

SUMMARY

Since the publication, in May 1997, of the *Conseil d'évaluation des technologies de la santé du Québec's* previous report on the state of knowledge regarding refractive surgery, this field has continued to evolve at a rapid pace. The purpose of the present report is to summarize the changes this technology has undergone since the previous report, with special emphasis on LASIK technology, which was not discussed in that report.

PRK

Photorefractive keratectomy (PRK) consists in sweeping the corneal surface with a laser beam of ultraviolet light in order to sculpt in the cornea a lens that will correct the eye's refractive error. PRK has enjoyed increasing popularity worldwide since 1989. It is a safe and effective technique for treating mild myopia of up to -6.00 diopters. The constant improvement in ablation programs, including multizone and multipass techniques, pretreatments for central islands, the refinement of excimer lasers, including the advent of scanning beams and the incorporation of tracking systems, and surgeons' accumulated experience in retreatment have led to a significant improvement in the outcomes of PRK for myopia of up to -8.00 to -10.00 diopters. The technique is simple. The outcomes, as with any other type of refractory surgery, depend on the initial degree of myopia. They are quite predictable for low myopia, slightly less so for moderate myopia and much less so for severe myopia.

One of the drawbacks of PRK is that it necessarily and irreversibly involves the central cornea, the eye's optical zone. The rehabilitation time, the time needed for the patient to see well with the operated eye, can sometimes be a problem with PRK. In addition to the reepithelialization of the operated cornea taking an average of three days, PRK tends to result in a slight initial overcorrection with temporary hyperopia lasting a

few weeks that patients in their early 40s or older find bothersome. Most often, this initial overcorrection occurs after the correction of higher degrees of myopia.

PRK does not affect accommodation. It is probably the procedure of choice among young patients with mild myopia, although the trend seems to be favouring LASIK, even for this category of patients. The cost is high because of the high cost of the laser and of maintaining it.

LASIK

LASIK stands for "laser *in situ* keratomileusis". Actually, it is PRK preceded by a step during which the surgeon cuts a thin corneal flap with a manual or semiautomatic instrument, the microkeratome. The flap remains attached to the cornea by a thin hinge of tissue. The surgeon then performs excimer laser photoablation. Once this is done, the flap is repositioned over the treated area. No sutures are necessary.

The LASIK technique has evolved at a very rapid pace over the past few years. Although some surgeons use it routinely for low myopia, LASIK is typically reserved for moderate and higher degrees of myopia. For low myopia (less than -6.00 diopters), PRK, which is simpler, predictable and associated with fewer complications, is perhaps preferred to LASIK. For high myopia, LASIK is limited by the ablation diameter and the depth under the flap. The degree of myopia above which a person should not undergo LASIK is a matter of debate. Experience has shown that neither PRK nor LASIK is indicated in cases of severe myopia. The efficacy of LASIK in correcting astigmatic myopia seems slightly superior to that observed with PRK. LASIK is technically limited by the complications and problems associated with the microkeratome.

The main advantage of LASIK over PRK in the treatment of myopia is the rapid postoperative rehabilitation and the refractive stability. Outcome predictability is moderate to good and should improve further with improvements to treatment algorithms and keratomes. LASIK is more expensive than PRK because of the use not only of the excimer laser but also of the keratome. Another drawback is a steeper surgeon learning curve.

Long-term Follow-up

Not enough time has passed to evaluate the long-term effects of PRK and LASIK. The longest duration of follow-up in the studies identified for this report is three to five years for PRK and two years for LASIK. Before one can express an opinion about the potential long-term complications, steps must be taken to ensure that patients who have already been operated on are followed for several years. If they have not already done so, refractive surgery centres presently in operation in Québec should take the necessary steps to document any complications in the medium and long terms.

Efficacy Parameters

The parameters used thus far for measuring the efficacy of refractive surgery techniques have generally been limited to the resulting refraction and to Snellen visual acuity. However, it is now known that a patient with a visual acuity of 20/20 after refractive surgery may nonetheless experience various visual symptoms, such as halos, glare and decreased night vision, which can be significantly troublesome when driving at night. These functional problems cannot be detected by Snellen charts and refraction, hence the need, in the future, to examine the other aspects of vision, such as contrast sensitivity, glare, the induction of optical aberrations and the effect of pupillary diameter, and the need to refine the pa-

rameters for assessing medium- and long-term patient satisfaction, specifically, in order to take the age factor into account.

Regulating the Diffusion of this Technology

What was said in *CETS*'s previous report applies to the need to better regulate the introduction and diffusion of this technology in Québec and Canada. We have noticed that, although there are, officially, only four models of instruments for unrestricted sale in Canada, several other models are already in general use in clinics in Québec. This situation is giving this technology—which, for some indications, can still be considered "experimental"—an irreversible character.

Status of the Technology

For mild and moderate myopia, PRK and LASIK can now be considered accepted technologies, although there is a lack of long-term follow-up. To maintain and improve the level of safety, the conditions governing the use of these technologies should be an integral part of a clinical risk management program or a quality management program, especially since they are intended for healthy patients. In this regard, it would be important to create information systems that would permit rigorous surveillance of the untoward effects of the use of PRK and LASIK.

For the correction of severe myopia or moderate and severe hyperopia, LASIK is still an innovative technology. This status implies that a certain amount of uncertainty persists as to various aspects of its use or even to its indications and that there is a need, in order to eliminate this uncertainty, to continue to systematically gather data on the use of this technology, to analyze them and to communicate them to the medical community.

Lastly, even though it is not discussed in detail in this report, it would be useful to mention that

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the insertion of phakic intraocular lenses or intracorneal rings is still considered an experimental technology. Nonetheless, this technology is presently gaining in popularity among surgeons and the public.

Prudence should be exercised. The past provides several examples in ophthalmology, especially in refractive surgery, of initial euphoria with a new technique or technology, with a very large number of patients being operated on in a short period of time before there was enough time to observe the short-, medium- and long-term untoward effects and complications.

Obligation to Inform the Patient

Lastly, *CETS* wishes to reiterate the fact that treating myopia or hyperopia by photorefractive keratectomy or LASIK seldom constitutes a medical necessity. Unlike the "optical" alternatives, such as glasses and contact lenses, PRK and LASIK are irreversible procedures whose long-term effects and impact on vision quality are unknown. *CETS* acknowledges that wearing glasses or especially contact lenses is not totally without its drawbacks and complications. However, this method of correcting refraction is extremely effective and much better known and is not associated with the complications observed with PRK and LASIK. Since intervention with either of these procedures does not constitute a medical necessity, the general obligation to inform the patient must be met with utmost rigour, with the patient being informed of the rare and even extremely rare risks.

