Laser Eye Surgery for the Correction of Refractive Errors

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Summary and Conclusions

TECHNOLOGY AND TARGET GROUP Surgery to correct refractive errors in the eye (myopia, hyperopia, astigmatism) has become increasingly common. Technology in the field has advanced rapidly, and new methods are continually emerging. Surgery is replacing other methods (mainly glasses and contact lenses) used to correct refractive errors. The results of surgery are compared with results achieved from using glasses. The goal of surgery is to enable young people to completely avoid using glasses or contact lenses, and to enable middle-aged and elderly people (whose natural lenses often no longer accommodate for different distances) to see at distance without using glasses or contact lenses. Many choose surgery for cosmetic reasons, or to avoid the inconvenience of using glasses and contact lenses. Others may choose surgery to facilitate their activities at work, in hobbies, or in sports.

Surgery for minor or moderate refractive errors (up to –6 diopters for myopia and up to +3.5 diopters for hyperopia) primarily involves methods that use an excimer laser to reshape the cornea, thereby changing its refractive power.

This evaluation addresses the three most common methods of excimer laser treatment. Photorefractive keratectomy (PRK) involves removing the surface corneal cells (epithelium) and using a laser to reshape the cornea. Laser assisted sub-epithelial keratomileusis (LASEK) involves loosening the surface epithelium and pushing it aside. Then, after the laser reshapes the cornea, the epithelium is placed back over the cornea. Laser in situ keratomileusis (LASIK) involves two steps. First, a mechanical knife (keratome) is used to cut a flap of the outer surface. A laser then reshapes the cornea in the same way as in PRK. In Sweden, 6000 to 7000 operations are performed annually with excimer lasers.

PRIMARY QUESTIONS

- What improvements in visual acuity can patients expect following refractive surgery?
- How are other measures of visual quality affected?
- What complications appear, how common are they, and what do they mean for the patient?
- Which method is most cost-effective?

PATIENT BENEFIT Surgery for moderate myopia results in visual acuity of 0.5 or higher (without glasses) in 96% to 99% of cases. This is the level required for a driving license. For moderate hyperopia, the corresponding rate ranges from 87% to 97%. Full visual acuity (ie, 1.0 or higher) is achieved in 76% to 89% of cases in myopia and 48% to 80% of cases in hyperopia. At higher levels of refractive error the results are consistently worse and vary more among the methods. It is difficult to estimate how many of those receiving surgery will be completely free from using glasses since this is determined largely by the individual's demand for visual acuity. Most never use glasses for distances, but some use them in more demanding situations, eg, night driving.

LASIK has the shortest rehabilitation time. Many patients report good vision on the day after surgery. However, it can take a few months for eyesight to stabilize following LASEK, and in some cases even longer following PRK. During the immediate postsurgical period, PRK and LASEK are associated with more problems than is LASIK. PRK and LASEK, in contrast to LASIK, can be used to treat higher levels of refractive error, although the outcomes are worse than in treating moderate refractive errors.

The more myopic a patient, the greater the risk for complications associated with surgery. This association is linear. In individuals with hyperopia, the risk for complications is substantially greater when the refractive error exceeds +3.5 diopters. Many of the complications are common to all three surgical methods and stem from the laser procedure itself. Haze in the cornea following surgery is more common after PRK and LASEK than after LASIK. With LASIK, the risk for complications is also associated with the mechanical knife used to cut the flap.

Effects of surgery on the patient's quality of life have been studied, but mainly for LASIK. Over 90% are very satisfied or satisfied. Dissatisfied respondents usually complain about persistent refractive errors and problems with vision (or suffer from glare) in the dark. This is probably the case even with the other methods.

Table A summarizes the data on patient benefits in relation to each of the methods.

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Table A Summary of data on patient benefits associated with PRK, LASEK, and LASIK.

Patient benefits	PRK	LASEK	LASIK
Visual acuity (% with UCVA ≥0.5)			
Myopia			
≤–6.0 D	96.3	96–99	98–98.2
>–6.0 D	68.4	95	89.4
Hyperopia			
≤+3.5 D	87.1–89.5	90.3–90.7	93.2–97
>+3.5 D	79.8	–	–
Visual acuity (% with UCVA ≥1.0)			
Myopia			
≤–6.0 D	79.2	76	80.6–89
>–6.0 D	20	57	45.2
Hyperopia			
≤+3.5 D	71.2–79.9	73.1–74.8	48.2–51.5
>+3.5 D	71.3	–	–
Rehabilitation time	A couple of months	A couple of months	A couple of days
Complications Vision loss ≥2 lines on the eye chart (% of patients operated)			
Myopia			
≤–6.0 D	0–4	<0.1	0–1.1
>–6.0 D	9–18	5–8.2	0–3.5
Hyperopia			
≤+5 D	2.1–2.4	0–0.8	0–3
>+5 D	–	–	7.3–16

D = *Diopters;* **UCVA** = *Uncorrected visual acuity*

ETHICAL ASPECTS In most cases, refractive surgical procedures are performed in patients having satisfactory vision with glasses or contact lenses. The methods addressed above have good potential to improve uncorrected visual acuity (without assistive eyewear/devices), but this must be weighed against the risk of sight-impairing complications. Hence, it is important for patients to receive complete and objective information about benefits and risks, and have the opportunity to consult with their attending physician when deciding whether the expected benefit of treatment outweighs the risk for complications.

ECONOMIC ASPECTS Private physicians usually perform refractive surgery in healthy eyes, and patients themselves cover the full cost. The average price at the about 10 clinics that offer this type of surgery in Sweden is approximately 12 000 Swedish kronor (SEK), ranging between SEK 10 500 and SEK 14 500.

A Danish assessment found refractive surgery to be a cost-effective alternative to glasses/contact lenses for myopia, and even cost-saving in younger patients (aged 27 years). In patients around 35 years of age, the additional cost per year to avoid glasses through LASIK treatment is estimated at SEK 1000 to SEK 2000 for patients with the least myopia, and nearly double that amount for those with a higher degree of myopia. The corresponding costs associated with PRK are somewhat higher. However, these findings are relatively sensitive to change in the assumptions on price, etc.

SBU's appraisal of the evidence

Assessments of three surgical methods to correct errors of refraction in the eye (PRK, LASEK, and LASIK) yield similar results in myopia up to –6 diopters. In 96% to 99% of the cases, surgery results in visual acuity of 0.5 or more in the operated eye. The corresponding results in hyperopia up to +3.5 diopters are 87.1% to 89.5% for PRK, 90.3% to 90.7% for LASEK, and 93.2% to 97% for LASIK. The percentages reaching full visual acuity (1.0 or more) are substantially lower. These conclusions are rated as Evidence Grade 1*.

The surgical procedures are associated with some risk for permanent side effects, eg, greater sensitivity to glare and increased contrast. Although many different complications have been reported, individually they are very uncommon. Vision loss (measured as two lines or more on the eye chart – a general measure of complications) is unusual with moderate errors of refraction. These conclusions are rated as Evidence Grade 1*.

There is insufficient* scientific evidence to draw firm conclusions on the cost-effectiveness of these methods. Considering treatment outcomes, complication risks, and surgical costs, LASIK would appear to be the most cost-effective. This, however, does not apply to high levels of refractive error.

**Criteria for Evidence Grading SBU's Conclusions;*
Evidence Grade 1 – Strong Scientific Evidence. The conclusion is corroborated by at least two independent studies with high quality and internal validity, or a good systematic overview.
Evidence Grade 2 – Moderately Strong Scientific Evidence. The conclusion is corroborated by one study with high quality and internal validity, and at least two studies with medium quality and internal validity.
Evidence Grade 3 – Limited Scientific Evidence. The conclusion is corroborated by at least two studies with medium quality and internal validity.
Insufficient Scientific Evidence – No conclusions can be drawn when there are not any studies that meet the criteria for quality and internal validity.
Contradictory Scientific Evidence – No conclusions can be drawn when there are studies with the same quality and internal validity whose findings contradict each other.

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SBU is an independent public authority which has the mandate of the Swedish Government to comprehensively assess healthcare technology from medical, economic, ethical, and social standpoints. SBU Alert is a system for identification and early assessment of new methods in health care.

This summary is based on a report prepared at SBU in collaboration with Prof. **Per Fagerholm**, Linköping University Hospital. It has been reviewed by Prof. **Ulf Stenevi**, University of Gothenburg. Project director: **Ingemar Eckerlund**, SBU, eckerlund@sbu.se.

The complete report is available only in Swedish.

PO Box 5650, SE-114 86 Stockholm, Sweden • alert@sbu.se