Conseil *d'*Évaluation *des* Technologies *de la* Santé *du* Québec

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THE EXCIMER LASER IN OPHTHALMOLOGY: A STATE-OF-KNOWLEDGE UPDATE

Report submitted to the

Minister of Research, Science And Technology of Québec

Conseil d'évaluation des technologies de la santé du Québec

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Conseil d'évaluation des technologies de la santé du Québec

MANDATE

To promote and support health technology assessment, disseminate the results of the assessments and encourage their use in decision making by all stakeholders involved in the diffusion of these technologies.

To advise the Minister on matters concerning the introduction, diffusion and use of health technologies and, to this end, give advice based on the assessment of their effectiveness, safety and cost, their impact on the health-care system, and their economic, ethical and social implications.

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THE EXCIMER LASER IN OPHTHALMOLOGY: A STATE-OF-KNOWLEDGE UPDATE

In May 1997, the *Conseil d'évaluation des technologies de la santé du Québec* (*CETS*) published a report dealing specifically with excimer laser photorefractive keratectomy (PRK). Since then, the ophthalmological applications of the excimer laser have continued to evolve at a rapid pace. Furthermore, these applications, which are available essentially in the private sector, given that they are services paid for directly by patients, have been diffused very rapidly. Questions must therefore be asked about the efficacy and safety of this technology.

The purpose of this report is to update the assessment of the benefits and disadvantages of PRK and to examine more specifically LASIK (laser in situ keratomileusis). It also provides an overview of the alternatives and future developments and the research in this field. The indications, contraindications and choice of procedure (PRK or LASIK) are discussed as well.

From its analysis, CETS concludes that for mild and moderate myopia, PRK and LASIK can now be considered accepted technologies, although there is a lack of long-term follow-up. For the correction of severe myopia and moderate and severe hyperopia, LASIK is still an innovative technology. The reason for this status is uncertainty as to various aspects of its use or even to its indications, uncertainty which would need to be eliminated by gathering and systematically analyzing data on the use of this technique.

CETS still believes that steps should be taken to better regulate the introduction and diffusion of this technology in Québec and Canada. Furthermore, since these interventions rarely constitute a medical necessity, the overall obligation to inform the patient should be met with utmost rigour, with the patient being informed of the rare and even extremely rare risks.

In disseminating this report, *CETS* wishes to provide the best possible information to patients and to policymakers concerned with the effective and safe use of the excimer laser in ophthalmology.

Renaldo N. Battista
President

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 accomodation. 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 parameters 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

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.

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1. INTRODUCTION

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 excimer laser photorefractive keratectomy [60], the ophthalmologic applications based on this means of intervention have continued to evolve at a rapid pace. Furthermore, these applications, which are available essentially in the private sector, given that they are services paid for directly by patients, have been diffused very rapidly in Québec and elsewhere.

Our first objective in this report is to update the assessment of the benefits and drawbacks of photorefractive keratectomy (PRK) in light of the developments that it has undergone. Also, we examine the LASIK technique in considerable detail and assess its efficacy and complications in the treatment of myopia and hyperopia.

After discussing patient satisfaction and optical quality of vision, we examine the indications and contraindications of PRK and LASIK and the criteria for choosing between the two procedures. We also look at the alternatives, future developments and research in this field. Lastly, we provide a recap and discussion, then, in a separate section, put forth a number of specific and general conclusions concerning the applications of the excimer laser.

For practical reasons, the general principles of excimer laser refractive surgery, which were explained in the first report, are explained again in Appendix A. Also, a brief summary of ocular anatomy and the main refractive errors is reproduced in the following section to make this report easier to understand by readers who might be less familiar with ophthalmology.

2. ANATOMY AND PHYSIOLOGY OF THE EYE

2.1 ANATOMY OF THE EYE

Figure 1 shows the main anatomical structures of the eye. The cornea is a transparent tissue at the front of the eye, anterior to the iris and pupil. Behind the iris is the lens, which is biconvex in shape. The back of the eye is covered by the retina, a membrane consisting of several layers of nerve cells that detect light signals. The visual axis is the line joining the eye's point of fixation of the object and the image point on the fovea, the central part of the retina. The cornea consists of six separate layers (see Figure 2): the epithelium, the basement membrane, Bowman's membrane, the stroma, Descemet's membrane and the endothelium.

2.2 PHYSIOLOGY OF THE EYE

The eye receives light rays from a distant object and bends them to a point called the "focus" (Figure 3). In an emmetropic, or normal, eye, in which there is no refractive error, the focus is on the retina and the image formed is clear. Such an eye therefore does not require optical correction. The process of bending light rays to a focus, refraction, is measured in diopters. Dioptric power (D) is defined as D = 1/f, where f is the focal distance in meters. A lens that bends light rays to a focus one metre behind it has a refractive power of one diopter, two diopters corresponds to a focus ½ metre behind the lens, and so on. A normal eye owes most of its refractive power to the cornea, but also some to the lens. During the process known as "accommodation", the curvature of the lens increases, which further augments the refractive power and permits clearer vision of near objects. Presbyopia is the normal loss of the lens's accommodative capacity, a normal phenomenon of aging.

2.3 MYOPIA

A myopic eye (Figure 4) is too powerful for its length, either because it is too long or, in some cases, because the cornea is too steeply curved. Rays from a distant object converge in front of the retina, and the image of this object on the retina is blurred. Near objects, on the other hand, are seen clearly. Myopia can be corrected with glasses, contact lenses or refractive surgery, all of which cause the rays to diverge so that the image is moved back to the retina. The degree of myopia is measured in terms of the refractive power of the lens required to correct it, and since this involves divergence, negative units of measurement are used, e.g. -1.00 or -2.00 diopters.

2.4 HYPEROPIA

A hyperopic eye (Figure 5) is not strong enough for its length, either because of insufficient refraction (e.g. cornea too flat) or because the eye is too short. In a hyperope, rays from a distant object converge behind the retina. Depending on the lens's accommodative reserve, they may be moved up to the retina, but this convergence is often insufficient, and the image, on the retina, of near objects remains blurred. Hyperopia can be corrected with glasses, contact lenses or refractive surgery, all of which cause the rays to converge and bring the image closer to the retina. The degree of hyperopia is expressed in positive diopters, e.g. +1.00 or +2.00 diopters.

2.5 ASTIGMATISM

The refractive power of an astigmatic eye varies according to the corneal meridians. In regular astigmatism, for example, there are two main meridians. They are situated 90° apart, and each

Figure 1: Anatomy of the eye

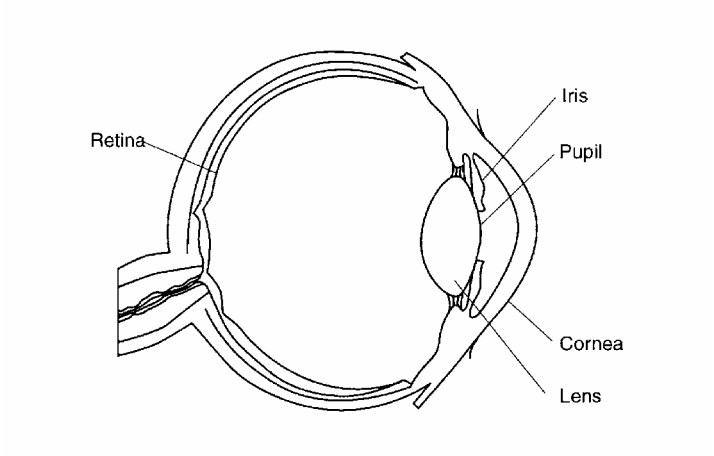


Figure 2: Histology of the cornea

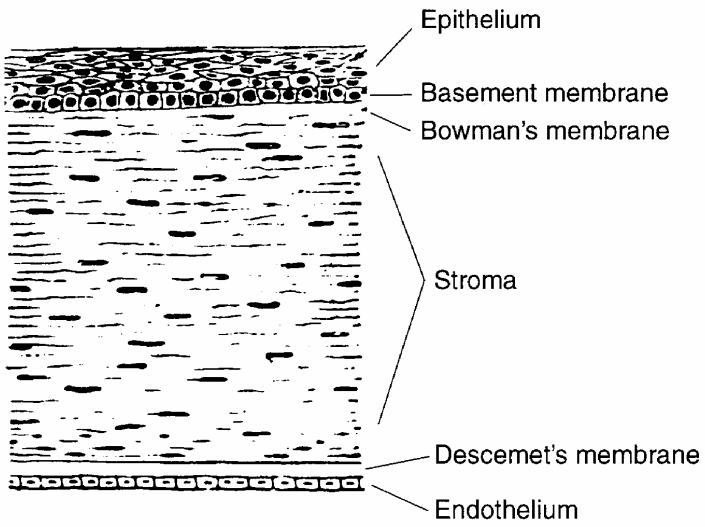


Figure 3: Emmetropic eye

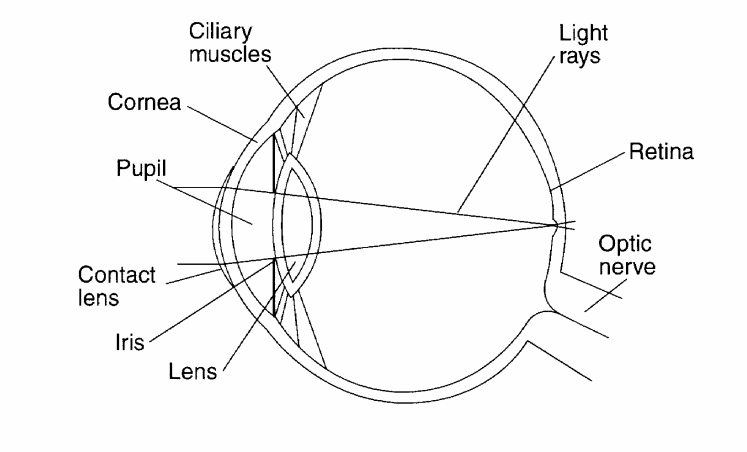


Figure 4: Myopic eye

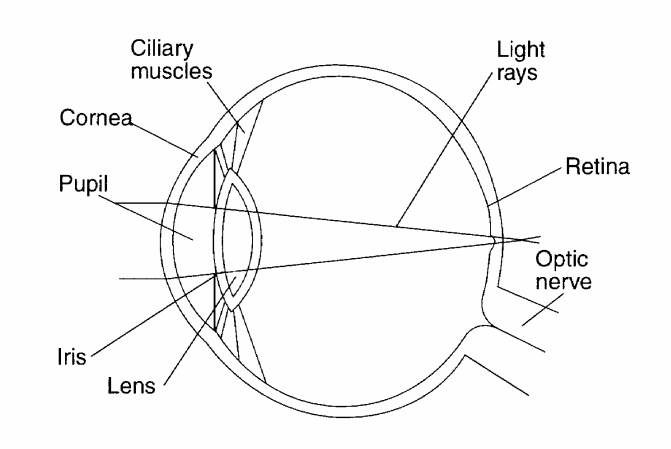
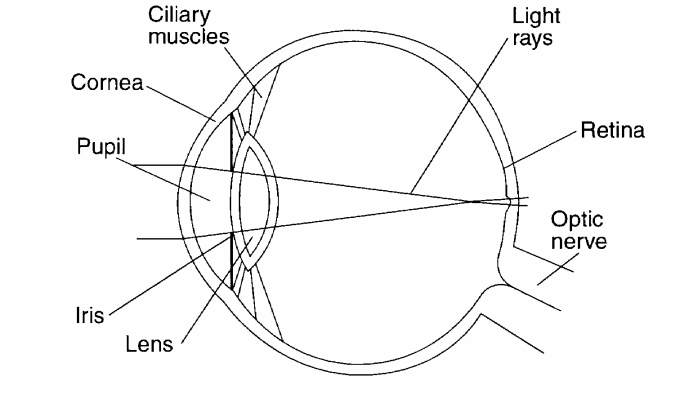


Figure 5: Hyperopic eye



has a different refractive power. In irregular astigmatism, the refractive power can vary within the same meridian and from one meridian to another. Irregular astigmatism is sometimes corrected better with gas-permeable or rigid contact lenses than with glasses. Astigmatism can be accompanied by myopia or hyperopia.

2.6 VISUAL ACUITY

Uncorrected refractive errors affect visual acuity. Visual acuity is the minimum angle (or size) that a letter projected at a given distance must have for the photoreceptors in the retina to be able to discriminate between the black and white spaces—the lines and the spaces between them—that make up the letter. Several other factors affect visual acuity, such as injury to the central retina and opacities in the transparent structures of the eye, especially the cornea and lens. Refraction and visual acuity are therefore two linked, but separate, parameters characterizing visual function. These two parameters are relevant when evaluating a patient for eye surgery.

Visual acuity of 6/6 is considered the standard of good vision in the general population. Visual acuity of 6/12 is poorer than 6/6, which means that the individual can see only at 6 meters what someone with normal vision can see at 12 metres. The *Société de l'assurance automobile du Québec* requires acuity of 6/12 or better for a driver's license under Section 4 (Division II) of the *Regulation respecting medical and optometrical standards for driving a road vehicle and the conditions attached to a license*.

Visual acuity is usually measured with a Snellen chart. Letters of different sizes enable the examiner to determine the level starting at which the patient can discriminate between two point sizes. A Snellen chart has lines ranging from 6/3, 6/4.5, 6/6,…to 6/60 and 6/120. The measurements can also be expressed in feet, as is usually the case in the American literature. Six metres corresponds to 20 feet, 6/6 thus being 20/20, and so on. The Snellen chart is not linear. In other words, the gain or loss of a line, for example, after an intervention like PRK or wearing new glasses, does not constitute the same "jump" for all the point sizes on the chart.

3. METHODOLOGY

CETS's first report on excimer laser photorefractive keratectomy for the correction of myopia and astigmatism, which was published in May 1997, was based on a review of the literature up to 1995. The present report provides an update on refractive surgery since the publication of the 1997 report.

A MEDLINE search was done for titles of articles published from 1995 up to and including October 1999 with the keyword "excimer". All the abstracts thus obtained were reviewed. The full articles chosen were then obtained and examined. This literature review was limited by the availability of the articles and the language in which they were written. Only those articles written in English or French were selected. Not all the articles examined are cited or mentioned in this report.

Paper abstracts were rarely used because it has been shown that they report results that are generally less rigorous than those published in articles from peer-reviewed journals [21].

The results are summarized in tabular form and discussed in the text *per se*. The tables are intended as a representative but not exhaustive summary of results obtained with PRK (Tables C.1 to C.7) and LASIK (C.8 to C.15) and of a comparison of the two techniques (Tables C.16 and C.17) based on the studies published between 1995 and October 1999. Special attention was directed to the publications in the last two years in question, i.e. 1998 and 1999. Studies in which the duration of follow-up was less than six months or in which the number of eyes was less than 20 were excluded. Where possible, the results were broken down according to the initial degree of ametropia (mild, moderate, severe myopia). When these subgroups involved fewer than 20 eyes, they were nonetheless reported if the entire study involved more than 20. Some studies in which the data were reported in a format that was too different from a tabular format could not be summarized in the tables. The number of eyes indicated in the tables is usually the number of eyes initially chosen for the study. Because of losses to follow-up, this number may be higher than the number of observations made during the postoperative follow-up.

These results should be interpreted with caution, since some studies include retreatments, while others do not. Also, some only include one eye per patient, others one or both. Preoperative corrected acuity is not always indicated, yet it may sometimes be very low, especially in high myopes. Some studies report only the difference between postoperative refractions and emmetropia, while others only indicate the difference in relation to the intended correction, which can be quite different. For this reason, the few studies where the degree of myopia treated differed too much from the actual degree of myopia (e.g. standardized treatment of -6.00 diopters in myopes with -6.00 diopters to -14.00 diopters) are not included in these tables. On the whole, we have observed, over the past several years, a trend towards standardizing the manner in which refractive surgery results are reported, which makes comparisons possible [270].

In conclusion, it should be noted that the descriptions of visual problems, such as myopia, hyperopia and astigmatism, provided in this report, while useful, are simplistic. The function of the eye is much more complex, and patients should bear in mind that problems associated with these refractive errors cannot always be solved simply by correcting the shape of the cornea.

4. PHOTOREFRACTIVE KERATECTOMY (PRK)

Photorefractive keratectomy (PRK) consists in sweeping the surface of the cornea with a laser beam of ultraviolet light in order to sculpt in the cornea a lens that will correct the eye's refractive error. The detailed description of the different steps in this treatment that was provided in *CETS's* previous report is reproduced in Appendix B.

4.1 UPDATE ON STUDIES OF THE EFFICACY OF PRK

The results of the latest studies of the efficacy of PRK in correcting myopia, astigmatism and hyperopia are summarized in Tables C.1 to C.7 and C.16 (Appendix C). Also, a tabular synopsis (Table 1) of the variations observed in these results is provided on page 18.

4.1.1 Mild myopia

The results of 22 studies involving subjects with mild myopia (up to -6.00 diopters) are provided in Table C.1 (Appendix C). Most of these studies report a follow-up of six months to one year. In one third of them, it was two, three or even five years.

Some authors report a correction to within one diopter of emmetropia in more than 95% of the cases [6, 10, 135, 158, 217, 244], a figure which is higher than the best results reported in *CETS's* previous report. Six studies indicate figures of less than 75%, with the proportion being as low as 52% in one case. However, these studies tended to involve subjects with a higher mean myopia. For example, Amano [10] reports separately the results for subjects with myopia of -2.00 to -3.00 diopters and those with myopia of -3.00 to -6.00 diopters. All of the 11 eyes in the first group were corrected to within one diopter of emmetropia, whereas only 75% of the 28 eyes in the second group were corrected to within one diopter of emmetropia. A correction to within ± 0.5 diopters of emmetropia is reported for 37 to 91% of the subjects, depending on the study.

Forty-eight to 100% of the subjects treated by PRK for mild myopia had a visual acuity of 6/12 without glasses. An uncorrected visual acuity of 6/6 or better was achieved in 30 to 100% of the cases.

It is important to note that the proportion of subjects with a postoperative loss of corrected visual acuity of two or more Snellen lines was 1% or less in 10 of the 15 studies that report this measure. The studies reviewed in *CETS's* first report indicate higher percentages.

The results suggest that already at -3.00 diopters, PRK is less effective in treating myopia. This was clearly documented by Shah et al [244], who broke down their results according to the initial degrees of myopia, which were expressed as increasing increments of one diopter. For each parameter studied, the success of the operation decreased as the degree of myopia treated increased. Hersh et al [123] confirmed that outcome predictability and the likelihood of achieving an uncorrected acuity of 6/12 or better decrease with the extent of the intended correction and the patient's age. This risk study involved 612 mild myopes (-1.50 to -6.00) operated on using small ablation diameters (4.5 to 5.00 mm). Similarly, Loewenstein et al [162] found that for a given intended correction (-4.00 or more), the patients aged 35 to 54 were overcorrected in relation to those aged 18 to 26. The ablation diameter also seems to be an important factor, since better results are obtained with larger diameters [135].

4.1.2 Moderate myopia

The results of 18 studies involving subjects with moderate myopia (-6.00 to -10.00 diopters) are presented in Table C.2 (Appendix C). The duration of follow-up in most of these studies was one year; in several it was two years. It was observed that the PRK success rate decreased with the extent of the intended correction. The proportion of subjects with a correction to within one diopter of emmetropia varied from 25 to 100%, while 29 to 80% of the subjects were corrected to within ± 0.5 diopters of emmetropia.

The percentage of patients achieving an uncorrected visual acuity of 6/12 was lower than for mild myopes, ranging from 47 to 95%. Five to 61% achieved an uncorrected visual acuity of 6/6 or better.

Lastly, the percentage of patients with a loss of corrected visual acuity of two or more Snellen lines was high, ranging from 0 to 12% for the 12 studies that reported this parameter.

On the whole, these results are a slight improvement over the data reported in *CETS's* first report.

4.1.3 Severe myopia

Table C.3 (see Appendix C) shows the results of 14 studies involving subjects with severe myopia (more than -10.00 diopters). The duration of follow-up in all of these studies was two years or less, except in one, in which it was up to five years. It is still seen that the PRK success rate continues to decrease with the extent of the intended correction. In these studies, the percentage of subjects who were corrected to within one diopter of emmetropia varied from 23 to 100%, the percentage of those corrected to within ± 0.5 diopters from 17 to 42%.

The percentage of patients who achieved an uncorrected visual acuity of 6/12 was still lower than for moderate myopia, being 22 to 87%, with 0 to 56% achieving an uncorrected visual acuity of 6/6 or better.

The ten studies in which the loss of corrected visual acuity was measured report a loss of two or more Snellen lines in 0 to 22% of the patients. It is interesting to note that although the loss of corrected acuity increases significantly with the degree of myopia treated, the number of patients gaining one line (10 to 44%) or two or more lines (0 to 21%) increased as well. It is thought that this is due to the fact that, prior to the operation, a high myope's corrective lens reduces the size of the images he perceives and causes a certain amount of distortion. Postoperative haze is significantly more frequent and more pronounced in high myopia than in low or moderate myopia [276].

4.1.4 Myopic and other types of astigmatism

Table C.5 shows the results of 15 studies concerning the correction of myopic astigmatism by PRK published since *CETS's* first report. The results are similar to those presented in that report, with no notable improvement. Thus, after 6 to 18 months of follow-up, 28 to 95% of the eyes with low myopia were corrected to ± 1.00 diopter of the intended correction. As for uncorrected visual acuity, 55 to 100% of the eyes achieved acuity of 6/12 or better and 0 to 62% achieved 6/6.

Table C.6 shows the results of three studies on the correction of hyperopic or compound astigmatism. Depending on the study, 81 to 91% of the subjects achieved refraction to within ± 1.00 diopter, 0 to 2% lost two or more lines of vision, and 82 to 97% achieved an uncorrected visual acuity of 6/12 or better.

However, it is difficult to interpret these results because the response to the treatment of astigmatism depends not only on the degree of astigmatism, but also on the relative degree of myopia to be corrected with the astigmatism, the technique

used (sequential or elliptical mode of treatment, crossed cylinders) [8] and on how the postoperative astigmatism is analyzed, since one can compare the absolute values of the pre- and postoperative cylinders (nonvectorial method) or take into account the change in the cylinder axis (vectorial method). The analysis of astigmatism induced by refractive surgery is an issue that is increasingly in vogue. It is reasonable to expect that the analytical methods will be refined in the next few years.

4.1.5 Hyperopia

The results of eight studies on the correction of hyperopia by PRK are presented in Table C.7 (Appendix C). PRK is much less effective and predictable in the treatment of hyperopia than it is in the treatment of myopia. Also, its efficacy decreases very quickly as the degree of hyperopia increases. For some, the objective is no longer emmetropia, but simply a reduction in hyperopia [214]. In the studies identified, 13 to 95% of the eyes achieved refraction to within ± 1.00 diopter, 0 to 7% lost two or more lines of vision, and 8 to 97% achieved an uncorrected visual acuity of 6/12 or better, with the follow-up ranging from 6 to 24 months.

4.2 EVOLUTION OF PRK

In general, the scientific data point to an improvement in the outcomes of the excimer laser treatment of myopia over the past few years. This improvement is due mainly to the constant improvement in lasers and their programs. More specifically, the observed improvements are attributable to the increase in the ablation zone diameter, the use of multizone and multipass techniques, pretreatment of the central cornea for the purpose of preventing central islands, the advent of scanning beams, and better success with retreatments.

4.2.1 Ablation zone diameter

Over the years, the improvement in lasers and a better understanding of the pathophysiology of excimer laser photoablation have led to a growing increase in the ablation zone diameter. It was initially 3.5 mm and has gradually increased to up to 9 mm.

Large diameters are used to minimize initial overcorrections, which makes for a speedier rehabilitation and a better outcome prediction [135, 197]. Large diameters also make for better optical outcomes, with less postoperative halo and night vision impairment. Theoretically, the ablation should be wider than the pupil, even at night, when the pupil dilates. The reason is that the transition zone between the ablation and the unoperated cornea should remain concealed by the iris, since this zone causes an aberrant deflection of rays, which results in decreased vision quality.

However, there is also a limit to increasing the ablation diameter, for the greater the optical zone diameter, the deeper, necessarily, the ablation. Too deep an ablation is also a problem because it jeopardizes the integrity of the eye wall, with an increased risk of ectasia and damage to the corneal endothelium.

4.2.2 Multizone and multipass techniques

The principle of the multizone technique is to divide the treatment into a series of concentric ablations of varying diameters and depths. This makes for a better ablation profile [9, 51].

The principle of the multipass technique is to divide the treatment into a series of successive treatments performed a few seconds apart. It is thought that in so doing, one can avoid an excessive increase in the temperature of the tissue during the ablation, thus giving it enough time to cool down between passes. The multipass technique was initially described by Mihaï Pop

[216], of Montréal, and quickly spread within the international scientific community. Some companies, such as VISX, have incorporated the multipass technique into their laser program.

The multizone and multipass techniques are now most often used together. It is thought that since the successive treatments in the multipass technique are not perfectly superimposed, there results a smoothing out of the concentric stair steps left by the multizone technique. It is believed that, because the resulting surface is smoother, it produces less scar tissue and less postoperative haze [217, 280]. In LASIK, the advantage of the multizone technique over monozone treatment seems less obvious than in PRK, at least in mild myopes [47].

4.2.3 Central pretreatments

Over the past several years, a number of authors have reported an elevation, or island, in the centre of the ablation zone. A central island is considered topographically significant starting at 3.0 diopters and 1.5 mm in diameter [203]. It can cause a decrease in vision quality, ghost images and double vision [91]. A central island can now be retreated [173] or prevented by including a pretreatment in the laser program. A better understanding of the pathophysiology of central islands, the advent of multizone/multipass techniques [43], preventing an excess accumulation of fluid on the corneal surface during ablation [203] and especially the advent of scanning beams have also helped optimize central island prevention.

4.2.4 Scanning beams and broad beams

The advent of scanning beams is probably the greatest recent advance in the field of excimer laser refractive surgery. They offer a certain number of advantages over the broad beams used up to this point, although they are not without their drawbacks either.

Broad beams are beams whose diameter covers the entire corneal ablation surface. Scanning beams are based on a totally different principle. Instead of covering the entire surface of the treatment zone, the beam is much smaller and moves everywhere on the surface to be treated. A scanning beam can be in the shape of a slit or spot.

4.2.4.1 Advantages and disadvantages of broad beams

Since, with each pulse, the entire ablation surface is covered, it takes less time to perform the operation than with a scanning beam. Also, the ablation frequency is lower. Decentrations can be compensated for more easily and potentially have fewer consequences. Lastly, with broad beams, a tracking system for better centration is not necessary.

On the other hand, since the beam must cover the entire ablation surface, it must be perfectly homogeneous, which requires that the laser be very powerful and that it include a complex energy release system. The frequency and complexity of maintaining the device are therefore greater. The device's complexity limits the number of possible treatment modes, such as that for asymmetric astigmatism. With broad beams, the acoustic shock wave is stronger. Lastly, the incidence of central islands is higher.

4.2.4.2 Advantages and disadvantages of scanning beams

Spot scans require significantly less energy. Since it is the scanning that determines the uniformity of the treatment zone, the beam's homogeneity is much less important, and since the instrument's optics are simpler, maintenance is easier. Different ablation modes are possible, including that for treating irregular astigmatism. The acoustic shock wave is considerably weaker. This technology has made it possible to eliminate the problem of central islands.

On the other hand, with spot scans, the fixation system is extremely important. Complex movement tracking systems must be used to ensure uniform application of the treatment. Also, the whole operation is much longer, since one must wait for the spot to scan the entire corneal surface, whereas with a broad beam, the entire surface is covered with each pulse. A high pulse repetition frequency is therefore required. New algorithms therefore had to be developed, since they were different from those for homogeneous-beam lasers.

As for the slit scanning system, the advantages and disadvantages are moderate, with, once again, less energy required, improved uniformity, a weaker acoustic shock wave, smoother ablation surfaces and the absence of central islands. However, the procedure takes longer than that with a broad beam.

4.2.5 Better success with retreatments

Better success with retreatments for regression [113, 218, 229], central islands [174], haze or decentration [157] following PRK has led to better outcomes with this technique.

A retreatment technique has been proposed for patients who have reduced night vision with halos, glare and night driving problems thought to be due to an insufficient optical zone diameter [76]. It consists in increasing the initial ablation zone diameter.

It was originally thought that this type of retreatment would lead to an overcorrection if the patients were not myopic at the time of retreatment. However, an alternative has been proposed by Dr. Gilles-P. Lafond, of Québec City [152], in which the ablation zone diameter can be increased without affecting refraction.

Haze remains the main drawback of PRK. However, its incidence has decreased significantly. In a review of 3,000 consecutive cases of PRK for mild, moderate and severe myopia with and without astigmatism, Alio et al [6] report, at one year, for these different groups, mild haze (0 to 1, out of a maximum of 4) in 85 to 100% of the cases and greater degrees of haze (2 or more) in 0 to 15% of the cases. At two years, 98 to 100% had mild haze, while 0 to 2.3% still had a greater degree of haze.

5. LASIK

5.1 GENERAL DESCRIPTION

LASIK stands for “laser *in situ* keratomileusis”. Actually, it is PRK preceded by a step in which the surgeon cuts a thin flap from the cornea with a manual 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.

5.2 PREOPERATIVE PATIENT EVALUATION

In LASIK, the preoperative evaluation is similar in many respects to that in PRK. Since, in LASIK, the ablation diameter is smaller than in PRK, special attention must be given to pupillary diameter. An examination of the anatomy of the eye and socket is especially important as well. Small, flat, enophthalmic eyes deeply set in a hollow orbital cavity dominated by a prominent brow ridge, small palpebral fissures or severe blepharospasm are guaranteed to make cutting a LASIK flap a laborious task. A suboptimal orbital structure alone can constitute a contraindication to LASIK.

5.3 LASIK SURGERY

5.3.1 Description of the operation

Usually, no systemic medication is administered to the patient prior to the operation. Mild sedation may occasionally prove necessary to calm an excessively anxious patient. Most surgeons prefer not to give anything, so as to avoid reducing the patient's attention level. To reassure the patient, the necessary explanations are given as the operation proceeds. He is told that he will experience discomfort at the beginning of the procedure, i.e. pressure on the eye and gradual blurring of his vision. An effort is made to familiarize him with the noises made by the keratome motor and the laser pulses. He is told that certain odours may be given off during the operation. He is asked not to move. The patient is placed supine under the microscope. His head is checked to make sure that it is properly aligned with the rest of his body, as any head rotation can alter the axis of the cylinder being treated.

Usually, a technician is responsible for calibrating the laser and preparing the instruments. The patient's data and the desired amount of correction are entered into the computer. It is generally the surgeon who assembles the microkeratome, inspects the blade and its glide, and checks the microkeratome’s gears and its travel on the fixation ring tracks. The division of the different tasks varies from centre to centre, but in the end, it is the surgeon who is responsible for all the aspects of the operation.

A lid speculum is inserted. Alignment marks are made on the epithelial surface of the cornea to make it easier to reposition the flap at the end of the procedure. A suction ring is installed. Applanation tonometry is used to ensure that the intraocular pressure is greater than 65 mm Hg. If it is not, the operation can generally not be performed. An applanation lens is used to estimate the diameter of the cut to be made with the keratome. This is being done less and less. The keratome is inserted into the suction ring grooves, and, moving by motor activation, raises a thin layer until it abuts against the brake, thus leaving a hinge to create a flap. The keratome is carefully removed. The target depth is usually 150 to 160 microns.

The flap is gently deflected. The surgeon uses pachymetry to check the residual thickness of the stroma, then performs excimer laser photoablation, which is centred on the centre of the pupil and aided by the patient's active fixation on a co-

axial light source. After the ablation, the flap is repositioned on the stromal bed. Great care is taken to remove the debris from the interface. This is usually done by irrigation. After five minutes of dehydration without excessive manipulation, the flap is usually sufficiently adherent for the lid speculum to be removed.

A drop of antibiotic and a drop of topical steroid are instilled. Most surgeons in Québec do not use contact lenses, unless there is a severe epithelial deficit. Nor is an eye patch necessary, except in some cases for a few hours after the operation. The flap adheres on its own without any sutures, except in a few rare cases where it detaches completely or is unstable. Its alignment is checked a final time before discharging the patient. A protective cap is recommended for the first 24 hours and at night for the first three weeks. Noncorrective-type safety glasses are recommended as well. The patient is advised not to rub his eye, as this could cause trauma to the flap.

5.3.2 Postoperative follow-up

The starting medication consists of acetaminophen tablets, which can be taken every six hours as needed, a drop of antibiotic administered four times a day until there is complete reepithelialization, and a topical antiinflammatory, usually a mild steroid, which is applied three times a day for one week.

The appointment schedule varies, but patients are usually seen again the day after the operation and at 1, 3, 6 and 12 months. Post-LASIK visits are less frequent and, even at the outset, shorter than those following PRK because of the rapid rehabilitation with LASIK.

According to Lindstrom [158], patients treated for myopia of less than -4.00 diopters typically achieve an acuity of 6/7.5 as early as the day after the operation. For myopia of -4.00 to -8.00 diopters, an acuity of 6/12 or better is often possible on the first day, although rehabilitation takes longer for higher degrees of myopia.

5.4 TREATMENT OF MYOPIA BY LASIK

5.4.1 Efficacy

The results of the latest studies of the efficacy of LASIK in correcting myopia, astigmatism and hyperopia are summarized in Tables C.8 to C.15 and C.17 (Appendix C). The synoptic table (Table 1), which shows the observed **differences** in the results obtained, provides a quick overview. The efficacy of this technique was not examined in *CETS's* first report**.**

5.4.1.1 Mild myopia

The outcomes of the treatment of myopia of -1.00 to -6.00 diopters by LASIK seem comparable or even slightly superior to those of treatment with PRK (see Table C.8 in Appendix C).

Thus, 89 to 100% of the eyes treated were corrected to ± 1.00 diopter of the intended correction, which seems superior to the figures obtained with PRK. However, only 9 to 44% were corrected to ± 0.5 diopters, which is inferior to the figures obtained with PRK.

Uncorrected visual acuity is slightly superior to that obtained with PRK. The vast majority of patients (90 to 100%) achieved an acuity of 6/12 or better, and 52 to 85% achieved 6/6 or better. However, a higher percentage of eyes (0 to 11%) experienced a loss of corrected visual acuity of two or more lines with LASIK.

Most of the studies identified report a duration of follow-up of only six months, with only two of the seven studies extending over a period of two years.

5.4.1.2 Moderate myopia

The outcomes with LASIK for the correction of moderate myopia (-6.00 to -10.00 diopters) are less satisfactory (see Table C. 9 in Appendix C). However, LASIK seems to yield slightly better results than PRK. The refractive effect is still difficult to predict, with 43 to 100% of the eyes having been corrected to ± 1.00 diopter of the intended correction. The risk of a decrease in best-corrected visual acuity seems lower with LASIK. Lastly, the proportion of patients who achieve uncorrected visual acuity greater than or equal to 6/12 is higher with PRK (63 to 96%). The durations of follow-up were once again very short (three months to one year).

5.4.1.3 Severe and extreme myopia

The 12 studies concerning the correction of severe or extreme myopia with LASIK that were identified also involved relatively short durations of follow-up (see Tables C.10 and C.11 in Appendix C). As with PRK, the results are not as good as for mild and moderate myopia. For the severe myopia studied in nine trials, 40 to 85% of the eyes were corrected to ± 1.00 diopter of the intended correction, and only 20 to 54% of them were corrected to ± 0.50 diopters. However, the percentage of patients with a loss of corrected visual acuity of more than one Snellen line was less than that observed with PRK (0 to 15% as opposed to 0 to 22%).

Extreme myopia is defined as that greater than -15.00 diopters. In *CETS's* 1997 publication, no studies concerning the correction of such degrees of myopia with PRK were reported. The results of eight studies on the correction of extreme myopia with LASIK are presented here. The refractive effect is quite unpredictable, with 31 to 68% of the eyes treated being within ± 1.00 diopter of emmetropia. In the four studies that report uncorrected visual acuity measurements, only 20 to 45% achieved acuity of 6/12.

5.4.1.4 Myopic and other types of astigmatism

The efficacy of LASIK in correcting myopic astigmatism seems slightly superior to that observed with PRK (see Tables C.13 and C.14 in Appendix C). Twenty-two to 95% of the eyes were corrected to within ± 1.00 diopter of emmetropia. If we exclude the extreme value of 22%, which pertains to a sample of subjects with extreme myopia (-15.00 to -29.00 diopters), the range is from 75% to 95%. These results are from only seven studies, one of which nonetheless involved 251 eyes. Once again, these studies are difficult to interpret, and not enough time has passed to evaluate the long-term effects.

5.4.1.5 Comparison between PRK and LASIK

Table C.16 in Appendix C shows the results of nine studies that directly compared the efficacy of PRK with that of LASIK for myopia ranging from -6.00 to -30.00 diopters. The results of these studies confirm that LASIK is slightly superior for treating this type of visual problem, both with regard to the level of correction achieved, uncorrected visual acuity and the loss of corrected visual acuity.

Table 1, which provides a synopsis of the efficacy measures for the two techniques, shows the differences found in the literature for the five efficacy indicators reported most often. The results are presented separately for the different refractive errors and according to the technique used, i.e. PRK or LASIK. This table is a summary of the results presented in Appendix C.

Table 1: Observed differences in results obtained with PRK and LASIK[a]

Condition		Correction to within ± 1.00 D of the intended correction (%age of eyes)	Correction to within ± 0.50 D of the intended correction (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)	Loss of corrected visual acuity ≥ 2 lines (%age of eyes)
Mild myopia	**PRK**	53% to 100%	37% to 91%	48% to 100%	30% to 100%	0% to 6%
	LASIK	89% to 100%	9% to 44%	90% to 100%	52% to 85%	0% to 11%
Moderate myopia	**PRK**	25% to 100%	29% to 80%	47% to 95%	5% to 61%	0% to 17%
	LASIK	43% to 100%	20% to 88%	63% to 96%	16% to 42%	0% to 5%
Severe myopia	**PRK**	25% to 100%	17% to 42%	22% to 87%	0% to 56%	0% to 22%
	LASIK	40% to 85%	20% to 54%	40% to 79%	0% to 15%	0% to 15%
Extreme myopia	**PRK**	-	-	-	-	-
	LASIK	31% to 68%	22% (only one study)	20% to 45%	-	1% to 9%
Astigmatism	**PRK**	28% to 95%	29% to 64%	55% to 100%	0 to 62%	0% to 17%
	LASIK	71%[b] to 95%	31% to 78%	40% to 95%	44% (only one study)	0% to 15%
Hyperopia	**PRK**	13% to 95%	8% to 85%	67%[c] to 97%	0% to 40%	0% to 7%
	LASIK	58% to 100%	39% to 87%	67% to 95%	15% to 17%	0% to 5%

[a] These figures are the minimum and maximum percentages of patients who met the efficacy criteria, as identified in the literature examined.

[b] 22% in the case of one study involving a sample with more severe astigmatism (-15.00 to -29.00 diopters).

[c] 8% in the case of one study involving a sample with more severe hyperopia of up to +9.75 diopters.

5.4.2 Complications

5.4.2.1 Complications associated with the keratome

The LASIK technique is more complex than PRK [19, 28, 74, 101, 102]. It requires more technical skill and attention on the part of the surgeon and the personnel involved. The keratome and suction ring are sophisticated instruments requiring meticulous care. The success of the operation depends directly on their performance.

The complications associated with the keratome and its operation can result in a flap that is too thick or too thin, of insufficient diameter or of variable thickness, or one that is perforated or that has irregular edges [102]. The flap may also be incomplete or free, i.e. completely detached. These complications may only require in-procedure adjustments or result in the operation being postponed. Irregular astigmatism resulting from a flap that is too thin, irregular or lost can be very difficult to correct [136].

Cases of perforation of the cornea by the keratome with penetration of the anterior chamber have been reported. This is the most dramatic complication of the LASIK technique [89]. These cases required lens extraction, iridoplasty and anterior vitrectomy. It is absolutely essential to always check that the plate has been properly installed, so as to limit the depth of cut. The new models of one-piece keratomes with integrated plate are designed to prevent this complication in patients with normal corneas.

Some patients with a history of contact lens wear may experience neovascularization of the peripheral cornea, especially in the superior cornea but sometimes in the inferior cornea. This zone may bleed after a cut is made with the keratome.

5.4.2.2 Complications associated with flap manipulation

Debris on the interface

Debris of different origins can settle on the interface between the stromal bed and flap [35, 148, 232]. It may subsequently be responsible for light diffraction and can adversely affect the healing process. In the case of iron debris, it can generate rust. Red blood cells can cause hematic impregnation.

Recently, the sands of the Sahara syndrome was described. It is a sterile, noninfectious keratitis of still unknown origin [92]. When this report was being prepared, the most likely hypotheses were an inflammatory or immunologic reaction in response to a noninert agent introduced into the interface during the procedure. It could also be due to particles released while handling the instruments, surgical fields or gloves, or to bacterial antigens. It is advisable to use powderless gloves, to thoroughly wash the instruments, and to irrigate, if possible, from the inside out and under the flap repositioned on its bed after photoablation. Some surgeons use suction to rinse and aspirate debris from the interface.

Epithelial ingrowth in the interface

During the weeks or months following the procedure, epithelial cells may spread under the flap [23, 108, 148, 212]. Carr [46] estimates the incidence of epithelial ingrowth to be as high as 14.7%. He observed that an epithelial deficit during the first 24 hours after the operation, reintervention with LASIK as opposed to primary LASIK, and flap displacement immediately after the operation are the main risk factors for epithelial ingrowth. The ingrowth occurs in the form of nests of opaque or translucent pearls with a varying degree of coalescence and progression. More often than not, this epithelial growth stabilizes without any complications. Sometimes, it continues to progress, with central or paracentral ingrowth, which is a potentially serious complica-

tion, since it can lead to melting of the lenticule [98].

If the epithelial growth progresses and starts to compromise the integrity of the flap and vision, intervention is required. The flap is lifted and the epithelium removed with a sponge or spatula. The flap must be repositioned with great care so as to prevent a recurrence.

Flap wrinkling

A flap that is too thin or improperly repositioned, especially if the ablation has been performed too deeply, can remain wrinkled [35, 108, 148, 232]. Pupillary dilation and retroillumination of the cornea can help diagnose wrinkles. Wrinkles can affect vision quality.

5.4.2.3 Complications associated with photoablation

Insufficient programming

Improper programming of the amount of intended correction can result in an overcorrection or undercorrection, a cylinder axis deviation or the induction of a cylinder.

Perforation of the flap by the laser beam

In LASIK, flap centration and photoablation centration are two separate steps. If the photoablation encroaches on the base of the deflected flap, a double ablation of the stroma results once the flap is repositioned on the cornea. Excessive depression of the surface at this site results in irregular astigmatism and an optical effect comparable to that of decentration.

To protect the base of the flap, some surgeons choose to intentionally decentre the suction ring by 0.5 to 1 mm nasally and protect the flap with an instrument [23]. This permits a larger ablation diameter without increasing the risk of decentration.

Ablation decentration

One study reports decentrations greater than 1 mm in 3% of the post-LASIK eyes [23]. Another study comparing PRK and LASIK observed a decentration rate of 50% (9/18) with LASIK when a criterion of 0.5 mm was used [191]. The authors report significantly greater decentration with LASIK than with PRK in patients with high myopia. These studies highlight the importance of improving the centration techniques used in LASIK surgery.

Decentration results in corneal astigmatism and decreased vision quality. The consequences can be particularly annoying in cases involving the correction of high myopia.

Treating decentration is difficult. Generally, if the myopia has been completely corrected when decentration is diagnosed, little can be done for the patient. However, if the patient is still myopic, which is often the case, treatment can be attempted, if warranted, based on his topography and symptoms.

Central islands

The central islands initially described with PRK can also occur with LASIK. However, corneal topography is usually smoother after LASIK than PRK [122], but unlike the central islands observed with PRK [2, 6], those observed with LASIK are less likely to regress with time. The incidence of central islands has diminished significantly both with PRK and LASIK, thanks to the advent of pretreatment programs and scanning beam lasers.

5.4.2.4 Early postoperative complications

Pain

For most patients, LASIK only causes discomfort and the sensation of a foreign body [148, 232]. Most patients simply use mild analgesics after the operation. Severe pain must be taken seriously because it suggests flap displacement or epithelial abrasion.

Infection

Infection following LASIK is extremely rare [16, 210, 223]. Fiander [88] reports no infections in 1,045 LASIK cases. Logically, one would think that respect for the integrity of the epithelium, only a thin band of which is normally cut around the flap, accounts for this low incidence. After LASIK, the epithelium heals in less than 24 hours, which is significantly faster than in PRK, where the average reepithelialization time is three days. Of course, the patient should be informed of the potential risk of infection and of the importance of using the prescribed topical antibiotics for the first few days. It is also advisable to avoid swimming in a swimming pool, a bath house, a lake or the ocean or any other contaminated water during the first few days after the operation.

Flap displacement

In LASIK, the flap is repositioned on the stromal bed after photoablation. It is probably because of the process of active stromal dehydration that the flap can stay in place without sutures. Shortly after the procedure, the flap is nonetheless very fragile and should be shielded from any trauma. Wearing protective glasses during the first 24 hours is advised. Some patients are also asked to wear an eye protector, at least the first night. If a diagnosis of flap displacement is made, the flap must be properly repositioned as soon as possible.

Flap displacement usually occurs within the first few hours after the operation and rarely more than 24 to 48 hours, unless trauma has occurred.

Complete loss of flap

A flap can be accidentally lost, usually as a result of trauma. Also, a flap that has sustained too much damage may be intentionally removed by the surgeon. When properly cut, the flap is theoretically flat and has no refractive power. The refractive effect of flap loss should therefore be limited to that of a decrease in the resulting axial length and a proportionate decrease in the ablation surface. The absence of a flap exposes the cornea to an increased risk of developing haze. The literature contains little about this rare complication, which should be better documented when it occurs.

5.4.2.5 Problems with scarring and wound healing

Haze

Post-LASIK haze is not the same type of opacity that occurs after PRK. The haze associated with PRK is central and subepithelial. That associated with LASIK occurs on the interface and is usually more discrete. This haze, which peaks at about one month, gradually disappears in the months that follow. A circular, gray scar appearing at about the sixth or eighth week around the edge of the flap, where the epithelium touches the stroma, may also be observed [232]. Most studies do not report any significant haze following LASIK [35, 89, 120, 121, 148].

The late-onset haze that occurs four months post-PRK [161, 186] does not seem to be a problem after LASIK either.

Stromal melting

A patient with aggressive epithelial ingrowth, especially if the flap is thin, may develop stromal melting [209]. Sometimes, stromal melting can progress very quickly. The edge of the flap deteriorates, and the latter becomes more grayish in colour. The prognosis of a flap with stromal melting is not good.

Treatment consists in lifting the flap and cleaning the underlying epithelium. If the flap is no longer viable, some authors recommend that it be removed in its entirety [166]. Theoretically, the flap is flat and has no refractive power. One should therefore be able to remove it, the conse-

quences basically being a decrease in the axial length and stimulation of the wound healing process comparable to that observed in PRK, with a risk of haze, regression and epithelial hyperplasia.

Recurring erosions

Recurring erosions are infrequent. When they do occur, it is mainly at the periphery of the flap.

5.4.2.6 Refraction problems

Over- and undercorrection

For some, the initial tendency was toward overcorrection [89, 209, 232]. The reported incidence of overcorrections varies. It can be as high as 2.5 diopters or more in 8.6% of patients [209, 232]. An overcorrection greater than +1.00 diopter is considered a complication. Improvements to nomograms and refinements to programs should, in the future, make it possible to minimize the gap between actual corrections and intended corrections.

Regression

Regression starts sooner, is less pronounced [85] and stabilizes faster in LASIK than in PRK, with few changes between the third and sixth months after the operation [118, 121, 148, 208, 209].

Lindstrom [58] reports a slight hyperopic shift on the first postoperative day, followed by a regression of about 0.5 diopters during the first month and of an additional 0.5 diopters between one and three months, after which the refraction remains stable. However, these figures vary and depend on the initial degree of myopia.

Fiander [89] reports that between the first and fifth months, 59% of the patients exhibited a myopic shift of less than 1 diopter, 30% of 1 to 2 diopters and 15% of 2 to 4 diopters, and 6% exhibited a hyperopic shift of 1 to 2.75 diopters.

Regression following LASIK is reportedly less likely to respond to steroids than after PRK.

Induced astigmatism

Hersh [121] seems to have observed that LASIK causes less induced astigmatism and in a more random fashion than PRK.

Variations in refraction with changes in barometric pressure

Variations in refraction during significant changes in atmospheric pressure (altitude, deep-sea diving) have been reported following radial keratectomy but not after PRK [168]. The stability of the post-LASIK flap needs to be studied [71].

5.4.2.7 The problem of postoperative diplopia

Refractive surgery can cause decompensation of latent strabismus and could account for postoperative diplopia [175]. It is also important to bear in mind that an eyeglass lens may have been intentionally decentered or that a prism may have been included in the lens to compensate for strabismus. If such eyes are operated on, they will be deprived of this prismatic effect and the patient will experience double vision. A trial with contact lenses is the most reliable test for ensuring that a patient at risk will not see double after the operation.

5.5 TREATMENT OF HYPEROPIA WITH LASIK

Refractive surgery for the correction of hyperopia has evolved favourably over the past few years, but it is still difficult to determine what the current state of knowledge is regarding this subject, since little literature is available (see Table C.15). However, it is increasingly a topic of discussion in the different refractive surgery societies. Surgeons in Québec and elsewhere in the world are starting to acquire the necessary equipment for treating hyperopia. It is important not to pass this matter over in silence. Because of

the insufficient number of references in peer-reviewed journals, we will summarize here the knowledge provided within the refractive surgery scientific community.

5.5.1 Efficacy

The results of six studies in which hyperopia was treated by LASIK are presented in Table C.15. As with PRK, LASIK is much less effective and predictable for hyperopia than for myopia. Also, its efficacy diminishes quickly with the degree of hyperopia. According to the studies identified, 58 to 100% of the eyes achieved refraction to within ± 1.00 diopter, 2 to 5% lost two or more lines of vision, and 67 to 95% achieved an uncorrected acuity of 6/12 or better, with, once again, a relatively short mean follow-up of 6 to 12 months.

5.5.2 Technical difficulties encountered

Hyperopic eyes are often small, and the corneas are flatter and smaller in diameter. The palpebral fissures are narrower as well. Such eyes are more difficult to operate on. Adjusting the suction ring and manipulating the keratome are more delicate tasks. A loss of suction during the cutting process can have serious consequences. Anesthesia must be optimal so as to minimize sudden patient movements and blepharospasm.

Since hyperopic ablation is performed over a very wide area, special attention must be given to carefully protecting the base of the flap during ablation. Once the flap is repositioned, it may appear smaller than the underlying stromal bed, especially in high hyperopia, because of the increase in central curvature. It is important at this point not to pull on the flap in an attempt to compensate.

5.5.2.1 Ablation diameters

Wider ablation diameters yield better results.

5.5.2.2 Flap diameter

It follows from what was just said that, if a wide ablation diameter is required, the diameter of the flap must be even wider. Thus, a diameter of 9 to 9.5 mm is required for the flap. However, not all keratomes can cut up to such diameters. Furthermore, for a given keratome, the shape and surface variations encountered from one eye to another can lead to variation in flap diameter.

5.5.2.3 Decentration

One of the major complications encountered in the treatment of hyperopia by LASIK is decentration, much more so than with PRK. This is because fixation is more difficult for the patient. The quality of the fixation system is crucial here, whether it is a mechanical system or an active eye-tracking system as is now found on certain lasers.

It can also be difficult to assess flap and treatment zone centration in hyperopes. Since the eye and cornea are often small and the visual axis often shifted nasally in relation to the geometric centre of the cornea, the visual axis may seem very close to the pupillary edge. Also, the flap may seem very decentred nasally, especially if it has been intentionally moved toward the nose in order to clear the ablation zone.

5.5.3 Complications

The two main postoperative complications encountered in the treatment of hyperopia are regression and the loss of best-corrected visual acuity.

5.5.3.1 Undercorrection and regression

Whereas the objective, when treating myopia, is to flatten the central cornea, in treating hyperopia, it is to increase its curvature by creating a midperipheral circular gutter. One of the main problems encountered in the treatment of hyperopia is regression due, among other things, to filling in of the circular gutter. The wider the gutter, spread out with smoothed edges, the smaller the risk of filling in. This is why the total ablation diameter is so important. It should be as wide as possible, ideally 8 to 9 mm. The results reported with 9-mm diameters are better than those reported with the treatment zones of 6 or 7 mm that were originally used.

Gauthier-Fournet [98] reports 20% regression for the treatment of hyperopia of +1.00 to +7.25 diopters.

5.5.3.2 Loss of best-corrected visual acuity

The treatment of hyperopia by LASIK is limited by the problem of a decrease in best-corrected visual acuity [59]. However, the outcomes of the treatment of hyperopia by LASIK seem more promising than those of the treatment of hyperopia by PRK.

6. PATIENT SATISFACTION AND OPTICAL QUALITY OF VISION

6.1 PATIENT SATISFACTION

It was only several years after refractive surgery evolved that the international scientific community began to examine the issue of patient satisfaction and the notion of postoperative quality of vision. In general, studies report a high level of postoperative patient satisfaction. Eighty to 90% said they were satisfied or very satisfied with the outcome of their operation [7, 26, 37, 72, 90, 93, 103, 112, 116, 125, 133, 171, 184, 206, 216, 230, 231, 234, 239, 245, 267, 269], and more than 85% considered that they had achieved their objective and would recommend the operation to their friends [37, 93, 133, 231]. An improvement in the quality of social and professional life is noted in most cases but reportedly occurs mainly in patients who have a low degree of preoperative myopia [90, 93, 133]. Fifty to 85% of subjects no longer wear glasses or contact lenses after the operation [26, 112, 133, 184, 230].

However, glare (49 to 64% of cases), fine-image distortion (37 to 89% of cases) and night vision disturbances, including night driving problems (10 to 32% of cases), are the main sources of discomfort and dissatisfaction [7, 26, 37, 72, 93, 112, 116, 125, 133, 171, 206, 220, 234, 239].

As Waring [269] reports, even though most patients say they are very satisfied, their response is most often qualified with a "but". As the years go by, our judgment of refractive surgery gets more and more critical. With the refinement of postoperative evaluation techniques, surgeons should learn to better detect discomfort and untoward effects. This should further contribute to their treatment and prevention.

6.2 OPTICAL QUALITY OF VISION

The theoretical objective of excimer laser photorefractive keratectomy is to enable the patient to see without glasses. Photoablation modifies the curvature of the cornea so as to change the refraction of central rays. However, this change in shape causes a loss of image precision. It was only recently that refractive surgeons started to realize that visual acuity under strong contrast and visual acuity under strong illumination, which have thus far been used as criteria of success, are not the best indicators of optical quality or vision in an operated eye [15, 267, 269]. Vision quality can be assessed in three ways: subjectively, according to the level of patient satisfaction; theoretically by modeling; and experimentally by direct objective or subjective measurements. The subjective assessment of patient satisfaction has contributed substantially to a better understanding of the notion of vision quality, but it is a subjective, multidimensional parameter that is too vast to be used alone to accurately and objectively determine the different facets of vision quality [32, 82, 88, 139, 184].

6.2.1 Theoretical estimates of an eye's optical quality

Some teams have attempted to model the effect of laser-assisted refractive surgery on the eye's optics, but these theoretical models have limitations. Some models consider a spherically shaped cornea [22, 224], even though a normal cornea is aspherical [140, 240, 242]. Other models are based on a tracing analysis of rays that pass through topographically determined, selected points on the corneal surface [143, 173, 180, 192, 201]. These models are limited by the accuracy of the topography system [132, 238] and by the fact that these predictions apply only to changes on the corneal surface [24]. They do

not provide an estimate of the optical quality of the entire eye, including the lens. At present, we know that the asphericity of the central surface changes [124], but there is no complete description of the corneal surface following refractive surgery that could serve as a basis for these models.

Theoretical models suggest that wider optical zone diameters for surgical ablation could lead to better preservation of the eye's optical quality [198, 224], with fewer patient complaints [117, 197].

6.2.2 Experimental measurements of vision quality

6.2.2.1 Measurement of optical aberrations

Thanks to the apparatus based on the Hartmann-Shack principle [42], it recently became possible to obtain an objective clinical measurement of all an eye's optical aberrations following excimer laser refractive surgery [40]. PRK and LASIK cause an increase in the operated eye's optical aberrations, and the greater the degree of preoperative myopia, the greater the increase. However, the increase is significant even with low myopia, which is consistent with a loss of corneal surface asphericity [124]. Aberrations increase with pupillary diameter, being at least 1.5 times greater than those of normal eyes with small pupils and at least 3.5 times greater in eyes with large pupils. Such changes were observed even with large ablation diameters of up to 7 mm.

6.2.2.2 Measurement of contrast sensitivity

There is an increasing number of studies showing a significant reduction in low-contrast acuity following PRK for the correction of myopia [38, 48, 99, 130, 163, 164, 199, 237, 255, 262]. This impairment is reportedly more pronounced and occurs earlier than the reduction in high-contrast acuity (Snellen charts), which is currently the reference measure when evaluating outcomes of this surgical procedure. It is observed with near and distant vision [127].

The reduction in contrast sensitivity can persist for at least 18 months after the operation [48]. It is proportionate to the initial degree of myopia and to pupillary dilation. It becomes worse under low illumination or in the presence of glare, topographic irregularities or subepithelial haze [48, 49, 50, 255, 262]. It is also correlated with the degree of ablation zone decentration [262]. It has been proposed that widening the ablation optical zone might result in a smaller reduction in postoperative contrast sensitivity [195].

Schallhorn et al showed, in United States Army personnel, that a prolonged reduction in night vision quality may occur after PRK and that it is proportionate to the decrease in low-contrast visual acuity [234]. Using a simulation system, they reportedly documented a decrease in post-PRK performance during nighttime driving. Katlun and Wiegand [138] showed that PRK can reduce contrast sensitivity to such a degree that the criteria for driving a car in Germany may not be met.

Contrast sensitivity is a sensitive and effective measurement technique that is very useful in evaluating the outcomes of refractive surgery [202]. A loss of low-contrast visual acuity has also been documented one year after PRK for hyperopia [130]. The reduction in contrast sensitivity after LASIK has yet to be investigated. Since the ablation diameter is limited by the LASIK flap diameter, it would be especially important to examine the effect of pupillary diameter in these patients.

6.2.2.3 Measurement of glare

Glare occurs when, on the retina, the image from a secondary and usually intense source, such as the sun or automobile headlights at night, encroaches on the image of the object the eye is

fixed on and reduces this image's contrast [25]. Patients who have undergone photorefractive surgery frequently complain of halos and glare [7, 26, 72, 93, 103, 116, 125, 133, 195, 196, 198, 199, 206, 220, 234, 239]. Different possible explanations for glare in such patients are provided in the literature: diffusion associated with the phenomenon of scarring (haze) [199], corneal surface irregularities [49, 187, 264], transition zone unevenness [77, 123], a spherically shaped paracentral cornea [242] and lastly, the refraction of light by the unoperated peripheral cornea near the fovea [224, 240, 242]. To the best of our knowledge, there are no experimental measures for determining the contribution of each of these causes.

6.2.2.4 Summary

The reduced optical quality of the eye following excimer laser photorefractive keratectomy is a problem, but the link between the clinical measurements, the cornea's new shape after the operation and the patient's symptoms has yet to be made. Not until this is done will it be possible to consider remedying or even preventing the effects of excimer laser refractive surgery on the optical quality of the eye.

7. INDICATIONS, CONTRAINDICATIONS AND CHOICE OF PROCEDURE

The clinical aspects discussed below are not the only ones, nor are they absolute, and they are likely to evolve in the more or less short term. Also, they are debatable. This discussion is a summary of what presently seems to be the most widely accepted, safest and the most satisfactory for the patient.

7.1 INDICATIONS FOR LASIK RATHER THAN PRK

The following factors warrant opting for LASIK over PRK:

- Problematic haze following PRK in the first eye
- The need for rapid rehabilitation
- Noncompliance with pharmacological treatment
- Ocular hypertonia due to steroid use

Although the incidence of clinically significant haze has decreased with improvements to surgical techniques, and although haze tends to diminish with time, this subepithelial stromal opacification is still one of the main drawbacks of PRK. In a study of 3,000 PRK cases, Alio [6] reports 17 cases of severe haze persisting at one year.

Noncompliance with drug therapy is a relative indication, since, although the risk of infection is lower and the duration of antibiotic treatment shorter with LASIK, the patient has to instill drops after LASIK, as is the case with PRK.

Ocular hypertonia due to steroid use is a relative indication as well. The efficacy of topical steroids on the outcome of PRK for mild and moderate myopia is still debated [97], and, more and more, surgeons are discontinuing the use of topical steroids beyond one week in these patients.

7.2 CONTRAINDICATIONS TO PRK AND LASIK

The following conditions are considered contraindications both to PRK and LASIK:

- History of herpes simplex eye infection
- Corneal ectasia
- Significant corneal thinning
- Rheumatoid arthritis
- Lupus erythematosus
- Patients with only one eye
- Exposure keratitis
- Neurotrophic keratitis (herpes zoster)
- Active inflammatory corneal disease

Several reports have documented the reactivation of a herpes simplex eye infection following excimer laser keratectomy, with keratitis, uveitis and, in one case, descemetocele, perforation and cataract, which can require an emergency triple operation [27, 221, 254]. It is therefore difficult to justify cosmetic excimer laser refractive keratectomy in a patient with a history of herpes simplex eye infection. Therapeutic intervention may nonetheless be medically necessary in certain cases of advanced corneal pathology. The ablation of superficial corneal scars or the correction of severe posttransplant astigmatism may enable a nonfunctional patient to rehabilitate and spare him another, higher-risk operation. Perioperative antiviral coverage is required in these patients.

Corneal ectasia, including keratoconus and pel-

lucid degeneration, and any significant corneal thinning are contraindications to PRK and especially to LASIK, since both of these procedures result in further corneal thinning. However, the case of keratoconus is still the subject of debate [14, 149, 190]. The hypothesis that there is an increased risk of iatrogenic keratectasia following LASIK or PRK requires further investigation [1, 53, 241].

Collagen diseases, specifically, rheumatoid arthritis and lupus erythematosus, are contraindications because of the increased risk of devastating spontaneous corneal ulceration in these patients and because of the little control that we have over this type of keratolysis once it has begun. At least one case of spontaneous perforation following PRK has been reported.

Certain types of work could be a contraindication to refractive surgery. For instance, the air traffic authorities and armed forces in several countries are presently examining the benefits and risks of allowing their personnel to undergo refractive surgery [75, 167, 170, 228, 234]. Currently, there is a tendency to advise waiting for advances to be made in the research and development of these surgical techniques.

7.3 CONTRAINDICATIONS TO LASIK

The following conditions are considered specific contraindications to LASIK:

- Flat corneas
- Small, enophthalmic eyes
- Prominent orbital ridges
- Significant ocular surface irregularities
- Dystrophy of the corneal epithelium basement membrane
- Post-radial keratectomy status
- Post-corneal transplant status

Flat corneas, small, enophthalmic eyes, prominent orbital ridges and significant ocular surface irregularities make it difficult or even impossible to install the suction ring and for the keratome to slide. It is the surgeon's responsibility to assess this risk.

Logically, if refractive surgery is warranted in a patient with corneal epithelium basement membrane dystrophy, PRK would be preferable to LASIK. One reason is that with LASIK, there is a risk of epithelial erosion around the wound and of epithelial ingrowth under the flap. The other reason is that surface photoablation is now considered a treatment of choice for this type of dystrophy when symptomatic [68, 84, 200].

LASIK performed on a cornea in which deep incisions have previously been made, as is the case with radial keratotomy (95% of the total corneal depth) or with a corneal transplant (100%), challenges the cornea's integrity. A number of cases of LASIK performed after radial keratotomy have been reported. As for corneal transplants, scarring is usually not homogeneous, and it is difficult to predict the effect and consequences of a lamellar keratectomy performed through a transplant wound.

7.4 CHOICE OF PROCEDURE

The above-mentioned contraindications aside, how does one choose between these two excimer laser refractive procedures? The decision to perform LASIK instead of PRK is the subject of debate, but the general principles that underlie the advantages, disadvantages and limitations of the two techniques can presently be summarized as follows.

7.4.1 PRK

Photorefractive keratectomy, or surface treatment, has enjoyed increasing popularity worldwide since 1989. It is a safe and effective tech-

nique 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 procedure is simple and does not require any special technical skill. The outcomes, as with any other type of refractive surgery, depend on the initial degree of myopia. They are quite predictable for mild myopia and slightly less so for moderate and severe myopia.

One of the drawbacks of PRK is that this operation necessarily and irreversibly involves the central cornea, the eye's optical zone. It does not affect accommodation. It is probably the procedure of choice in young patients with mild to moderate myopia. The cost is high, in general, being approximately $2,000 per eye in North America and now less in a number of clinics in Canada. This high cost is due to the high cost of the laser and its maintenance.

The rehabilitation time, the time needed for the patient to see well with the operated eye, is longer with PRK. In addition to the reepithelialization of the operated cornea requiring an average of three days, PRK tends to result in a slight initial overcorrection with temporary hyperopia that patients in their early 40s or older find bothersome. Most often, this initial overcorrection occurs after the correction of higher degrees of myopia. It can make the patient less functional for a variable length of time, usually ranging from a few days to, more rarely, a few weeks [222].

7.4.2 LASIK

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 generally reserved for moderate and higher degrees of myopia. The degree of myopia above which a person should not undergo LASIK is a matter of debate. For low myopia (less than -6.00 diopters), PRK, which is simpler, predictable and associated with fewer complications, is usually preferred to LASIK. For high myopia, LASIK is limited by the ablation diameter and the depth under the flap. LASIK is also limited technically by the complications and problems associated with the microkeratome. Unlike the central islands observed with PRK, those that occur in LASIK are less likely to regress with time.

The main advantage of LASIK over PRK is the rapid postoperative rehabilitation and the refractive stability. Outcome predictability is moderate to good (see tables in Appendix C) and should improve further with refinements to treatment algorithms and improvements to keratomes. This procedure is more expensive than PRK, i.e. about $2,100 to $2,400 per eye (sometimes less in Canada), because it also involves the use of the keratome. Another drawback is a steeper surgeon learning curve.

7.4.3 Simultaneous bilateral surgery

The question of simultaneous bilateral surgery is a controversial one [80, 104, 147, 271, 272]. In successful cases, simultaneous bilateral surgery is the quickest option for the patient and physician. It involves less operating time and fewer visits. It also eliminates the problem of anisometropia (difference in refractive power) between the operated eye and the unoperated eye.

However, complete rehabilitation of the operated eyes can take several days or even weeks, especially in the case of PRK or high myopia or if there is an overcorrection, an undercorrection or a complication. During this time, the patient is

unable to function. With just one eye operated on, he can still use the unoperated eye until the operated eye heals.

The extent to which the outcome for the first eye can influence the choice of treatment parameters for the second eye is still unclear. Presbyopic patients are among those who would benefit the most from such adjustments.

Lastly, in the rare cases of postoperative infection, the infectious agent is very likely to be transmitted to the other eye as long as the epithelium has not healed. Infections in refractive surgery are very rare, but when severe, they can lead to blindness.

Occasionally, some patients dissatisfied with the outcome choose not to have their other eye operated on. After bilateral surgery, this option is not available.

7.4.4 Costs: refractive surgery vs. contact lenses

In 1994, Javitt and Chiang [131] calculated that, from the patient's perspective, a cost of about $2,000 per eye for PRK was equivalent to that of using daily-wear soft contact lenses over a 10-year period and considerably less than that of using extended-wear soft contact lenses. Applying the calculations to a 20-year period, excimer laser PRK is much less expensive than the use of either daily-wear or extended-wear soft contact lenses. LASIK is a more expensive operation than PRK, with the result that it may take more time to reach the break-even point. However, there are fewer lost days of work following LASIK than PRK. Patients who pay reduced rates for their surgery will reach the break-even point even faster.

8. ALTERNATIVES AND FUTURE DEVELOPMENTS

8.1 LENS REMOVAL

If there is a cataract, the refractive surgery of choice is clearly crystalline lens removal and the insertion of an intraocular lens with the desired refractive power for correcting the patient's myopia or hyperopia.

If there are no cataracts, removing the clear lens is an option, but one must examine the benefits, risks and drawbacks.

From a refractive standpoint, this intervention yields a very high level of accuracy, being about ± 1 diopter in 90% of cases, and this for most of the formulae used for calculating the power of intraocular lenses. With the latest techniques involving phacoemulsification of the crystalline lens, soft lenses and small, self-sealing, sutureless incisions, refraction stabilizes very quickly after the procedure (a few days). This technique may be used for any degree of ametropia.

However, this is an invasive procedure. It necessarily involves a permanent loss of accommodative power, which has major consequences in patients under the age of 40, who have not yet reached the age of presbyopia.

The risks inherent in lens removal surgery must be taken into consideration as well. They include vitreal loss, dropped nucleus, infection, macular edema and retinal detachment. There is reportedly 1 chance in 1,000 of losing vision in the eye, this risk increasing with the degree of myopia.

Clear lens removal is performed in Québec. The cost is high because an operating room is required and because of the cost of the lens. Québec's public health insurance plan does not cover the costs associated with clear lens removal.

8.2 PHAKIC INTRAOCULAR LENSES

Phakic intraocular lenses are an option available in Québec, but to a limited degree. This technique is still experimental, and the future will reveal the role that it may eventually play. The technique consists in implanting a lens in the eye without removing the crystalline lens.

There are several types of lenses, and they have been investigated to varying degrees. Some models have had to be withdrawn from the market because of a significant problem with glare (*ZB5M, Chiron Vision Inc*.). Other models used in Europe, Asia and Africa are presently being evaluated in the United States (*Staar Surgical Co*.: phase 2; *International Vision Inc*.: phase 1 on blind eyes; *Ophtec BV*: phase 1, 10 unilateral operations on seeing eyes). *Staar Surgical Co*. just obtained authorization to begin Canadian trials.

In theory, these lenses should not affect accommodation. However, the posterior chamber models may press against the anterior surface of the crystalline lens and adversely affect accommodation. The safety of posterior chamber lenses as regards their potential cataractogenic effect, the stability of their position and the risk of injury to the blood-aqueous humor barrier has yet to be demonstrated. The choice of lens diameter is reportedly a problem as well, since it is not presently possible to accurately determine the diameter of the sulcus *in vivo*.

As for anterior chamber lenses, important solutions must still be found for the problems of intermittent contact with the corneal endothelium and the angle, ocular pain, pupillary deformation and glare. Phakic lenses are designed to remain in the eye—between the crystalline lens, iris and corneal endothelium—for several decades.

Lenses that are not angle-fixated but rather attached to the peripheral portion of the anterior surface of the iris (the Artisan™, manufactured by *Ophtec BV*) seem promising, although they are still in the experimental stage in Canada.

Phakic intraocular lens technology might eventually be used in high myopes who achieve suboptimal results with LASIK or PRK. It does not offer any advantages for individuals with cataracts who would require cataract surgery. Since, in presbyopic patients, there is no accommodation, lens removal might be preferable if refractive surgery is required.

8.3 OTHER TECHNOLOGICAL DEVELOPMENTS

Other technological developments are in the pipeline, including the intrastromal excimer laser, the picosecond laser, intracorneal rings, multifocal corneal ablations for presbyopia and individualized ablations using the excimer laser with topography or a system for analyzing the eye's optics. However, the immediate fate of these technologies and their role in the future are unclear. They will therefore not be examined any further in this report.

9. RESEARCH

9.1 AEROSOLIZATION OF VIRAL PARTICLES

Moreira et al [189] treated cell monolayers infected with herpes simplex virus and adenovirus with an excimer laser in order to mimic the corneal photoablation performed in patients with these viruses. They observed that, after the ablation, viral spread to adjacent sentinel dishes occurred with both viruses, with the likelihood of spread being proportionate to the titer of the virus in the infected cell monolayers and the location of the dishes in relation to the laser vacuum aspiration tube. They conclude that there is a risk of aerosolization of viral particles during corneal photoablation using a large-diameter laser beam, although they realize that this cannot be demonstrated with their methodology. They recommend that surgeons and other individuals present in the room during photoablation wear micropore masks as protection.

Hagen et al [110], also concerned about the risk of HIV and hepatitis virus transmission, ablated tissue culture plates infected with a virus similar in structure and life cycle to the human immunodeficiency virus and the herpes simplex virus. None of the 20 plates placed successively above the infected plates while they were being ablated was infected. The authors showed that even under conditions engineered to maximize the likelihood of transmission, the excimer laser ablation plume was incapable of transmitting this particular live virus. They conclude that excimer laser photoablation of a cornea of an HIV- or HSV-infected person does not pose a health hazard for the surgeon.

9.2 HISTOPATHOLOGY

Histopathologic studies have been conducted on eyes treated by LASIK in rabbits [13] and in humans [154, 155].

These studies showed less stromal disorganization after LASIK than PRK. The process involves the deeper stroma following LASIK. A loss of stromal keratocytes is observed with LASIK and PRK. Since most of the nerves are located in the anterior stroma, more nerve destruction occurs upon surface treatment with PRK. With LASIK, the nerves in the flap are partially destroyed, whereas those in the stroma under the flap are more or less preserved. Epithelial nerve regeneration occurs 1.5 to 4 months after LASIK.

After LASIK, one does not observe the epithelial hyperplasia that occurs below the refractive zone after PRK. The epithelial abnormalities involve instead the edge of the incision made by the keratome. An epithelial plug of 100 to 300 microns forms temporarily under the flap margins, then resolves spontaneously with time.

9.3 ENDOTHELIUM

The endothelium is a monolayer of fragile cells on the posterior surface of the cornea, whose transparency it controls. Endothelium cells do not regenerate. A human being is born with 3,500 endothelial cells per mm^2, then gradually loses them over his lifetime at the rate of 0.3% per year [12, 56, 278]. Below a density of 500 cells per mm^2, control of corneal hydration is no longer ensured [31], and the cornea becomes edematous and opacifies irreversibly [142], which can result in blindness.

Excimer laser photoablation, especially in LASIK, often approaches up to 250 microns of the endothelium and could damage it, whether the assault is of phototoxic, photochemical or acoustic origin. There have been several divergent reports concerning the effect of the excimer laser on the corneal endothelium [11, 44, 128, 176, 194, 209, 211, 212, 226, 227, 249, 251, 256], with some studies reporting cell losses of up to 8.5 to 10.6% [208], others reporting an in-

crease in cell density counts of about 3.5% [211, 212] to 7% [259] in relation to preoperative values. Yet endothelium cells do not multiply *in vivo*.

One interesting explanation for this apparent increase in cell density is that proposed by Trocme. During prolonged contact lens wear, endothelial cells tend to migrate toward the periphery of the cornea. After the discontinuation of contact lens wear following surgery, these cells apparently return toward the centre of the cornea, where specular microscopy is usually performed [165, 259].

Another explanation for this apparent increase in central cell density is that there is a change in the magnification of the specular microscope induced by the corneal thinning and the change in corneal curvature due to the refractive surgery. There used to be a correction factor for the specular microscope [30], but it was only more recently that new equations were proposed for the non-contact specular microscope [41].

Lastly, no study has yet described the long-term effect of this surgery on the endothelium. It will be recalled that an operated cornea is thinned and that the amount of ultraviolet (UV) radiation reaching the corneal endothelium is probably greater after the operation. It is also known that there is a correlation between the ambient UV level and the occurrence of polymegathism (increase in the coefficient of variation of the cell surface) and pleomorphism (increase in cell form diversity) in the corneal endothelium [107, 137]. This is one more reason for monitoring the long-term effects of excimer laser photorefractive keratectomy.

9.4 CATARACTS

Costagliola et al [63, 64, 65] reported an increase in the oxidation level in the aqueous humor and lens immediately after excimer laser photorefractive keratectomy. They reported 1) an increase in the peroxide level in the aqueous humor; 2) an increase in the level of malondialdehyde (an indicator of lipid peroxidation) in the lens; 3) an increase in the oxidized glutathione level in the aqueous humor and lens; and 4) a decrease in the level of ascorbic acid (an antioxidant) in the aqueous humor.

These findings are disquieting because the biochemical modifications described are markers of cataractogenesis. However, the assay method used by Costagliola's team was criticized in two articles [29, 92], and after improving the method, no increase in the oxidation level in the anterior segment was observed after excimer laser corneal photoablation [100]. Presently, there is no indication that the radiation used in excimer laser photoablation can cause damage to the lens.

9.5 HORMONE STATUS

A few studies seem to indicate that pregnancy has an effect on wound healing after PRK [182, 248, 253]. Corbett et al [62] report a risk of regression 13.5 times higher in women taking oral contraceptives. The administration of hormone replacement therapy during menopause might also reduce the effectiveness of PRK. However, these preliminary results are debatable [119] and need to be confirmed.

9.6 ULTRAVIOLET RADIATION

Exposure to ultraviolet radiation, specifically UV-B, during the first year after excimer laser refractive surgery might increase the risk of regression and haze [62, 194]. This is why a number of clinics in Québec systematically give patients a pair of tinted glasses on the day of surgery.

9.7 INTRAOCULAR PRESSURE

The intraocular pressure may appear artificially low after photorefractive keratectomy when measured by Goldman tonometry. This decrease

is reportedly about 0.5 to 3.1 mm Hg [3, 52, 86, 177, 225].

Measurements taken at the centre of the cornea are reportedly lower than the values obtained temporally [3, 235]. Apparently, this reduction is strongly correlated with the degree of myopia treated [52] and the degree of corneal thinning [193] and is more pronounced in older patients [86].

The proposed hypotheses are central corneal thinning, the absence of Bowman's membrane and topographical changes [52]. According to a study involving rabbits with control by intraocular manometry but not Goldman tonometry, pneumotonometry measures the intraocular pressure reliably both on the central and peripheral corneas [3, 260].

These observations are important because myopia is a known risk factor for developing glaucoma. Also, myopes are at greater risk for developing intraocular hypertonia due to the use of topical steroids, and, after PRK, patients may sometimes receive topical steroids for several months.

9.8 CONTACT LENSES

An over- or undercorrection or regular astigmatism after PRK can be adjusted with soft or rigid gas-permeable contact lenses [20, 236]. However, some of these patients can no longer tolerate contact lenses. In general, when it is just a simple undercorrection, patients are usually retreated. To the best of our knowledge, there are no published studies on the adjustment and tolerance of contact lenses after LASIK. Preoperative contact lens wear does not seem to affect postoperative wound healing [62].

9.9 BIOMETRY

Some patients who underwent excimer laser photorefractive keratectomy for myopia during the first few years have now reached cataract age, which has generated a new type of problem—that of calculating intraocular lens power [134, 169, 243, 252]. Keratometry underestimates corneal flattening due to excimer laser refractive surgery. This results in an underestimate of the lens power and postoperative hyperopia. A small-diameter optical zone, the correction of a high degree of myopia and low keratometry values are three factors that could affect these measurements. The best way to calculate corneal power in these patients has yet to be determined.

10. DIFFUSION AND QUÉBEC PRACTICE

10.1 DIFFUSION

At the time this report was being prepared, there were 15 laser centres in Québec: 7 in Montréal, 3 in Québec City, 2 in Sherbrooke, 1 in Chicoutimi, 1 in Hull and 1 in Trois-Rivières. All the lasers in question are privately owned, except for the one at Montreal General Hospital (McGill University Health Centre) and that at Hôpital Maisonneuve-Rosemont. The laser at Hôpital Notre-Dame (Centre hospitalier universitaire de Montréal) is privately owned by ophthalmologists in university hospital practice. The excimer lasers used in Québec are the *VISX 20/20*, the *Technolas 116*, *117* and *217*, the *NIDEK EC-500*, the *Meditec Mel 60*, the *Schwind*, the *Laser Sight* and the *Autonomus*. The keratomes used are the *Chiron ALK*, *Phoenix Keratec*, *Moria* and *Technolas*.

10.2 APPROVAL OF INSTRUMENTS

A list of the instruments whose use has been approved by Health Canada's Bureau of Medical Devices is provided in Table 2. It is important to note that, to date, most devices have been officially approved only for experimental use. Only the *VISX 20/20 Excimer Laser System* (or its more recent version, *VISX Excimer Laser Model C*) and *Summit Technologies*' *SVX Apex* have been approved for unrestricted sale.

10.3 COST OF PROCEDURES

Up until December 1998, the average cost of an operation for the patient was $2,000 to $2,400. PRK generally cost $2,000, LASIK between $2,000 and $2,400.

In December 1998, a price war started in Montréal, then quickly spread to the rest of the province. The average cost of LASIK surgery for the patient dropped dramatically, then went back up and stabilized at around $1,000 per eye, these prices being adjusted upward according to the degree of myopia or astigmatism. A refractive surgery clinic's expenses are very high. They include the cost of the laser (about half a million dollars), its maintenance ($60,000 to $100,000 per year), the purchase of keratomes (about $100,000 each), all the sophisticated equipment needed for evaluating patients, and the cost of maintaining the clinic's various activities. Furthermore, the laser has to be replaced on a regular basis in order to keep up with the very rapidly evolving technology. Since these expenses could hardly be reduced, the only way to make this up was to increase patient volume. Thus, there was a significant increase in public advertising and an increase in the number of delegated procedures, with the physician spending less and less time with his patient. We expect that this mode of operation will favour high-volume clinics at the expense of smaller clinics. It is reasonable to suspect that the price war will probably not benefit the patient or the physician.

10.4 NUMBER OF PROCEDURES

It is difficult to determine the number of excimer laser refractive surgeries performed annually in Québec. One survey estimates the number at about 25,000 per year. The number of ophthalmologists who perform refractive surgery is increasing year by year, and the number of ophthalmologists who have performed PRK is still higher than those who perform LASIK. Most operations are for correcting myopia with or without astigmatism. Over the past few years, certain centres have begun to perform other procedures, namely, the correction of hyperopia, clear lens removal with mono- or multifocal lens insertion, and the insertion of an intraocular lens in a phakic eye.

Table 2: Instruments whose use has been approved by Canada's Bureau of Medical Devices

RESTRICTED SALE (FOR EXPERIMENTAL PURPOSES ONLY)	
MANUFACTURER	**MODEL**
Herbert Schwind GmbH and Co.	Keratom Excimer Laser
Aesculap-Meditec	Meditec MEL-60 Excimer Laser
Autonomous Technologies	T-PRK Scanning Excimer Laser T-PRK/T-LASIK Scanning Excimer Laser
Chiron Vision Corporation	Keracor 116 Excimer Laser
LaserSight Technologies, Inc.	Compak-200 MiniExcimer Laser Laser Scan 2000
Nidek	Nidek EC-5000 Laser Corneal Surgery System
Novatec Laser Systems, Inc.	Novatec Light Blade Work Station
UNRESTRICTED SALE	
MANUFACTURER	**MODEL**
Summit Technologies	SVS Apex SVS Apex Plus (Apogee)
VISX, Inc.	VISX 20/20 Excimer Laser System VISX Excimer Laser Model C (STAR)

10.5 RESEARCH AND ASSESSMENTS EFFORTS

The outcomes and the exact complication rate of refractive surgery in Québec are unknown. Although Québec has one of the most developed excimer laser refractive surgery markets, with a high volume of LASIK surgeries, very few results have been published in peer-reviewed scientific journals.

In 1995, a vision health network was set up in Québec as part of a Fonds de la recherche en santé du Québec program. One of its main research activities is the assessment of new technologies. Laser-assisted refractive surgery is one of the technologies being examined by this group of ophthalmologists, vision researchers, physicists and engineers. They have set up a database on the refractive surgeries performed at Hôpital Maisonneuve-Rosemont and Hôpital Notre-Dame (CHUM), and they plan to extend the database to other Québec hospitals.

The interface between this research group, ophthalmologists at private clinics and policymakers in the health-care system remains to be devel-

oped. Because of their expertise and under *An Act respecting health and social services*, university hospitals are in a good position to play that role. One of the problems that will have to be overcome is to make new technologies readily accessible to these researchers so that they can assess them in a timely fashion, before they are diffused too widely.

11. RECAP AND DISCUSSION

11.1 PRK

Photorefractive keratectomy 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 refractive surgery, depend on the initial degree of myopia. They are quite predictable for mild myopia, slightly less so for moderate myopia and much less so for severe myopia.

PRK has certain drawbacks. One 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.

This procedure does not affect accomodation. 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 purchase cost of the laser and the cost of maintaining it.

11.2 LASIK

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 myopia. For low myopia, (less than -6.00 diopters), PRK, which is simpler, predictable and associated with fewer complications, may be 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. 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. This procedure 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.

11.3 HYPEROPIA

As for the correction of hyperopia, refractive surgery has evolved favourably over the past few years, but it is still difficult to determine what the current state of knowledge is regarding this subject, since very little literature is available on it. According to the results of the few studies identified, the LASIK technique seems to be more effective than PRK in correcting hyperopia. However, LASIK is less accurate in correcting hyperopia than it is in correcting myopia.

11.4 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 listed in this report is three to five years for PRK [180] and two years for LASIK. Before one can render a verdict 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 [171]. If they have not already done so, the refractive surgery centres presently in operation in Québec should take the necessary steps to document any complications in the medium and long terms.

In this regard, CETS agrees with what the *Comité d'évaluation et de diffusion des innovations technologiques (CEDIT)* of the Assistance Publique - Hôpitaux de Paris states in its latest report on the excimer laser, published in December 1997 [58]. In response to a request from a hospital, CEDIT recommended purchasing an excimer laser for the treatment of low and moderate myopia. In connection with these indications, CEDIT recommends instituting a patient register that would, insofar as possible, make it possible to assess the long-term outcomes of this technology. CEDIT also concludes that the hospital that made the request should take part in evaluating the treatment for disorders for which laser treatment has yet to be validated, specifically, high myopia and hyperopia.

11.5 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 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 considerably 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 to refine the parameters for assessing medium- and long-term patient satisfaction.

11.6 STATUS OF THE TECHNOLOGY

PRK and LASIK for mild and moderate myopia can now be considered accepted technologies[1], although there is a lack of long-term follow-up. To maintain and improve the level of safety, the conditions governing the use of this technology should be an integral part of a clinical risk management program or a quality management program, especially since this technology is 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 technology.

LASIK for the correction of severe myopia or moderate and severe hyperopia is still an innovative technology[2].

[1] *Accepted technology* here refers to "a well-established technology for which there is a long history of use and a knowledge of, or failing that, universal acceptance of, its effectiveness in all its applications." [61]

[2] *Innovative technology* here refers to "a technology which has passed the experimental stage and whose effectiveness has been established. However, because of a lack of experience, certain indications for its use and various aspects of its application are not yet clearly defined. To gain further knowledge of such technology, it would be important to gather systematically all the information acquired from its utilization and to communicate it to the medical community in the form of a clinical research report or systematic review or to an appropriate registry. To further these objectives and to prevent its premature widespread use, such technology should be restricted to certain authorized university hospitals which have the necessary resources and knowledge." [61]

Lastly, even though it is not discussed in detail in this report, it would be useful to mention that the insertion of phakic intraocular lenses or intracorneal rings is still considered an experimental[3] technology. Nonetheless, this technology is presently gaining in popularity among surgeons and the public.

11.7 REGULATING THE DIFFUSION OF THIS TECHNOLOGY

What was said in the previous *CETS* 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 only four models of instruments officially available 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 "innovative"—an irreversible quality.

Prudence is required. 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 adverse effects and complications [268].

Listed here are a number of refractive surgery procedures whose use spread too quickly, in the United States and elsewhere, before they were properly assessed and which had to be withdrawn from the market because of too many complications:

- The first models of anterior-chamber intraocular lenses with or without iris fixation
- Hexagonal keratotomy for the correction of hyperopia
- Myopic epikeratoplasty
- Automated lamellar keratoplasty (ALK)
- Connected trapezoidal keratotomy for the correction of astigmatism
- High-vaulted Baikoff phakic anterior-chamber intraocular lenses for myopia
- Deep lamellar keratotomy for hyperopia (hyperopic ALK)
- Fyodorov hot-needle radial thermokeratoplasty
- Radial keratotomy with small-diameter optical zones

Since *CETS's* first report, the practice has also evolved considerably in Québec and Canada:

- The use of small ablation diameters, of about 4.5 or 5 mm, for the correction of myopia by excimer laser has been discontinued. They resulted in too much haze, with regression and a reduction in optical quality.
- Also, it was realized that neither PRK nor LASIK yielded good results in very high myopes. Currently, the trend is not to use these techniques in such patients, hence the craze for another new technology, phakic intraocular lenses.

To avoid the situation where too many surgeons have operated on too many patients before the risks and benefits have been identified, high-volume surgeons should publish their results in peer-reviewed journals. This would be particularly useful in Québec, where the refractive surgery market is highly developed. Because of their large number of patients, these surgeons are in the best position to document the natural evolution and complications of a procedure in which

[3] *Experimental technology* here refers to "a procedure whose effectiveness has yet to be established. Such a procedure should therefore not be used in health-care facilities, except in the context of research projects." [61]

a new technology is used. Their publications would speed up their less experienced colleagues' learning curve and the transfer of technical developments and result in fewer patients experiencing complications. However, most private clinics do not have access to the expertise in epidemiology, public health, statistics, etc. needed to develop research protocols and analyze large research databases. It would be desirable to facilitate their access to such expertise.

Lastly, the juxtaposition of the notions of business and health care, as found in refractive surgery, is not something which Québec society is used to in medicine. This situation invites caution [171, 205, 268].

11.8 OBLIGATION TO INFORM THE PATIENT

The overwhelming majority of refractive surgeries are not medically required. Esthetics, comfort and practical considerations are the chief motivations for refractive surgery, since effective correction can be achieved by wearing glasses or contact lenses. In this regard, *CETS* recommends that careful attention be given to the obligation to inform the patient. This obligation should be fulfilled "with utmost rigour and include the rare and even extremely rare and benign risks" [58] .

12. CONCLUSION

The purpose of this report was to provide an update on the scientific knowledge concerning the efficacy and safety of excimer laser photorefractive keratectomy for the correction of myopia (with or without astigmatism) and hyperopia. The discussion concerned both the "traditional" approach, PRK, and a more recent approach, LASIK.

From its systematic analysis of the scientific literature published between 1995 and October 1999, *CETS* concludes that PRK and LASIK can now be considered "accepted" technologies for the treatment of mild and moderate myopia, although there is a lack of long-term follow-up. Also, LASIK can be considered an "innovative" technology for the correction of severe myopia and of hyperopia. The treatment of these conditions by LASIK therefore requires tighter control to prevent premature widespread use.

Although it did not provide a systematic assessment of them, the report did mention other alternatives and future developments concerning vision correction, such as lens removal, phakic intraocular lenses and intracorneal rings. These technologies are still considered "experimental" and, as such, should be made available to patients only in the context of a research project.

The extremely rapid pace at which refractive surgery is being diffused in Québec, together with the out-of-hospital context in which such surgery is performed, invites caution. Thus, *CETS* recommends that the refractive surgery centres presently in operation in Québec should, if they have not already done so, take the necessary steps to document, in the medium and long terms, any adverse effects or complications experienced by their patients. In concrete terms, this type of research should be conducted with the collaboration of experts in epidemiology, statistics and public health and lead to publications in peer-reviewed scientific journals.

For now, the literature reveals that the untoward effects reported most often following treatment by PRK or LASIK are problems with the eye's optical quality. Light halos and glare occur in nearly a third of patients and can sometimes be very incapacitating. However, these problems diminish with time and do not prevent more than 90% of patients from stating that they are "satisfied" or "very satisfied" with their operation. Research is needed to remedy or even prevent this reduction in the eye's optical quality following excimer laser refractive surgery.

CETS wishes to reiterate the fact that treating myopia by photorefractive keratectomy seldom constitutes a medical necessity. Unlike the "optical" alternatives, such as glasses and contact lenses, photorefractive keratectomy is an irreversible procedure whose long-term effects and impact on vision quality are unknown. *CETS* acknowledges that wearing glasses and 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 this intervention is not 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.

Experience with excimer laser photorefractive keratectomy in Québec has revealed the difficulties encountered when evaluating a new technology in a timely fashion, especially when it is being used almost exclusively in a commercial context, as is the case with PRK and LASIK in Québec. The high demand for a technology that

offers benefits perceived as real and significant by a large number of people willing to pay, the availability of service providers who are naturally willing to meet this demand, the absence of a third-party payer, all combined with the absence of a formal mechanism for assessing technologies and monitoring them on a long-term basis, have contributed to creating an environment conducive to the explosion of this technology, although we still know little about its actual efficacy and safety.

A new technology should be subjected to a systematic clinical-assessment process before it is diffused on a wider scale, when it is still innovative or experimental. In addition, given the constant and rapid technological changes that most technologies are undergoing, and this certainly includes refractive surgical procedures, it would be essential to continue systematically gathering all the data arising from the use of the technology and to communicate them to the medical community, whether as a clinical research report, systematic review or an appropriate register.

Such projects are difficult because of the lack of interaction between the main players. In the case of refractive surgery, we are specifically referring to policymakers in the health-care system, ophthalmologists who perform the procedures, ophthalmologists in clinics and experts in clinical research.

Because of their expertise and the health technology assessment mandate given to them under *An Act respecting health and social services*, university hospitals are in a good position to serve as the interface between all of these groups, but steps must be taken to ensure they have access to the advanced technologies that one wishes to assess.

APPENDIX A: THE EXCIMER LASER

Appendix A: The excimer laser

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Excerpt from the *CETS* report entitled:
***Excimer laser photorefractive keratectomy: The correction of myopia and astigmatism* (December 1997)** [60]

The acronym LASER stands for *Light Amplification by Stimulated Emission of Radiation*. A laser essentially consists of a cavity containing a lasing medium (solid, liquid or gas) activated by an energy source (electricity, light, chemical reaction, etc.). The electrons in the molecules of the lasing medium are activated by the energy source. This energy is released in the form of light. Laser cavities are equipped with completely and partially reflective mirrors between which the light emitted by the excited electrons travels. The design of the cavity is precision-calculated so that the emitted light (laser) possesses specific characteristics. The characteristics sought for developing medical lasers are mainly brightness (light intensity), coherence (property whereby the light wave varies in a regular and predictable manner in time and space) and monochromaticity (a single colour).

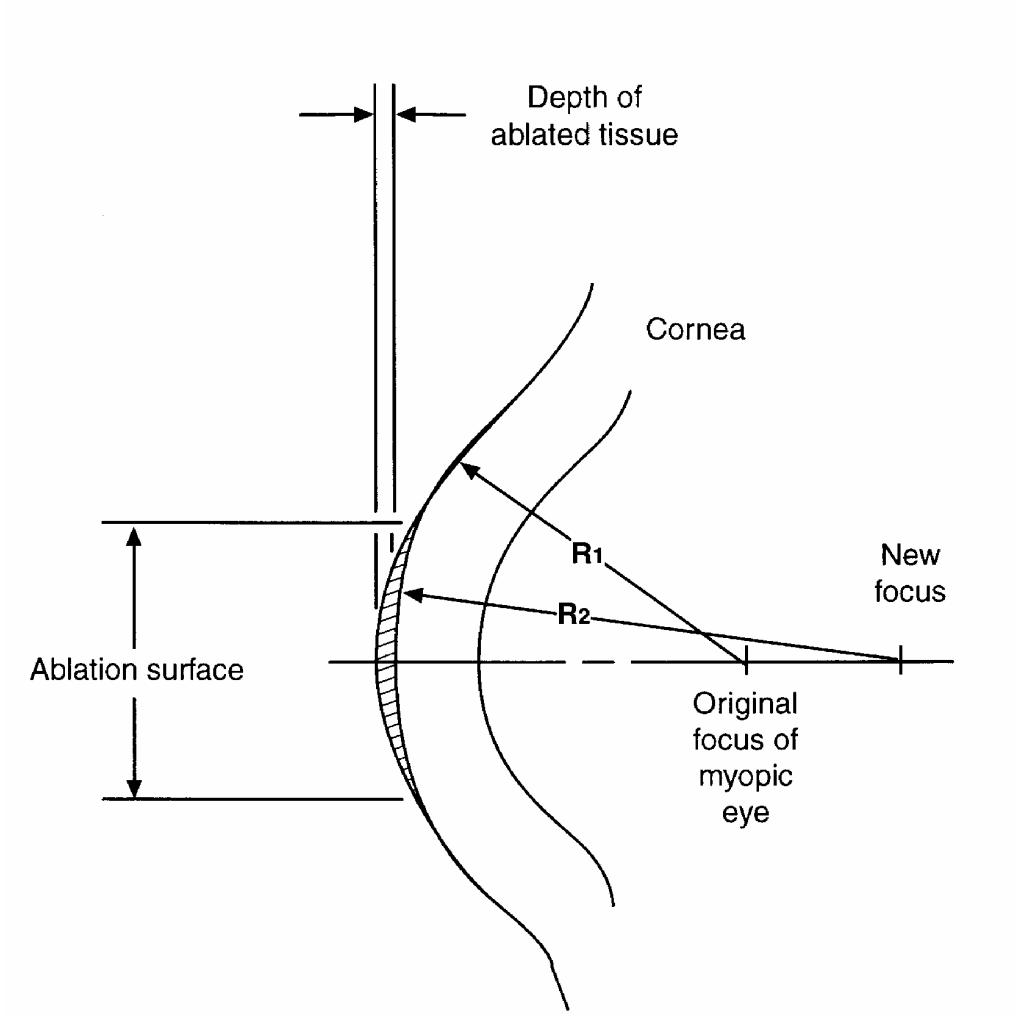
In some types of lasers, such as CO_2 and argon lasers, the interactions between the laser beam and tissues is based mainly on the absorption of energy from the beam by the tissues, which are then destroyed by heat. With the monochromaticity of lasers, the surgeon can choose the wavelengths (or colour) than can go through certain tissues without damaging them, to selectively reach other tissues.

Other lasers are used because of their ability to concentrate such a high energy density at a given point that the tissue fragments by microexplosion (e.g. the Nd-YAG laser).

The excimer laser, developed in the early 80's, was first used to etch integrated circuits. The most useful excimers emit a beam of ultraviolet light that has so much energy that it can break chemical bonds between molecules without generating significant amounts of heat (hence the more or less correct expression "cold laser"). In human tissues, these characteristics permit extremely precise excision. Layers sometimes 100 times thinner than a single cell can thus be removed.

In refractive surgery, the surgeon scans the corneal surface with a laser beam of ultraviolet light to "sculpt" in the cornea a lens that will correct the eye's refractive error.

Figure A.1: Diagram of the effect of the excimer laser in the treatment of myopia by photorefractive keratectomy



APPENDIX B: TREATMENT BY PRK: THE STEPS INVOLVED

Appendix B: Treatment by PRK: The steps involved

APPENDIX B: TREATMENT BY PRK: THE STEPS INVOLVED

Excerpt from the *CETS* report entitled
***Excimer laser photorefractive keratectomy: The correction of myopia and astigmatism* (December 1997)** [60]

Patient selection

PRK is usually an option for individuals who have never had eye surgery. Patients are chosen on the basis of different criteria, such as age and the absence of certain pathologies that could adversely affect the prognosis. It can sometimes also be used in patients who have undergone radial keratectomy in the past with unsatisfactory results or to correct ametropia caused by intraocular surgery, such as cataract extraction or a corneal graft. We will not discuss these other, very specific applications of PRK in this technology brief.

Preoperative examination

The preoperative examination is performed after the patient has not worn contact lenses for a specific length of time, which is shorter (1 to 14 days) for soft lenses than for hard or gas-permeable lenses (sometimes more than two weeks). The refraction and the corneal curvature measurements must be stable.

There are several parts to the preoperative examination. Visual acuity is measured with and without correction. Refraction is performed to measure the degree of myopia and astigmatism and the axis of astigmatism. A slit-lamp examination is carried out to determine if there is any corneal pathology. The transparency of the lens is noted. The intraocular pressure measurement will serve as a point of comparison for postoperative measurements in patients with elevated pressure following the use of topical steroids. An optic fundus examination is performed to identify any retinal degeneration, which is more common in myopes, and corneal topography is performed to obtain an accurate view of all the corneal curves. It can also be used to diagnose pathologic changes in corneal curvature, such as keratoconus (the cornea gradually becomes conelike in shape), which are contraindications to laser surgery. If the pupil diameter is greater than 6 mm, the patient should be advised of the possibility of glare after PRK, especially when driving at night.

Surgical procedure

The procedure is relatively standardized, with, on the whole, few variations specific to any one surgeon. The *Collège des médecins du Québec* states that, exceptional cases aside, only one eye should be operated on at a time. The procedure is performed under topical anesthesia. A retractor holds the eyelids, and to facilitate fixation of the operative eye, the contralateral eye is occluded. First, the epithelium is removed, which can be done entirely by hand or entirely by laser. There is also a combined technique, which consists of laser pretreatment to a depth of 45 microns (the thickness of the epithelium) over a diameter slightly greater than or equal to that of the treatment zone, after which the residual epithelial debris is delicately swept away with a blade.

The keratectomy per se consists in ablating a certain quantity of tissue to a depth of a few microns in the stroma. The photoablation is centred on the physiologic pupil , i.e. neither dilated nor contracted by a drug. This centration requires the cooperation of the patient, who must maintain

constant fixation without eye movements. The specific treatment parameters, such as the shape of the ablation, its depth and its diameter, are determined by a computer program integrated into the laser. The treatment lasts only a few seconds, after which a contact lens, together with a drop of an antibiotic and a drop of a nonsteroidal antiinflammatory, is usually placed on the eye.

Postsurgical follow-up

The patient is then seen daily until there is complete closure of the epithelial wound, or usually for two to five days, after which the contact lens is removed.

The antibiotic and nonsteroidal antiinflammatory are continued at the rate of two to four times a day until there is complete reepithelialization. They are then replaced with a corticosteroid at the rate of one drop one to four times daily for several weeks.

Usually, there is considerable improvement in vision within a few weeks. Overcorrection is frequent shortly after the operation. It gradually subsides, the eye subsequently stabilizing at its final level of correction. The stabilization takes 3 to 18 months or even longer, depending on the degree of myopia. With the new generations of excimer laser and the new software programs available, the length of the postoperative recovery period can be reduced. However, it is too early for us to evaluate these new instruments.

Time Between Treatment of the Two Eyes

It is generally recommended that one wait a few months before treating the other eye, the length of time varying according to the degree of myopia and the patient's response. In the interval after treatment of the first eye, during which there is an imbalance between the eyes, a patient able to wear a contact lens in the yet-untreated eye will achieve more comfortable vision. If the patient does not tolerate contact lenses, the interval between the two operations can be shortened, especially for patients with high myopia, as a difference greater than three diopters between the two eyes is intolerable.

APPENDIX C: SYNOPTIC TABLES ON STUDIES OF THE EFFICACY OF PRK AND LASIK

Appendix C: Synoptic tables on studies of the efficacy of PRK and LASIK

Table C.1: Results of corrections of mild myopia (up to –6.00 D) by PRK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Montes, 1999 [188]	-1.50 to –6.00	6 months	168	± 0.50 D: 94% ± 1.00 D: 100%	2 lines: 0% 1 line: 1.2%	100%	81%
McDonald, 1999 [183]	-1.00 to –5.99	12 months	318	± 0.50 D: 76% ± 1.00 D: 94%	2%	98%	72%
Wee, 1999 [274]	-1.00 to –6.00	6 months	296	74%	0.4%	93%	-
Alio, 1998 [6]	≤ -0.60	1-2 years	937	*At 1 year* (n=475) ± 1.00 D: 95% *At 2 years* (n=135) ± 1.00 D: 100%			
Ozdamar, 1998 [204]	-3.53 ± 1.13 (-2.25 to –6.00) astigm. < 1.00	24 months	20	± 0.50 D: 80% ± 1.00 D: 90%	5%	95%	55%
Matta, 1998 [181]	-1.25 to -6.25 -2.00 to -6.25	3 years 5 years	106 30	± 0.50 D: 45% ± 1.00 D: 70% ± 0.50 D: 37% ± 1.00 D: 53%	- -	80% 67%	50% 30%
Pietilä, 1998 [215]	-1.25 to -6.00 (-4.10 ± 1.20)	1 year	226	± 0.50 D: 68% ± 1.00 D: 87%	Loss ≥ 2 L: 1% Loss of 1 L: 8 % Unchanged: 72% Gain of 1 L: 17% Gain ≥ 2 L: 2%	48%	40%
Shah, 1998 [246]	-1.00 to -7.60	6 months	226	90%	3%	96%	52%
Tuunanen, 1998 [261]	-1.50 to -6.00 (-4.28 ± 1.29)	12-24 months	52	*At 12 months* ± 0.50 D: 58% ± 1.00 D: 87%	Loss ≥ 2: 6% Gain ≥ 2: 4%	*At 12 months*: 87% (excluding corrections of astigmatism)	*At 12 months*: 56% (excluding corrections of astigmatism)
Langrova, 1997 [153]	-3.00 to –6.00	6 months	45	74%	0%	93%	54%
Carones, 1996 [43]	-4.50±2.50 (single pass) -4.98±2.17 (multipass) -5.03±1.98 (multizone)	6 months	25 25 25	52% 54% 68%	0%	92% 88% > 96%	6/7.5: 80% 79% 96%

Table C.1 (Cont'd): Results of corrections of mild myopia (up to -6.00 D) by PRK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Kalski, 1996 [135]	-1.00 to -6.00 optical zone: 5 mm 6 mm	6 months	 34 32	 85% 100%	 0 0	 94% 100%	 71% 81%
Kwitko, 1996 [151]	-1.00 to -6.00	1 year	106	-	-	96%	-
Rao, 1996 [221]	<-6.00 -4.60 ± 0.91	6-22 months	35	89%	3%	94%	-
Schallhorn, 1996 [234]	-2.00 to -5.50 (-3.35 ± 1.07)	1 year	30	93%	0%	100%	100%
Shah, 1996 [247]	-1.50 to -6.00 (-4.99 ± 1.43)	6 months	45	± 0.50 D: 62% ± 1.00 D: 84%	Loss ≥ 2 L: 0% Loss of 1 L: 24 % Unchanged: 53% Gain of 1 L: 20% Gain ≥ 2 L: 2%	100%	62%
Tabin, 1996 [258]	-5.00 and less	1 year	105	88%	-	94%	61%
Vidaurri-Leal, 1996 [263]	-1.00 to -6.00 (-3.61 ± 1.14)	6 months	76	81%	0%	94%	55%
Amano, 1995 [10]	 -2.00 to -3.00 -3.01 to -6.00	 2 years 2 years	 11 28	± 0.50 D ± 1.00 D 91% 100% 50% 75%	-	-	-
Hamberg-Nyström, 1995 [114]	-1.50 to -6.00	9 months	23	-	-	91%	-
Kim, 1995 [141]	-2.00 to -6.00	3 years	35	60%	-	100%	6/7.5: 83%
Pop, 1995 [217]	-1.00 to -6.00 (-4.44 ± 1.21)	6 months	170	± 0.50 D: 82% ± 1.00 D: 94%	Loss ≥ 2 L: 1% Loss of 1 L: 4 % Unchanged: 82% Gain of 1 L: 13% Gain ≥ 2 L: 1%	98%	6/7.5: 89%

Table C.2: .Results of corrections of moderate myopia (-6.00 to -10.00 D) by PRK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
McDonald, 1999 [183]	-6.00 to -10.00	12 months	121	± 0.50 D: 67% ± 1.00 D: 88%	2%	93%	61%
Lipshitz, 1999 [160]	Summit -2.50 to -8.75 Nidek -2.50 to -8.80	12 months	30 30	± 0.50 D: 73% ± 1.00 D: 97% ± 0.50 D: 80% ± 1.00 D: 87%	- -	95% 95%	47% 53%
Hadden, 1999 [109]	-6.00 to -10.00	6 months	192	± 0.50 D: 77% ± 1.00 D: 94%	1%	94%	60%
Alio, 1998 [6]	-6.25 to -10.00	1-2 years	327	± 1.00 D *At 1 year*: 91% (n=195) *At 2 years*: 100% (n=44)	-	-	-
Pietilä, 1998 [215]	-6.10 to -10.00 (-7.80 ± 1.10)	1 year	104	± 0.50 D: 29% ± 1.00 D: 43%	Loss ≥ 2 L: 5% Loss of 1 L: 11% Unchanged: 51% Gain of 1 L: 25% Gain ≥ 2 L: 8%	47%	5%
Tuunanen, 1998 [261]	Intended correction -6.10 to -8.00 (-7.04 ± 0.7)	1-2 years	34	*At 12 months*: ± 0.50 D: 50% ± 1.00 D: 79% *At 24 months*: ± 0.50 D: 47% ± 1.00 D: 71%	Loss ≥ 2 L: 9% Gain ≥ 2 L: 6%	*At 12 months*: 71% (excluding corrections of astigmatism) *At 24 months*: 71 %	*At 12 months*: 30% (excluding corrections of astigmatism) *At 24 months*: 35% (n=16)
Williams, 1997 [274]	-6.00 to -10.00 (-7.54 ± 1.29)	2 years	26	± 0.50 D: 65% ± 1.00 D: 77%	Loss ≥ 2 L: 12% Loss of 1 L: 31% Unchanged: 46% Gain ≥ 1 L: 12%	89%	31%
Brancato, 1996 [33]	-1.50 to -10.00 (-7.07)	1 year	21	50%	0%	40%	-
Kwitcko, 1996 [151]	-6.00 to -10.00	1 year	52	-	-	69%	-

Table C.2: Results of corrections of moderate myopia (-6.00 to -10.00 D) by PRK (Cont'd)

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
O'Brart, 1996 [197]	-5.50 to -9.13 (-6.74) Ablation Profile: 5 mm spherical 6 mm spherical 6 mm multizone	1 year	 20 21 19	 25% 67% 26%	 5% 0 10.5%	-	-
Rao, 1996 [221]	-6.00 to -9.90 (-7.83 ± 1.05)	6 to 22 months	72	± 1.00 D: 46%	6%	72%	-
Tabin, 1996 [258]	-5.00 to –10.00	1 year	40	77%	-	87%	46%
Williams, 1996 [275]	-6.00 to –10.00	1 year	44	90%	-	-	-
Amano, 1995 [10]	-6.00 to –14.00	2 years	21	± 0.50 D: 33% ± 1.00 D: 52%	-	-	-
Hamberg-Nyström 1995 [114]	-6.10 to –10.00	9 months	14	-	-	79%	-
Kim, 1995 [141]	-10.50	1 year	62	71%	-	84%	25/30 75%
Menezo, 1995 [185]	-6.00 to –12.00 (-9.59 ± 1.79)	1 year	88	78%	2 L: 0% 1 L: 1%	-	-
Pop, 1995 [217]	-6.00 to –10.00 (-7.62 ± 1.05)	6 months	105	± 0.50 D: 65% ± 1.00 D: 83%	Loss ≥ 2 L: 2% Loss of 1 L: 12% Unchanged: 67% Gain of 1L: 15% Gain ≥ 2 L: 4%	92%	6/7.5: 75%

Table C.3: Results of corrections of severe myopia (≥ -10.00 D) by PRK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Gabrieli, 1999 [95]	-8.00 to –23.50	18 months	76	68%	-	87%	-
Wee, 1999 [273]	-6.00 to –15.25	6 months	171	50%	5%	75%	-
Pop, 1999 [219]	-10.00 to –27.00	1 year	42 single pass 53 multipass	± 0.50 D: 30% ± 1.00 D: 48% ± 0.50 D: 32% ± 1.00 D: 79%	1 line: 7% 2 lines: 4% 1 line: 3% 2 lines: 0%	74% 85%	19% 56%
Alio, 1998 [6]	-10.25 to -14.00	1-2 years	96	*At 1 year* (n=42) ± 1.00 D: 83% *At 2 years* (n=16) 1.00 D: 100%	-	-	-
Pietilä, 1998 [215]	-10.10 to -25.00 (12.4 ± 2.7)	1 year	39	± 0.50 D: 23% ± 1.00 D: 31%	Loss ≥ 2 L: 0% Loss of 1 L: 5% Unchanged: 44% Gain of 1L: 44% Gain ≥ 2 L: 8%	26%	0
Spadea, 1998 [250]	-11.9 ± 2.8 (-8.00 to -17.00)	24-60 (34.1 ± 10)	53	± 2.00 D:53% ± 4.00 D:79%	Loss ≥ 2 L: 6% Loss = 1 L: 0% Gain = 1 L: 10% Gain ≥ 2 L: 21%	45%	-
Tuunanen, 1998 [261]	Intended correction: -8.10 to -11.50 (-9.40 ± 1.13)	12-24 months	24	*At 12 months*: ± 0.50 D: 29% ± 1.00 D: 67% *At 24 months*: (n=15) ± 0.50 D: 40% ± 1.00 D: 60%	Loss ≥ 2 L: 4% Gain ≥ 2 L: 0%	*At 12 months*: 75% (excluding corrections of astigmatism) *At 24 months*: 73% (n=15)	*At 12 months*: 35% (excluding corrections of astigmatism) *At 24 months*: 33% (n=15)
Williams, 1997 [274]	-10.25 to -25.75 (-14.29 ± 3.34)	2 years	33	± 0.50 D: 42% ± 1.00 D: 48%	Loss ≥ 2 L: 18% Loss of 1 L: 21% Unchanged: 33% Gain ≥ 1 L: 27%	42%	18%
Kwitco, 1996 [151]	> -10.00	1 year	23	-	-	30%	-
Rao, 1996 [221]	> -10.00 (-13.09 ± 2.46)	6 to 22 months	32	44%	22%	28%	-
Tabin, 1996 [258]	-10.01 to -18.50	1 year	10	78%	-	22%	0%

Table C.3: Results of corrections of severe myopia (≥ -10.00 D) (Cont'd)

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Hamberg-Nyström, 1995 [114]	-10.10 to -18.00	9 months	8	-	-	30%	-
Menezo, 1995 [185]	-12.50 to -22.00 (-14.69 ± 5.27)	1 year	45	37%	4%	26%	-
Pop, 1995 [217]	-10.00 to -27.00 (-13.8 ± 3.77)	6 months	40	± 0.50 D: 41% ± 1.00 D: 57%	Loss ≥ 2 L: 6% Loss of 1 L: 16% Unchanged: 44% Gain of 1 L: 25% Gain ≥ 2 L: 9%	60%	6/7.5: 26%

Table C.4: Results of corrections of mild to severe myopia (-1.00 to -12.00 D or more) by PRK

First author Year	Preoperative cylinder (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)		Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)		Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Gabrieli, 1999 [95]	-8.00 to -23.50	18 months	23	± 0.50 D 56%	± 1.00 D 69%			87%	30%
Shah, 1998 [244]				± 0.50 D	± 1.00 D	-1 L	-2 L		
	1.00 to -2.00			93%	97%	2%	0.2%	100%	82%
	-2.00 to -3.00			83%	97%	4%	0.5%	98%	72%
	-3.00 to -4.00			78%	94%	7%	0.6%	97%	65%
	-4.00 to -5.00			72%	91%	8%	1%	95%	54%
	-5.00 to -6.00			64%	88%	9%	1%	91%	48%
	-6.00 to -7.00			54%	78%	14%	2%	85%	32%
	-7.00 to -8.00			46%	72%	16%	3%	84%	29%
	-8.00 to -9.00			54%	74%	11%	2%	84%	25%
	-9.00 to -10.00			25%	43%	20%	8%	54%	7%
	-10.00 to -11.00			17%	25%	-	-	42%	17%
	-11.00 to -12.00			33%	67%	-	1%	67%	0%
Mean	-3.75 ± 1.73	6 to 35 months	3,218	73%	91%	6.7%	1%	94%	59%
Range	-1.00 to -11.88								

Table C.5: Results of corrections of myopic astigmatism by PRK

First author Year	Preoperative myopia and cylinder (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Gabrieli, 1999 [95]	-8.00 to -23.50 Mean: -13.69 ± 4.62	18 months	44	± 0.50 D: 59% ± 1.00 D: 66%		91%	48%
McDonald, 1999 [183]	-0.50 to -6.00 Cylinder up to -10.00	12 months	116	95%	3%	97%	62%
Febbraro, 1999 [87]	-0.75 to -4.00 (mean: -4.50) Preoperative spherical equivalent -0.75 to -4.00	1 year	27	78%	2 lines: 0% 1 line: 11%	81%	-
Alpins, 1998 [8]	Preop. astigm. -1.25 to -6.00 (mean: -2.17 ± 1.05) Spherical equivalent -1.00 to -15.00	1 year	97	Elliptical treatment ± 0.50 D: 29% ± 1.00 D: 51% Sequential treatment ± 0.50 D: 64% ± 1.00 D: 82%	-	57%	20%
Brodovsky, 1998 [36]	Cylinder up to -7.00 Degree of myopia: < 5.00 > 5.00	6 months	 195 137		 2% 17%	 91% 61%	 54% 13%
Colin, 1998 [57]	Preop. astigm. ≤ 5.00 <u>Sequential mode</u> Mild astigm. High astigm. <u>Elliptical mode</u> Mild astigm. High astigm. <u>Hybrid</u> Mild astigm. High astigm.	1 year	 22 33 20 18 32 19	 - - - - - -	 0% 3% 3% 5% 5% 1%	 86% 64% 72% 74% 55% 67%	 18% 9% 34% 21% 0% 0%

Table C.5: Results of corrections of myopic astigmatism by PRK (Cont'd)

First author Year	Preoperative myopia and cylinder (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Lee, 1998 [156]	<u>Mild myopia</u> Preop astigm. -2.74 ± 0.88 Preoperative SE* -5.88 ± 1.39	6 months	47	Postop. Astigm. -0.89 ± 1.56 Postop. SE -0.06 ± 1.23	<u>% correction</u> Astigm. 70.0 ± 30.8 Sphere: 90.6 ± 20.1	94%	<u>6/7.5</u> 74.4%
	<u>Moderate myopia</u> Preop astigm. -2.34 ± 0.42 Preoperative SE -9.37 ± 1.21	6 months	43	Postop. Astigm. -1.04 ± 1.38 Postop. SE -0.86 ± 2.08	Astigm. 69.0 ± 25.6 Sphere: 80.1 ± 17.1	93%	58.1%
	<u>Severe myopia</u> Preop astigm. -2.30 ± 0.47 Preoperative SE -12.53 ± 0.71	6 months	20	Postop. Astigm. -1.84 ± 1.75 Postop. SE -2.97 ± 4.08	Astigm. 55.7 ± 31.3 Sphere: 69.0 ± 25.7	65%	30.0%
Tuunanen, 1998 [261]	Mean target astigm. -1.75 ± 0.64 (-1.00 to -3.25) Preoperative SE -7.27 ± 3.20 (-1.50 to -11.50)	1 year	21	Postop. Astigm.: -1.30 ± 0.55 (0.00 to –2.75) Postop. SE: -1.16 ± 2.15 (-9.25 to 1.25)	Cylinder change: 42.3% ± 28.1% Axis rotation: 0^o to 60^o (mean: $20.0^o \pm 20.1^o$)		
Danjoux, 1997 [66]	Cylinder: 2.02 ± 1.04 Degree of myopia: -4.88 ± 3.20	1 year	59	0.84 ± 0.84 -0.02 ± 0.67	5%	79%	

* SE = Spherical equivalent

Table C.5: Results of corrections of myopic astigmatism by PRK (Cont'd)

First author Year	Preoperative myopia and cylinder (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Goggin, 1997 [115]	Entire group: Spherical equivalent: -5.68 ± 2.67 Cylinder: -1.40 ± 0.75 -0.50 to 5.00	1 year	89	± 1.00 D: 80% Postop. Astigm.: -0.36 ± 0.28 (0.00 to -1.25)	-	89%	-
	Myopia < 6.00	1 year	51	± 1.00 D: 89%	-	98%	-
	Myopia > 6.00	1 year	38	± 1.00 D: 68%	-	76%	-
Hamberg-Nyström, 1996 [150]	Myopia 0.50 to 1.75 / Cylinder 0.05 ± 0.40	1 year	75	84%	0%	80%	-
	2.00 to 4.50 / -2.47± 0.64		38	80%	0%	90%	-
Kremer, 1996 [150]	Mild astigm. -0.50 to 1.00 (-0.84 ± 0.22)	1 year	28	Postop. cyl.: -0.40 ± 0.33 ± 0.50 D: 68%	-	95%	-
	Moderate astigm. -1.25 to -2.50 (-1.77 ± 0.42)	1 year	44	Postop. cyl.: -0.54 ± 0.48 ± 0.50 D: 64%	-	100%	-
	Severe astigm. -2.75 to -5.00 (-3.54 ± 0.64)	1 year	20	Postop. cyl.: -0.69 ± 0.32 ± 0.50 D: 80%	-	100%	-
Tabin, 1996 [258]	Cylinder up to -6.00 Degree of myopia:	1 year					
	< -5.00		161	85%		87%	47%
	-5.00 to -10.00		136	62%		71%	25%
	> -10.00		36	28%	6%	27%	2%

Table C.5: Results of corrections of myopic astigmatism by PRK (Cont'd)

First author Year	Preoperative myopia and cylinder (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Vidaurri-Leal, 1996 [263]	Preop. cylinder: -1.00 to -4.50 (-2.39 ± 0.92) Preop. spherical equivalent (SE): -2.75 to -6.50 (-4.87 ± 1.16)	6 months	38	± 0.50 D: 59% ± 1.00 D: 71% Postop. Cylinder: -0.99 ± 0.75 (0.00 to -2.50) Postop. SE: -0.17 ± 0.74 (-1.00 to -1.50)	Loss ≥ 2 L: 12% Loss 1 L: 17% Unchanged: 65% Gain of 1 L: 6%	77%	18%
Alio, 1995 [5]	Preop. astigm.: -2.50 ± 0.70 (-1.50 to –4.00) Preop. sphere: -0.25 ± 0.25 (0 to –0.50)	1 year	46	Postop. Astigm.: -0.50 ± 0.20	0%	100%	26%

Table C.6: Results of corrections of hyperopic or compound astigmatism by PRK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Dausch, 1997 [69]	+2.00 to +8.25 (+4.85 ± 1.45)	1 year	68	± 0.50 D: 59% ± 1.00 D: 81%	Loss ≥ 2 L: 2% Loss of 1 L: 6% = or better: 88%	97%	40%
Jackson, 1997 [130]	+1.00 to +4.00 (mean: +2.48) Cylinder +0.63 (+0.25 to +1.00)	6 months	25	± 0.50 D: 80% ± 1.00 D: 88%	Loss ≥ 2 L: 0% Loss of 1 L: 12% Unchanged: 88%	88%	6/7.5: 88%
Dausch, 1996 [67]	Hyperopic compound astigmatism Mean SE: +4.30 Mean cylinder: +2.33 Mixed astigmatism Mean SE: +0.46 Mean cylinder: +4.75	18 months	30 17	82% 91%	0% 0%	93% 82%	27% 36%

Table C.7: Results of corrections of hyperopia by PRK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Num-ber of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Fust, 1998 [94]	+2.00 to +8.00 (+4.23 ± 1.18)	6 months	20	60%			
Carones, 1998 [44]	+1.50 to +6.25 (+2.86 ± 1.46)	12-24 months	25	12 months (n=25) ± 0.50 D: 44% ± 1.00 D: 76% 24 months (n=11) ± 0.50 D: 73% ± 1.00 D: 82%			
Jackson, 1998 [129]	+1.00 to +4.00 (+2.35 ± 0.88)	6-18 months	65	6 months (n=65) ± 0.50 D: 85% ± 1.00 D: 95% 18 months (n=24) ± 0.50 D: 75% ± 1.00 D: 92%			
Vinciguerra, 1998 [265]	Gr. A: ≤ +3.00 Gr. B: +3.10 to +6.00 Gr. C: +6.00 to +9.00	1 year	A: 12 B: 30 C: 13	Gr. A: 67% Gr. B: 13% Gr. C: 23%	Loss of 2 L: 6% Loss of 3 L: 2%	-	-
Dausch, 1997 [69]	+2.00 to +8.25 (+4.85 ± 1.45)	1 year	68	± 0.50 D: 59% ± 1.00 D: 81%	Loss ≥ 2 L: 2% Loss of 1 L: 6% = or better: 88%	97%	40%
Daya, 1997 [70]	+0.25 to +6.00 (+3.15 ± 1.45) Mild hyperopia: ≤ 3.50 Moderate hy-peropia: > 3.50	6 months	45 (n=26) (n=19)	All: 87% Mild: 92% Moderate: 79 %	Loss of 2 L: 7% Loss of 1 L: 18% Unchanged: 42% Gain of 1 L: 20% Gain ≥ 2 L: 13%		
Jackson, 1997 [130]	+1.00 to +4.00 (mean: +2.48) Cylinder +0.63 (+0.25 to +1.00)	6 months	25	± 0.50 D: 80% ± 1.00 D: 88%	Loss ≥ 2 L: 0% Loss of 1 L: 12% Unchanged: 88%	88%	6/7.5: 88%

Table C.7: Results of corrections of hyperopia by PRK (Cont'd)

First author Year	Preoperative re-fraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Pietilä, 1997 [214]	+1.50 to +6.00 (+4.20 ± 1.30)	1 year	19	± 0.50 D: 20% ± 1.00 D: 40%	Loss of 2 L: 7% Loss of 1 L: 20% Unchanged: 53% Gain of 1 L: 13% Gain of 2 L: 7%	67%	6%
	+6.25 to 9.75 (+7.70 ± 1.30)	1 year	15	± 0.50 D: 8% ± 1.00 D: 17%	Loss of 2 L: 0% Loss of 1 L: 25% Unchanged: 50% Gain of 1 L: 25% Gain of 2 L: 7%	8%	0%

Table C.8: Results of corrections of mild myopia (up to -6.00 D) by LASIK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Arbelaez, 1998 [17]	0 to -6.00	6 months	49	98%	Loss ≥ 2 L: 3% Loss of 1 L: 9% Unchanged: 79% Gain of 1 L: 9% Gain ≥ 2 L: 13%	97%	85%
Lindstrom, 1998 [158]	-1.00 to -10.00	6 months	202	95%	Loss ≥ 2 L: 2%	93%	68%
Salchow, 1998 [238]	-1.50 to -5.50 (-3.14 ± 1.28)	6 months	28	± 0.50 D: 9% ± 1.00 D: 96%	Loss ≥ 2 L: 11% Loss of 1 L: 21% Gain of 1 L: 11% Gain ≥ 2 L: 0%	100%	52%
Lindstrom, 1997 [159]	-1.00 to -6.00	-	101	89%	-	90%	-
Pesando, 1997 [213]	-3.50 to -8.00 (-5.27 ± 1.41)	6 months	16	± 0.50 D: 44% ± 1.00 D: 100%	-	100%	69%
Machat, 1996 [166]	< -3.00	2 years	61	-	0	100%	-
Salah, 1996 [232]	-2.00 to -6.00	3-8 months	40	93%	-	95%	68%

Table C.9: Results of corrections of moderate myopia (-6.00 to -10.00 D) by LASIK

First Author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Cheloud-tchenko, 1999 [55]	-2.75 to -9.25	3 months	21	± 0.50 D: 88% ± 1.00 D: 100%	-	-	-
Arbelaez, 1998 [17]	-6.00 to -11.00 (intended cor-rection)	3-6 months	21	-	Loss ≥ 2 L: 4% Loss of 1 L: 15% Unchanged: 58% Gain of 1 L: 8% Gain ≥ 2 L: 15%	96%	42%
Knorz, 1998 [146]	-5.00 to -9.90	1 year	8	± 0.50 D: 88% ± 1.00 D:100%	0%	88%	-
Salchow, 1998 [233]	-6.25 to -9.00 (-7.90 ± 0.99)	6 months	25	± 0.50 D: 50% ± 1.00 D: 73%	Loss ≥ 2 L: 5% Loss of 1 L: 9% Gain of 1 L: 27% Gain ≥ 2 L: 27%	75%	29%
Zaldivar, 1998 [278]	-5.50 to -11.50 (-8.62 ± 1.27)	3-6 months	84	± 0.50 D: 56% ± 1.00 D: 83%	Loss ≥ 2 L: 1%	77%	22%
Knorz, 1997 [145]	-5.00 to -9.90	1 year	20	85%	Loss ≥ 2 L: nil	75%	-
Pallikaris, 1997 [207]	-8.00 to -14.00	1 year	21	43%	-	-	
Perez-Santonja, 1997 [209]	-8.00 to -12.00	6 months	59	72%	-	-	
Pesando, 1997 [213]	-8.12 to -14.00 (-10.68 ± 1.40)	6 months	25	± 0.50 D: 20% ± 1.00 D: 72%	-	84%	16%
Machat, 1996 [166]	-6.00 to -9.00 -9.00 to -15.00	2 years	250 228		1% 2%	94% 65%	
Salah, 1996 [232]	-6.00 to -12.00	5 months	29	75%	0	63%	18%
Kremer, 1995 [148]	-3.50 to -11.75 (-6.25)	6 months	31	74%	Loss: 0 Unchanged: 84% Gain ≥ 2 L: 9%	81%	

Table C.10: Results of corrections of severe myopia (-10.00 to -15.00 D) by LASIK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Knorz, 1998 [146]	-10.00 to -14.90	1 year	10	± 0.50 D: 50% ± 1.00 D: 60%	Loss ≥ 2 L: 5%	78%	-
Lindstrom, 1998 [158]	-10.00 to -30.00	6 months	21	52%	Loss ≥ 2 L: 5%	52%	10%
Salchow, 1998 [233]	-10.25 to -16.00 (-11.89 ± 1.72)	6 months	13	± 0.50 D: 54% ± 1.00 D: 62%	Loss ≥ 2 L: 15% Loss of 1 L: 15% Unchanged: 31% Gain of 1 L: 31% Gain ≥ 2 L: 7%	54%	15%
Knorz, 1997 [145]	-10.00 to -14.90	1 year	33	73%	Loss ≥ 2 L: 6%	79%	-
Pallikaris, 1997 [207]	-8.50 to -14.00 (11.53 ± 1.77)	12 to 24 months	39	± 2.00 D: 91% (at 12 months) 73% at 24 months	-	-	-
Perez-Santonja, 1997 [209]	-12.00 to -16.00	6 months	54	46%	-	-	-
Pesando, 1997 [213]	-14.12 to -20.00 (-16.24 ± 2.10)	6 months	5	± 0.50 D: 20% ± 1.00 D: 40%	-	40%	0%
Guëll, 1996 [108]	-7.00 to -12.00 (-9.3 ± 1.31)	6 months	21	± 1.00 D: 85%	Loss ≥ 2 L: 0%	71%	0%
Salah, 1996 [232]	-12.00 to -20.00	3-8 months	19	43%	-	37%	0%

Table C.11: Results of corrections of extreme myopia (> -15.00 D) by LASIK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Knortz, 1998 [146]	-15.00 to -29.00	1 year	18	± 0.50 D: 22% ± 1.00 D: 39%	6%	33%	-
Knorz, 1997 [145]	-15.00 to -29.00	1 year	32	31%	Loss ≥ 2 L: 6%	-	-
Pallikaris, 1997 [207]	-15.00 to -26.00 (-18.14 ± 3.04) intended correc-tion: ≤-16.00	12 to 24 months	18	± 2.00 D: 89% (at 12 months) 85% (at 24 months)	-	-	-
Perez-Santonja, 1997 [210]	-16.00 to -20.00	6 months	30	50%	1%	-	-
Guëll, 1996 [108]	-12.25 to -18.50 (-14.86 ± 1.87)	6 months	22	± 1.00 D: 41%	-	45%	0%
Kremer, 1996 [150]	-19.00 to -25.00	-	-	-	1%	20%	-
Machat 1996 [166]	> -15.00	2 years	48	-	4%	23%	-
Marinho, 1996 [179]	-10.00 to -22.50 (-14.18 ± 2.96)	6 months	34	68%	Loss ≥ 2 L: 9% Loss of 1 L: 9% Unchanged: 44% Gain of 1 L: 12% Gain ≥ 2 L: 27%	-	-

Table C.12: Results of corrections of myopia (all degrees combined) by LASIK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Esquenazi, 1997 [83]	-3.00 to -26.00 (-8.50 ± 1.03)	12-18 months	308	81%	0.7%	-	-
Higa, 1997 [126]	-1.00 to -19.00	1 year	980	72%	6.5%	75%	34%
Pesando, 1997 [213]	-3.00 to -20.00	1 year	113	75%	7% > 0 line	77% > 6/7.5	-
Knorz, 1996 [144]	-6.00 to -29.00 (-14.80 ± 7.28)	6 months	62	± 0.50 D: 37% ± 1.00 D: 47%	Loss of 2 L:12% Loss of 1 L: 28%	68%	-
Bas, 1995 [23]	-4.00 to -25.00	3-10 months	97	47%	Loss ≥ 1 L:13%	50%	-
Fiander, 1995 [89]	-3.75 to -27.00 (-7.65)	3-11 months	124	± 0.50 D: 44% ± 1.00 D: 70%	0%	81%	≥ 6/7.5: 50%

Table C.13: Results of corrections of astigmatic myopia by LASIK

First author Year	Myopia (diopters)	Preoperative astigmatism (diopters)	Duration of follow-up	Number of eyes	Postoperative astigmatism (diopters)	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)
Gauthier-Fournet, 1998 [98]	Preop. spherical equivalent: -3.23 ± 1.35	2.98 Pure astigmatism (cyl. > sphere)	3 months	13	-	92%	Loss ≥ 2 L: 8%
	Preop. spherical equivalent: -8.57 ± 2.57	2.06 Astigmatism included in sphere (sphere > cyl.)	3 months	251	-	71%	Loss ≥ 2 L:12%
Knortz, 1998 [146]	-5.00 to -9.90 -10.00 to -14.90 - 15.00 to -29.00	-1.00 to 4.50	1 year	12 23 14	- - -	75% 78% 22%	70% 86% 40%
el Danasoury, 1997 [79]	-2.25 to -15.50 (-5.79 ± 2.45)	0.50 to 3.00 (1.19 ± 0.62)	1 year	87	-2.13 to +1.25 (-0.33 ± 0.52)	93%	95% Loss ≥ 2 L: nil
Zaldivar, 1997 [279]	-1.13 to -7.25 (-3.54 ± 1.41)	≤ 4.00 (-1.64 ± 1.14)	3 to 6 months	83	< 0.50: 57% Postop. sphere: -0.65 ± 0.62 Postop. cyl.: -0.50 ± 0.63	Spherical equivalent: ± 0.50: 53% ± 1.00: 80% Cylinder: ≤ 0.50: 57%	76%

Table C.14: Results of corrections of mixed, myopic and hyperopic astigmatism by LASIK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Arbelaez, 1999 [18]	Astigmatism: +1.00 to 7.50 Hyperopia:						
	+1.00 to +3.00	1 year	23	± 0.50 D: 78%	0		
	+3.10 to +5.00		14	± 0.50 D: 36%	14%		
	+5.10 to +9.50		13	± 0.50 D: 31%	15%		
Chayet, 1998 [54]	SE: +0.67 ± 1.33 Cyl: -3.82 ± 0.95 (simple, mixed myopic and simple hyperopic astigm.)	3-6 months	41	Spherical equivalent: ± 0.50 D: 78% ± 1.00 D: 90% Cylinder: ± 0.50 D: 76% ± 1.00 D: 95%	-	85%	44%
Suarez, 1996 [257]	Sphere: +1.00 to +8.50 with cyl. < 0.75 Astigmatism:						-
	+1.00 to +6.50	3 months	154		1.3%	72%	
	+1.00 to +8.50	3 months	172		1.2%	58%	

Table C.15: Results of corrections of hyperopia by LASIK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 0.50 D or ± 1.00 D of the intended correction (%age of eyes)	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Arbelaez, 1999 [18]	+1.00 to +3.00	1 year	24	± 0.50 D: 55%	0		
	+3.10 to +5.00		20	± 0.50 D: 44%	0		
	+5.10 to +9.00		16	± 0.50 D: 38%	13%		
Arbelaez, 1998 [17]	0.00 to + 4.00	6 months		86%	-	-	-
	+4.00 to +10.00	6 months		100%	-	-	-
Ditzen, 1998 [73]	+1.00 to +4.00 (+2.50 ± 1.70)	1 year	20	± 1.00 D: 85%	Loss ≥ 2 L: 5% Loss of 1 L: 5% Gain of 1 L: 20% Gain ≥ 2 L: 35%	95%	
	+4.25 to +8.00 (+5.28 ± 1.92)	1 year	23	± 1.00 D: 58%	Loss ≥ 2 L: 4% Loss of 1 L: 13% Gain of 1 L: 9% Gain ≥ 2 L: 17%	90%	
Göker, 1998 [106]	+4.25 to +8.00 (+6.50 ± 1.33)	6 months	54	± 0.50 D: 43% ± 1.00 D: 82% ± 2.00 D: 87%	-	72%	17%
		18 months	54	± 0.50 D: 39% ± 1.00 D: 75% ± 2.00 D: 87%	-	67%	15%
Knorz, 1997 [145]	+2.50 to +8.00	1 year	16	± 0.50 D: 64% ± 1.00 D: 82%	-	-	-
Suarez, 1996 [257]	+1.00 to +8.50	6 months	154	± 0.50 D: 87% ± 1.00 D: 98%	2%	72%	-

Table C.16: Comparative results of corrections of myopia by LASIK and PRK

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Ahn, 1999 [4]							
PRK	-1.75 to -8.25 Mean: -5.14 ± 1.78	6 months	87	± 0.50 D: 67% ± 1.00 D: 86%	0%	91%	48%
LASIK	-2.75 to -14.37 Mean: -6.01 ± 1.90	6 months	41	± 0.50 D: 66% ± 1.00 D: 88%	5%	100%	24%
el-Maghraby, 1999 [81]							
PRK	-2.50 to -8.00 Mean: -4.80 ± 1.60	2 years	30	± 0.50 D: 65% ±1.00 D: 73%	Loss > 2 L: 0% ± 1 L: 96% Gain > 2 L: 4%	96%	37%
LASIK (on same patient)	-2.50 to -8.00 Mean: -4.70 ± 1.50	2 years	30	± 0.50 D: 71% ± 1.00 D: 88%	Loss > 2 L: 0% ± 1 L: 92% Gain > 2 L: 8%	100%	63%
el-Danasoury, 1999 [78]		1 year	48	Mean refraction:			
PRK	-2.00 to -5.50		24	-0.08 ± -0.38	0%		63%
LASIK (on same patient)	-2.00 to -5.50		24	-0.14 ± -0.31	0%		79%

Table C.16: Comparative results of corrections of myopia by LASIK and PRK (Cont'd)

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Brint, 1998 [34]							
Multizone PRK	-6.00 to -14.38 (-9.28)	3 to 12 months	99	*At 1 year*: ± 0.50 D: 43% ± 1.00 D: 53%	-	*At 6 months*: 64%	*At 6 months*: 18%
LASIK	-6.00 to -22.63 (-0.10)	6 to 12 months	106	*At 1 year*: ± 0.50 D:50% ± 1.00 D: 81%	-	*At 6 months*: 57%	*At 6 months*: 18%
Multizone PRK Summit	-6.00 to -13.63 (-8.70)	3 to 12 months	44	-	*At 9 months*: Loss > 1 L: 5% Loss of 1 L: 16% Unchanged: 58% Gain of 1 L: 21%	*At 6 months*: 69% *At 12 months*: 92%	-
LASIK Summit	-6.25 to -22.00 (-9.56)	3 to 12 months	56	-	*At 9 months*: Loss > 1 L: 0% Loss of 1 L: 16% Unchanged: 63% Gain of 1 L: 21%	*At 6 months*: 57% *At 12 months*: 66%	-
Hersh, 1998 [121]							
PRK	-6.00 to -15.00	6 months	105	± 0.50 D:29% ± 1.00 D: 57%	Loss ≥ 2 L: 12% Loss of 1 L: 21% Gain of 1 L: 21% Gain ≥ 2 L: 3%	66%	19%
LASIK	cyl. ≤ 2.00 D	6 months	115	± 0.50 D: 27% ± 1.00 D: 41%	Loss ≥ 2 L: 3% Loss of 1 L: 23% Gain of 1 L: 24% Gain ≥ 2 L: 6%	56%	26%

Table C.16: Comparative results of corrections of myopia by LASIK and PRK (Cont'd)

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Lindstrom, 1998 [158]							
	Very mild myopia						
PRK	-1.00 to -3.75	1 year	28	97%	0%	100%	73%
LASIK	-1.00 to -3.75	6 months	123	98%	0%	93%	78%
	Mild myopia						
PRK	-4.00 to -6.00	1 year	61	92	0.5%	99%	73%
LASIK	-4.00 to -6.00	1 year	177	96	0.6%	92%	71%
	Moderate Myopia						
PRK	-6.25 to -10.00	1 year	95	76	6%	86%	39%
LASIK	-6.25 to -10.00	1 year	25	88	4%	96%	48%
	Extreme Myopia						
PRK	-10.25 to -30.00	1 year	148	54%	14%	52%	0%
LASIK	-10.25 to -30.00	6 months	21	52%	5%	52%	10%

Table C.16: Comparative results of corrections of myopia by LASIK and PRK (Cont'd)

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Marinho, 1998 [178] PRK Summit 5 mm	> -6.00 to -12.80 (-8.60 ± 1.8)	1 year	325	± 1.00 D: 73%	14% Loss of 1 or 2 lines	-	-
Wang, 1997 [266]							
PRK	-1.25 to -6.00	1 year	432	± 0.50 D: 61% ± 1.00 D: 83%	4%	94%	72%
LASIK	-1.25 to -6.00	1 year	137	± 0.50 D: 71% ± 1.00 D: 89%	1%	98%	83%
Helmy, 1996 [120]							
PRK	-6.00 to -10.00 (-7.00 ± 0.53)	1 year	40	± 0.50 D: 39% ± 1.00 D: 64%	Loss ≥ 1 L: 5%	68%	13%
LASIK	-6.00 to -10.00 (-7.30 ± 0.35)	1 year	40	± 0.50 D: 60% ± 1.00 D: 86%	Loss ≥ 1 L: 5%	75%	18%
Marinho, 1998 [178] PRK Summit 5 mm	> -6.00 to -12.80 (-8.60 ± 1.8)	1 year	325	± 1.00 D: 73%	14% Loss of 1 or 2 lines	-	-
PRK Summit 5 mm	> -6.00 to -12.80 (-9.60 ± 1.5)	1 year	58	± 1.00 D: 78%	8% Loss of 1 or 2 lines	-	-

Table C.17: Results of corrections of myopia by LASIK: sequential intervention (one eye at a time) vs. simultaneous intervention (both eyes at the same time)

First author Year	Preoperative refraction (diopters)	Duration of follow-up	Number of eyes	Correction to ± 1.00 diopter of the intended correction	Loss of ≥ 2 lines of corrected visual acuity (%age of eyes)	Uncorrected visual acuity 6/12 or better (%age of eyes)	Uncorrected visual acuity 6/6 (%age of eyes)
Gimbel, 1999 [104]							
Sequential	-2.50 to -16.00	3-6 months	291	1st eye: ± 0.50 D: 50% ±1.00 D: 74%	1st eye: Loss ≥ 2 L: 3% Loss of 1 L: 3% Unchanged: 90% Gain of 1 L: 3% Gain ≥ 2 L: 0.7%	1st eye: 87%	1st eye: 45%
				2nd eye: ± 0.50 D: 71% ±1.00 D: 89%	2nd eye: Loss ≥ 2 L: 3% Loss of 1 L: 3% Unchanged: 92% Gain of 1 L: 2% Gain ≥ 2 L: 0.7%	2nd eye: 85%	2nd eye: 46%
Simultane-ous	-1. to -19.25	3-6 months	1546	1st eye: ± 0.50 D: 57% ±1.00 D: 80%	1st eye: Loss ≥ 2 L: 2% Loss of 1 L: 3% Unchanged: 92% Gain of 1 L: 3% Gain ≥ 2 L: 0.8%	1st eye: 87%	1st eye: 50%
				2nd eye: ± 0.50 D: 56% ±1.00 D: 83%	2nd eye: Loss ≥ 2 L: 2% Loss of 1 L: 3% Unchanged: 94% Gain of 1 L: 2% Gain ≥ 2 L: 0.8%	2nd eye: 85%	2nd eye: 47%

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