT AND OBJECTIVE OF THIS REPORT

Refractive errors occur when the shape of the eye prevents light from focusing directly on the retina. The four main types are myopia, hyperopia, astigmatism and presbyopia.

This report is the second of a three-part study on the correction of refractive errors. The first part (see KCE report 202) described their underlying mechanism, their frequency as reported by the population and how these disorders and their correction methods are perceived and experienced by the patients.

This second report is a health technology assessment that examines the effectiveness, safety and cost-effectiveness of refractive eye surgery. The growing popularity of this correction method gave rise to a number of questions from policy-makers, sickness funds and patients.

The organisational questions of this health technology assessment will be analyzed in a forthcoming report that will focus on the legislation and organisation of the extramural eye surgery centres, a setting where refractive surgery is increasingly performed.

## 1.1. Refractive errors under study

The population considered in this report are adult patients with myopia, hyperopia and/or astigmatism. Conditions related to age such as cataract, presbyopia and other medical eye conditions (glaucoma, corneal disease and eye injuries) are excluded. The inclusion of these conditions would have required a larger range of comparators with other techniques such as clear lens extraction.

The objectives of this health technology assessment are:

- to examine the effectiveness and safety of refractive eye surgery;
- to compare long-term costs of the various correction methods;
- to gain an insight into the determinants of the patient's decision-making process for refractive eye surgery. For that purpose the researchers carried out qualitative interviews with 36 patients who considered refractive surgery, planned it or experienced (n=12) it.

# 2. REFRACTIVE EYE SURGERY: A MULTI-STEP DECISION PROCESS

## 2.1. Refractive eye surgery: growing in popularity

Since there is neither reimbursement by the national health insurance nor official registration, data on the number of performed refractive eye surgery interventions are missing. Data from the previous KCE report indicate that about two thirds of adults use an eye correction method. Glasses are the most commonly used, by 96% of the respondents having a refractive error. Contact lenses are used by 14% of this population.

Most users are satisfied, i.e. 96% of the glass wearers and 94% of contact lens wearers. Nevertheless, 15% of people with refractive error already considered refractive surgery and 3% effectively took the step to it.

## 2.2. The demand for refractive surgery is likely boosted by reimbursement from complementary insurance schemes

Refractive eye surgery is not reimbursed by the national compulsory health insurance. However, some patients may get a partial refund by their complementary insurance according to reimbursement schemes that vary greatly between and within the sickness funds. This reimbursement likely strengthens the demand for surgery.

This is comparable to the situation in neighbouring countries (France, the Netherlands, the United Kingdom and Germany), where the national compulsory insurance does not reimburse this surgical intervention either. Denmark is an exception: the national compulsory insurance fully covers both laser and intra-ocular lens surgery for patients aged 18 to 55 years under specific conditions (severity of the refractive error). In the Netherlands reimbursement may be allowed by insurers according to a restricted list of medical indications.

### 2.3. Many motivations to undergo refractive surgery

Interviews with patients who considered or underwent the operation highlighted their motivations to undergo surgery. Their main reasons are functional, aesthetical, emotional or financial.

While refractive surgery is in most cases optional, there are situations in which surgery appears to be a therapeutic necessity, as for example patients with severe anisometropia (large difference between refractive errors of both eyes) and who do not support contact lenses.

### 2.4. The choice of the surgeon determines the setting and the technical decision

Once the patient has decided to undergo surgery, the next step in his or her decision process is the choice of surgeon. Interviews with patients show that patients choose their surgeon according to their trust and confidence in him/her or in his/her reputation. The choice of the surgeon will eventually determine whether the patient is operated in a hospital or in an extramural eye surgery centre.

Interviews with patients show that patients tend to leave the technical decision to the surgeon. He/she will decide upon the technique and whether one or both eyes will be operated at the same time. Some patients prepare themselves by seeking information on surgery, others state that they prefer to know as little as possible.

# 3. HOW EFFECTIVE IS EYE SURGERY?

### 3.1. What patients tell us...

The patients interviewed in this study are in general positive about the outcomes of the surgery, at least in the short term (they underwent the operation maximum 4 years ago). Overall, they seem to be well informed upfront of the fact that success depended on the severity of the refractive error and that there was no guarantee on complete correction or long term stability.

However the sample of interviewed patients was not built to draw conclusions on effectiveness and safety: these aspects were further covered by a literature review summarised in the following sections.

### 3.2. What scientific literature shows...

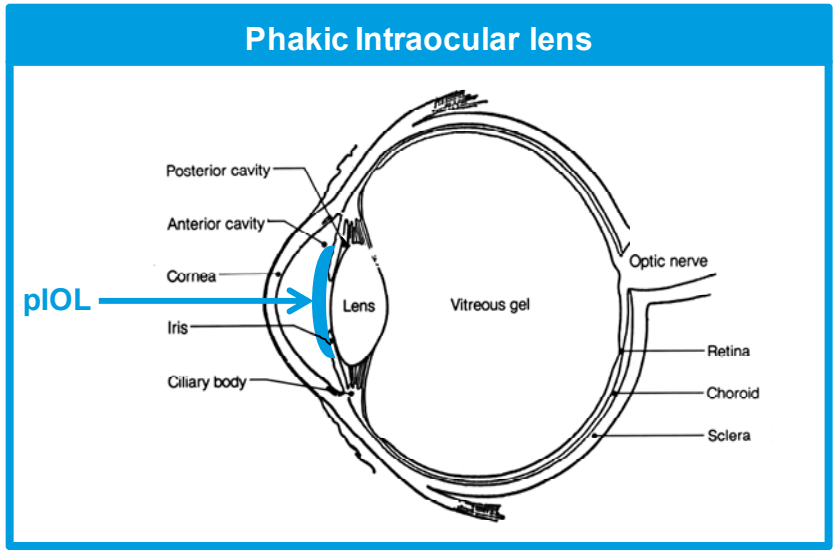
#### *3.2.1. The interventions under review*

Refractive eye surgery can be divided into laser (extra-ocular) surgery and intra-ocular procedures. The text box below describes the different techniques.

- Laser surgery: a laser reshapes the cornea in order to modify its refractive properties and thereby to correct myopia or hyperopia (with or without astigmatism). Surgical techniques are evolving rapidly: the newest techniques such as EpiLASIK (surface ablation), FemtoLASIK and SMILE (deep ablation) are not considered in this study as it is still too soon to examine their medium or long term effects.
- Intra-ocular procedures: a lens is inserted in front of the original lens, leaving this original lens in place. The operation that removes the original lens (as in a cataract operation) and replaces it by a synthetic lens was not considered in this report as this surgery is not the first choice for the correction of refractive errors when the crystalline lens is healthy.

**Figure 1 – Illustration of laser and phakic intraocular lens procedures**


*Source: www.lasik.fr*




*Source : www.wpclipart.com*

**Surface ablation laser surgery**

- **Photorefractive keratectomy (PRK)**

The surgeon first removes a small area of the cornea epithelium by abrasion (scraping) and then reshapes the cornea using Excimer laser: this computer-controlled beam of light removes microscopic amounts of the surface of the cornea (surface ablation). After the procedure the epithelial layer spontaneously regenerates. "Keratectomy" refers to incision of the cornea.

- **Laser-assisted sub-epithelial keratomileusis (LASEK)**

This surface ablation technique is similar to PRK but in this procedure, the epithelium is not removed but an epithelial flap is first prepared with the help of ethanol, before the application of the Excimer laser. This epithelial flap is replaced afterwards and will heal during the following days. “Keratomileusis” refers to the reshaping of the cornea.

**Deep ablation laser surgery**

- **Laser in-situ keratomileusis (LASIK and Femto LASIK)**

This technique is the most commonly used one today. “In situ” refers to the fact that the procedure is performed at the site where the problem occurs. The difference with the previously mentioned surface ablation techniques is the creation of a flap that involves the epithelium but also the outer part of the corneal stroma. This flap is made using either a microkeratome (LASIK) or another type of laser (Femtosecond laser for Femto LASIK). The Excimer laser energy is applied at this deeper level of the corneal stroma.

- **ReLEx smile**

This most recent technique creates in a single step a thin lenticule together with a small access in the cornea. The lenticule will be removed through this incision, thereby changing the form of the cornea [1].

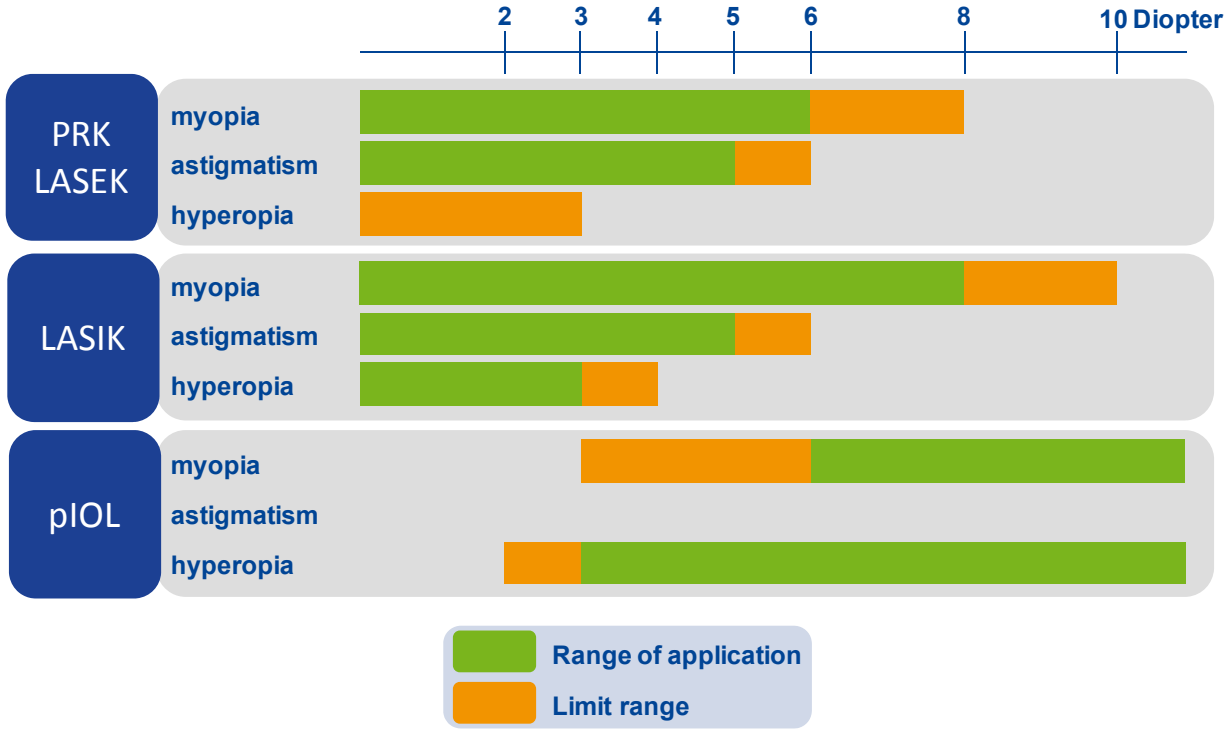
**Phakic Intraocular lens insertion (pIOL)**

A lens is inserted in front of the original lens, leaving this original lens in place and keeping the mechanism of accommodation. Two types of phakic intra-ocular lenses are considered: iris supported (iris claw fixated anterior chamber) lenses and sulcus supported (posterior chamber) intra-ocular lenses. The third type, angle supported (anterior chamber) phakic intraocular lenses were excluded as they are not used in Belgium.

### *3.2.2. Not all surgery techniques are suitable for all patients*

Guidelines have been published in other countries on the respective indications of laser surgery and phakic intra-ocular lenses as each technique applies to specific patient populations. Figure 1 illustrates the indications outlined by the German Commission of Refractive Surgery. The recommended range of indications refers to the range in which a procedure is considered eligible and side effects are rare. The range of limited application is the range in which surgery may be performed with less predictable results and more side effects. Besides the ranges for application, the guidelines list the contraindications per type of surgery. PRK is for instance sometimes the only technique available for patients with low to moderate myopia with thin or irregular cornea. Note that the upper limit of application for phakic intraocular lenses is not clear in the German guideline, as in the guideline from the Netherlands.

**Figure 2 – Indications according to the German Commission of Refractive Surgery [2]**



### 3.2.3. The success of refractive eye surgery is difficult to assess solely on the basis of clinical outcomes

The primary goal of the patients who undergo refractive surgery is to reduce their dependency on glasses or contact lenses. Yet the most commonly reported effectiveness measures in the scientific literature are visual acuity (e.g. UCVA ≥20/20) and the residual refractive error (e.g. ± 0.5 Diopter) (see definitions in the box below).

**UCVA (Uncorrected Visual Acuity)**

UCVA is the best possible vision that a person can achieve without correction. 20/20 vision is considered as normal visual acuity. In the expression, 20/X vision, 20 is the distance in feet between the subject and the chart. The X means that the subject can read the chart (from 20 feet away) as a normally seeing person could read the same chart from X feet away. A vision of 20/40 is considered half as good as normal performance. A vision of 20/10 is considered twice as good as nominal performance.

**BCVA (Best Corrected Visual Acuity)**

BCVA is the best possible vision a person can achieve with corrective lenses.

**Correction within ± 0.5 Diopter**

A diopter is a unit of measurement of the optical power of an optical lens. A negative diopter value applies to an eye with myopia and a positive diopter value applies to an eye with hyperopia.

These clinical parameters respectively measure the efficacy and precision of the correction technique. They can be proxies for glasses/contact lenses dependency after surgery but do not perfectly distinguish between patients who still need a (partial) correction or not. Some patients with good clinical outcomes may still need correction after surgery - be it mostly on occasional basis, e.g. for driving at night or reading subtitles on television. Also vice versa, patients not achieving UCVA ≥20/20 may not need any correction.

### 3.2.4. Importance of the patient's perspective

Benefits of surgery go beyond vision-related outcomes. A number of quality-of-life questionnaires include questions on e.g. possible activities, look and/or vision problems. There is growing acknowledgement of the importance of the patient's perspective in the evaluation of surgery but these questionnaires have not been used in large comparative studies.

Numerous patient satisfaction questionnaires have been developed as well. Most of the studies report high satisfaction rates but the instruments used are usually not validated and therefore unreliable. Consequently the following sections focus on the most commonly reported clinical outcomes.

### 3.2.5. Laser techniques: better results achieved in myopic eyes compared to hyperopic eyes

Laser techniques are somewhat more successful in hyperopic than myopic eyes:

- In myopic eyes, laser techniques achieve around 70% success for normal visual acuity (UCVA ≥20/20) and around 70%-80% for precision (correction within ± 0.5 Diopter). Moreover the results for myopia seem better with LASIK and LASEK techniques than with PRK. However this finding is based on studies of 'moderate' or 'low' quality: more research could have an important impact on these estimates.
- In hyperopic eyes, normal visual acuity is achieved roughly in 50% to 60% of eyes; approximately 60% of eyes achieve a correction within ± 0.5 Diopter. Only few data are available: the only comparisons are between PRK and LASEK; no comparisons were found with the most recent technique LASIK.

### 3.2.6. Intra-ocular lenses: more effective than laser surgery in high myopic patients

Intra-ocular lenses are indicated with patients with severe refraction error (see indications above): studies showed that they give better results than laser surgery in patients with myopia more severe than 6 Diopters. Still this evidence is of low quality.

For hyperopic eyes there is no randomised controlled trial that compares intra-ocular lenses with laser.

## 3.3. What experts tell us...

### *3.3.1. Evidence on older practices; the techniques and indications evolve*

The ophthalmologists' main critics are the fact that the randomised controlled trials are old and the techniques are not congruent with today´s medical practice. Illustrations are the current use of Femtolaser techniques that aim to decrease the occurrence of flap-related complications and the development of flexible iris-fixated intra-ocular lenses. Indications changed as well: some studies included patients with severe myopia up to -14 Diopters while today´s practice limits the indication for laser surgery to -10 Diopters.

Changes in techniques and indications may explain why members of the expert group were sceptical about the success (and complication) rates presented in this study. According to some experts, almost all operated patients are free of correction or wear it only occasionally. If this goal is not achieved, a reoperation can be done in most cases.

### *3.3.2. Long term stability of results*

According to experts, inferior long-term results for hyperopia could be partly explained by the natural worsening of hyperopia with age. Still long term stability is poorly documented in studies.

# 4. HOW SAFE IS REFRACTIVE SURGERY?

In contrast to glasses and contact lenses, refractive surgery is an invasive, non reversible method. As it is used in otherwise healthy eyes, the procedure was initially considered controversial; however it gained popularity amongst physicians and patients. This section analyses the safety of refractive surgery.

## 4.1. What patients tell us...

The patients interviewed mentioned in particular the risk of under- or overcorrection and lengthy recovery as possible side effects. Yet, they did not mention other frequent side effects such as halos, glare, and problems with night driving. It is unclear whether this is because they did not experience them, were not informed about them or simply did not remember being informed about.

## 4.2. What scientific literature shows...

### *4.2.1. Nonsurgical correction methods are not free of risk*

The safety of refractive surgery has to be compared with the safety of the alternative correction methods. Spectacles are the safest method for correcting refractive errors even if injuries might occur in sports, work, falls or other.

Contact lenses are not free of risks (see KCE report 202): the most severe complication is infectious keratitis. Keratitis is often due to poor compliance with the replacement schedule of contact lenses and care instructions. The yearly incidence of microbial keratitis is estimated at 0.011% for hard lens wearers and 0.035% for soft lens wearers; it rises to 0.2% when lenses are worn overnight (extended wear soft lenses). A Dutch study showed that about 5% of all keratitis cases led to severe loss of vision, with nearly two thirds of the cases that required corneal transplants.

### 4.2.2. Refractive surgery is associated with various complications

Besides under or overcorrection (sometimes with possible retreatment), numerous complications have been reported. Some of them depend on the technique:

- LASIK is associated with flap problems;
- Surface ablation treatments (PRK and LASEK) are associated with (severe) pain due to abrasion of the epithelium;
- Intra-ocular surgery carries more vision-threatening risks than laser surgery (see the second section below).

#### 4.2.2.1. A clear view on all safety problems is difficult

There is a need for a standardised, systematic monitoring of safety in large patient cohorts. There is today a lack of data on the incidence of complications after refractive surgery:

- Safety was either not considered in the study designs or not reported in a standardized systematic way - other than the loss of ≥2 lines of BCVA;
- Many studies were small sized and could not detect scarce safety events, although these complications may have major consequences for the vision. Reliable data on rare but potentially sight-threatening harms such as endophthalmitis after intra-ocular lenses are for instance not available.
- Most studies have short follow-up but complications may appear in the longer run.

#### 4.2.2.2. Serious vision-threatening side effects are a reality

Intra-ocular surgery entails a greater risk of vision-threatening complications than laser surgery as laser applies on the cornea only (see Table 1). Yet as stated above, indications for both techniques differ as well. Retinal detachment, cataract, raised intra-ocular pressure and endophtalmitis are possible major side effects.

Still in severe myopic eyes (more than 6 diopters) intra-ocular lenses appear to be safer than laser surgery. Compared to eyes treated with intra-ocular lenses, more laser-treated eyes lost ≥2 lines of their BCVA (i.e. loss of vision that cannot be corrected with glasses, contact lenses, or repeated surgery).

This loss of ≥ 2 lines of BCVA occurs more frequently in hyperopic than in myopic eyes. Moreover the treatment of hyperopic eyes involves a greater risk of raised intra-ocular pressure compared to myopic eyes.

The importance of tailoring the technique to the patient (see above) is mandatory to decrease the risks: a report from NICE [3] concluded that the majority of patients with ectasia after surgery had a contraindication to LASIK or received an inappropriate treatment.

**Table 1 – Overview of most severe perioperative complications[a]**

| Complication | Laser | Intra-ocular lenses |
|---|---|---|
| **Loss of ≥ 2 lines of BCVA** | myopia: up to 0.7%<br>hyperopia: up to 3.4% | |
| **Retinal detachment** | up to 0.19% | up to 2.2% |
| **Cataract** | up to 0.3% | up to 2% |
| **Corneal ectasia** | up to 0.25% | |
| **Keratitis** | up to 0.6% | |

[a] This summary presents the maximum of the median results (by technique) found in the studies for PRK, LASEK, LASIK and pIOL.

#### *4.2.2.3. Dry eyes, halos, glare and pain are frequent complications*

Besides refractive loss and peri-operative complications other undesired consequences (temporary or definitive) may pose problems:

- dry eyes: a frequent reported side effect after LASIK. A recent trial found for example that after one year about half of the patients used artificial tears after a LASIK operation;
- problems related to overall visual performance such as halos, glare, starburst, blurred/double/fluctuating/ghost vision, night driving difficulty, variation of vision in bright/normal/dim light. Halos and glare are in particular frequently reported after laser interventions. Halos create rings of light around lights at night. Glare makes points of light look brighter and indistinct. In PRK treatment of myopia, halos and/or glare were reported in 17% of cases. There is no evidence that they are more frequent in PRK than in LASEK or LASIK. In intra-ocular lens treatment of a mixed indication population they were reported in 8.8% (iris fixated lenses) and 5.9% (posterior chamber lenses);
- pain or other undesired consequences, such as burning, gritty feeling, itching, light sensitivity, oedema, redness, tearing, twitch and headaches;
- raised intra-ocular pressure (median up to 4.8% in studies with pIOL). Raised intra-ocular pressure is usually transient but can lead to glaucoma if not treated appropriately.

## 4.3. What experts tell us...

The comments formulated by experts on the evolution of indications and techniques for the data on effectiveness also hold for safety aspects. Safety problems would be less pronounced with the most recent techniques, with the exception of dry eyes.

## 4.4. What the legal framework guarantees...

In Belgium safeguarding safety and quality in extramural centres currently relies on voluntary initiatives of the professional body. These centres do not fall within the definition of “hospital” in the sense of the hospital law and therefore they do not have the legal obligation to comply with the recognition and quality norms applicable to recognized hospitals.

Patient information should be warranted by the law on patients’ rights which stipulates that patients need to be well informed about the outcomes and risks of medical procedures.

These legal aspects will be further studied in the following report.

# 5. IS REFRACTIVE EYE SURGERY WORTH THE INVESTMENT?

## 5.1. What patients expect...

The former report analysed the attitudes, drivers and inhibitors for refractive surgery in a population with refractive error (n=404). The answers highlighted that the financial investment of surgery can be a motivation or a barrier to undergo surgery. Initially people face a significant outlay and this may be a hindrance for some of them.

However many of the patients interviewed weighed off the initial investment against a lifelong spending on eye glasses, lenses and lens care products and they expected the investment to be paid back in the longer term.

## 5.2. What a theoretical cost analysis shows...

The cost analysis was done from the health care payer perspective: it included health care related payments made by patients as well as by the statutory, complementary and private insurance.

### *5.2.1. Time horizon: age of presbyopia*

A theoretical cost analysis compared these financial expectations with actual data. Long term costs of eye surgery, glasses and contact lenses were accumulated from the age where surgery is considered until the age of 45. The choice of this time horizon was based on data on incidence of presbyopia as most patients develop it from 45 years onwards. Due to presbyopia their expenditure patterns may change and are less predictable:

- people with myopia/hyperopia and presbyopia may need unifocal or progressive (i.e. bi-, tri or multifocal) correction;
- people who underwent surgery may also need reading glasses but this need may be delayed.

Fourty-five years is therefore considered as a conservative time horizon: expanding it beyond 45 years would likely result in more favourable cost outcomes for the surgical options.

### *5.2.2. Cost items included for surgery, glasses and lenses*

Various short- and long-term costs were considered for the three options:

- The costs considered for surgery consisted of the operation cost, including the cost of a potential re-operation and possible complications, followed by a discounted monthly cost of glasses for patients who still needed correction after surgery. Since refractive eye surgery is not eligible for national obligatory reimbursement, tariff setting is free, independent of the setting in which it is performed. The patient price is directly charged to the patient. A website search on 14 centres showed average prices per eye of €1 200 for PRK and LASEK, €1 300 for LASIK and €1800 for phakic intra-ocular lenses.
- The costs for eyeglasses consisted of the discounted monthly costs of wearing glasses. The cost did not include any complication. Back-up glasses and sunglasses with correction were not included.
- The costs for contact lenses consisted of the discounted monthly costs of contact lenses and back-up glasses. These patients ran a small monthly risk of keratitis. We assumed people with keratitis moved to the glass wearers group after one month and a small proportion lost vision and needed a transplant.

The previous KCE report showed high variation in costs for glasses and contact lenses. Distributions were used in the calculations to reflect these variations.

### 5.2.3. Many factors influence the final cost balance

Surgery can be either a cost-saving investment or an expensive option, depending on the factors considered: correction method, age and time horizon, individual spending behaviour (factors known ex ante) and the successfulness of the operation (only known ex post). The cost balance may also differ in function of the type and severity of refractive error, but no subgroup analyses were performed to analyse this.

As a summary:

- For all age categories, eyeglasses appear on average the least costly option.
- Surgery shows cost-saving potential compared to all types of contact lenses for persons aged 20-25. For persons aged 30-35, surgery still shows cost-saving potential compared to daily contact lenses but no longer to cheaper types of lenses. From the age of 40 onwards, surgery appears the most expensive option.

The cost balance varies considerably according to the scenario data as there is a large overlap in cost distributions across the correction methods. The average results should be therefore put in perspective. Obviously, the balance turns out less positive for surgery when people spend little on glasses or contact lenses (both before and after surgery) or when the surgery is more expensive, and vice versa. In case of unsuccessful surgery, the balance more easily turns out negative. We recall that the time horizon stopped at 45 years.

### 5.2.4. Balancing costs and outcomes

In the evaluation of health care interventions, outcomes are usually balanced against associated costs. A well known summary measure for outcomes that has been developed across therapeutic areas is the number of quality-adjusted life years (QALY). The number of QALYs measures the impact of an intervention on both the quality and length of life. This measure allows comparisons between various types of health care interventions to inform the policy-making process. New interventions that have a favourable cost-effectiveness ratio, in terms of cost per QALY, are considered to provide good value for money and can be recommended for reimbursement.

A search in the peer-reviewed literature did not identify studies that measured generic quality-of-life in the domain of refractive error correction. One explanation might be that generic quality-of-life instruments are not expected to be very sensitive to discriminate the relatively small differences in health status for the different eye correction methods for an average patient, although there may be patients for whom surgery leads to a particularly high gain. Therefore we further searched for vision specific outcomes, such as correction independency and vision-related quality-of-life instruments but did not find robust evidence on these outcomes either.

Consequently, no conclusions are drawn on whether one method is superior to the other both in terms of costs and effectiveness, nor on whether a more expensive method is worth the extra cost.

### 5.2.5. The question of possible reimbursement

**Societal point of view: willingness to pay for the correction of refractive errors**

The former KCE report provided interesting insight on the perception of the population with refractive error on a potential reimbursement by the compulsory health insurance. On one hand persons who have a refractive error were surprisingly more willing to pay taxes or social security contribution for reimbursement of refractive surgery than for reimbursement of glasses or contact lenses. Probably the notion of “surgery” more specifically relates to medical interventions and to high costs, thereby justifying and necessitating intervention of the health care insurance. On the other hand interviewees thought that refractive surgery falls within the notion of luxury surgery: it should not be fully reimbursed by the health insurance because it would be too heavy for the tax payer.

A general consensus was that correction methods should be accessible to all and therefore benefit from some kind of reimbursement, based on the severity of the refractive error.

**The national insurance and sickness funds point of view**

Today glasses and lenses are reimbursed by national compulsory insurance for severe cases. Assuming that this reimbursement reflects the societal willingness to pay for treating patients with refractive error, could surgery be reimbursed for the same indications? In particular this reimbursement question arises for two small and partly overlapping subgroups of patients:

- Patients who fall within the current reimbursement criteria for eyeglasses (with correction of at least 8 diopters) or for contact lenses (e.g. anisometropia of at least 3 diopter, ametropia of at least 8.25 diopter)
- Patients for whom glasses do not lead to sufficient correction and who are intolerant to contact lenses.

These patients are those for whom refractive surgery could lead to a high vision gain. In these cases, surgery can be more a necessity than a luxury option. As stated above, Dutch insurers reimburse refractive surgery on case-by-case basis according to a restricted list of medical indications based on a consensus from the Nederlands Gezelschap voor Refractiechirurgie.

Still a last important ethical question is to decide upon the reimbursement of an intervention with safety risks for a condition that can be (partly) remedied in a safe way.

# 6. CONCLUSION

**Success rates are difficult to quantify and publication results differ from expert opinion**

Success rates varied between studies but were worse than the rates reported by expert ophthalmologists. Experts mentioned the obsoleteness of some of the studies, with less stringent patient selection and use of techniques that are not congruent with today´s medical practice. As is often the case in health care, studies lag behind medical advances. However, not all ophthalmologists in Belgium currently use the most recent techniques and follow the latest guidelines on patient selection. Furthermore there are no Belgian guidelines available to optimize and standardize the practice.

**A long list of possible risks summarised in a nutshell**

Appropriate patient and technique selection is an important lever to reduce the incidence of side effects but risks remain more frequent than with contact lenses. The first risks are under or over correction, sometimes reversible with additional treatment. Therefore patients may need glasses or contact lenses after surgery, continuously or occasionally.

Serious vision-threatening side effects are rare but may lead to irreversible (partial or total) vision loss. Phakic intra-ocular lenses are more invasive and therefore associated with more severe risks than laser surgery. Less severe but more frequent annoying consequences, particularly of laser treatment, are dry eyes, glare and halos.

**Long-term results remain largely unknown**

Corrective eye surgery is a relatively new technology and therefore, the long-term safety and effectiveness, especially of the newest techniques, is not known. However, long-term stability of laser seems worse in hyperopic than in myopic patients.

**A selected group of patients may take advantage of refractive surgery and be eligible for reimbursement**

Consensus of experts state that surgery is the only alternative to provide correction for a small group of patients with severe refractive error. The insurers from the Netherlands provide reimbursement on a case-by-case basis for patients who correspond to these specific criteria.

**Surgery has cost-saving potential in the long term**

Surgery can be either a cost-saving alternative or an expensive option, depending on the alternative correction method (glasses or contact lenses), the individual spending behaviour, the age and considered time horizon, the type and severity of refractive error, the price set by the surgeon and the successfulness of the operation. Younger patients have higher potential saving, especially in comparison with contact lenses.

Also from the perspective of the national compulsory insurance, surgery has a cost-saving or cost-neutral potential for young patients who fulfil the current reimbursement criteria, as current reimbursement is recurrent whilst surgery could imply a (partial) one-time reimbursement. Nevertheless, surgery remains an intervention with risks for a condition that can be very well remedied in a safe manner in most cases.

**Patients should be well informed**

Patients are entitled to full, objective information, as stipulated in the patient's rights law. Yet, the interviews showed that perceptions on outcomes and risks might be overoptimistic. In any case, patients should be aware that good clinical outcomes do not necessarily imply freedom of correction, and that severe complications, although rare, may occur whilst undesirable effects such as dry eyes, halos and glare are frequent.

# RECOMMENDATIONS[b]

**With regard to refractive eye surgery (laser and phakic IOL techniques) for the correction of myopia, hyperopia and/or astigmatism.**

***To clinicians and sickness funds:***

- **Patients should receive objective information about risks, expected outcomes and costs of refractive surgery, allowing them to make an informed decision.**

***To the professional organisations:***

- **Guidelines on indications, contra-indications, ranges of application and quality norms should be developed.**
- **An information leaflet that describes the expected results and the risks of refractive surgery should be developed and validated for its scientific content and its clarity for a general public.**
- **Outcomes after refractive surgery should be registered, including safety data and need of glasses, with short-term and long-term follow-up.**

***To the National Institute for Health and Disability Insurance:***

- **Reimbursement of surgery is not recommended except for the small patient group who already benefit from reimbursement of glasses or contact lenses by the national compulsory health insurance. Provided the existence of well validated guidelines, additional beneficiary groups with an identified medical need could be considered. This reimbursement should be coupled to mandatory case registration.**

[b] The KCE has sole responsibility for the recommendations.

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