

**Rapport CÉTS 97-5 RE  
EXCIMER LASER PHOTOREFRACTIVE KERATECTOMY: THE CORRECTION OF  
MYOPIA AND ASTIGMATISM.  
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**Summary**

*Introduction*

Excimer laser photorefractive keratectomy is a surgical technique whose use has increased considerably over the past few years. The operation consists in modifying the shape of the eye by removing a thin layer from the surface of the cornea, the transparent tissue at the front of the eye. The excimer laser emits a beam of ultraviolet light that can be used to "sculpt" in the cornea a lens that will correct the eye's refractive error. Thus, one can treat vision problems like myopia and astigmatism, two refractive errors usually corrected with glasses or contact lenses.

Other highly useful applications of the laser in the treatment of eye diseases include laser in situ keratomileusis (LASIK), annular photo-ablation and phototherapeutic keratectomy. The first two, although highly promising, are still at the experimental stage, and their limitations still need to be determined more clearly. As for phototherapeutic keratectomy, it is mainly used to treat corneal diseases responsible for decreased vision and pain. The analysis of its effectiveness and risks is thus quite different.

This technology brief is therefore limited to a discussion of the most widespread application of the excimer laser in ophthalmology – photo-refractive keratectomy for the correction of myopia and myopic astigmatism. It describes this new technique and the main steps involved in the treatment, and reviews the current knowledge regarding its effectiveness, reliability and safety, and patient satisfaction.

*Anatomy and Physiology of the Eye*

To make the present topic easier to understand, here is a brief description of the main anatomical structures of the eye concerned. 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 tissue that detect light signals. The cornea consists of six separate layers: the epithelium, the basement membrane, Bowman's membrane, the stroma, Descemet's membrane and the endothelium.

The eye receives light rays from a distant object and bends them to a point called the "focus". 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. The process of bending light rays to a focus, refraction, is measured in diopters, and it is the cornea that accounts for most of this refractive power.

The myopic eye is too powerful for its length either because the refraction is excessive (e.g. cornea too steeply curved) or because the eye is too long. Rays from a distant object are brought to a focus in front of the retina and the image of the object is blurred. Correction causes the rays to diverge so that the image is moved back onto the retina. The degree of myopia is measured in terms of the refractive power of the lens required to correct it, and since it involves divergence, negative units of measurement are used, e.g. -1.00 or -2.00 diopters. The refractive power of an astigmatic eye varies according to the corneal meridians. Astigmatism can be regular or irregular and can be accompanied by myopia. Uncorrected refractive errors affect visual acuity, which 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. Visual acuity is measured by means of a Snellen chart.

#### *Steps Involved in Treatment by Photo-refractive Keratectomy*

Certain eligibility criteria must be met when selecting patients for excimer laser photorefractive keratectomy. The *Collège des médecins du Québec* states that patients should be at least 18 years of age. The operation is contra-indicated in the presence of certain pathologies. A thorough preoperative examination of the eye is required to identify these pathologies and to ensure stable refraction, visual acuity and corneal curvature measurements.

The operation itself lasts only a few seconds and is a relatively standardized procedure. The first step consists in removing the epithelium. This is followed by the keratectomy per se, which consists in ablating a certain quantity of tissue to a depth of a few microns in the stroma. The specific parameters of this treatment, such as the shape of the ablation, its depth and its diameter, are determined by a computer program integrated into the laser. After the procedure, a contact lens is usually placed on the eye and a drop of an antibiotic and a drop of a nonsteroidal antiinflammatory are instilled.

The patient is then seen again on a daily basis until there is complete epithelial wound closure, or usually for two to five days, after which the contact lens is removed. The medications are continued until there is complete reepithelialization, then replaced with a corticosteroid for several weeks.

Vision usually improves considerably within a few weeks. Overcorrection is common shortly after the operation but gradually subsides, the eye subsequently stabilizing to its final level of correction. This stabilization takes from 3 to 18 months or even longer, depending on the degree of myopia.

When both eyes need to be operated on, only one should be done at a time. It is recommended that the other be treated a few months later. This interval may vary according to the healing response of the first eye and the degree of myopia.

#### *Effectiveness of Photorefractive Keratectomy*

The criteria used to evaluate the outcome of photorefractive keratectomy include postoperative visual acuity without correction by glasses or contact lenses, postoperative refraction, certain psychophysical tests (e.g. contrast sensitivity) and the level of patient satisfaction. Most authors define uncorrected postoperative acuity 6/12 as a success (in this report, distance is expressed in metres, so that 6/12 is equivalent to 20/40 when feet are used). Achieving refraction to within one diopter of emmetropia is the second most commonly used criterion for success. Henceforth, we will refer to it as a "near-perfect correction".

The outcome for low myopia is generally better than for high myopia. A near-perfect correction of vision is achieved in a single treatment in almost 90 % of cases of low myopia, whereas in high myopia, a near-perfect correction is achieved in only 40 % of cases (and 50 % within two diopters). Visual acuity 6/12 is achieved in 90 to 100 % of cases of low myopia, the figure varying from 7 to 60 % for high myopia.

As for myopic astigmatism, the success rate varies from 68 to 87.5 % for a near-perfect correction, with visual acuity 6/12 (distance is expressed here in metres and this is equivalent to 20/40 when distance is expressed in feet) achieved in 62.5 to 91 % of cases. The range of outcomes for simple astigmatism is broader, depending on the study.

#### *Adverse Effects and Complications*

There are several types of lasers, and their methods of use are constantly evolving. The types of adverse effects and their frequency can vary according to the laser and the technique used. The results in the literature should be interpreted with caution.

*Adverse effects associated with the healing process per se.* Some patients may experience considerable pain during the 24 hours following the operation. The pain can be reduced or eliminated in nearly 90 % of cases with the temporary use of a therapeutic contact lens on the operated eye. Also, epithelial healing may be delayed, i.e. four days or longer, in 2 to 3 % of patients.

During the first few postoperative weeks, corneal ulcers or perforations may occur in a very small percentage of cases. On the other hand, following photorefractive keratectomy, a decrease occurs in corneal transparency referred to as "haze", the extent of which is associated with the depth of ablation. Haze causes the patient to see a starburst effect around lights, and, in the most severe cases, can cause a decrease in visual acuity. Haze peaks at around the third month postoperatively and gradually disappears after 6 to 12 months, rarely persisting for more than a year. In most cases, vision is little affected by haze, if at all. In low myopes, haze persists for more than a year in less than 2 % of cases. In patients with more severe myopia (> 10 diopters), the proportion can be as high as 50 %. The persistence of haze may require a repeat treatment with the excimer laser.

Physicians frequently prescribe steroidal drugs in the form of eyedrops for the first few months following a keratectomy. The purpose of the drops is to promote the healing process. However, their use sometimes leads to increased intraocular pressure, a complication that is more frequent in high myopes. The physician should monitor the pressure closely and, if necessary, treat it. The use of steroids is also associated, in a very

small percentage of patients, with drooping of the upper eyelid, which is generally minor and which disappears in most cases after the steroids are discontinued.

*Refractive complications.* The outcome of the correction is not always perfect, since there may be overcorrection or undercorrection. Overcorrection greater than one diopter occurs in about 3.5 % of cases, its incidence being higher in high myopes than in low myopes. However, it rarely persists over time. Undercorrection (residual myopia greater than one diopter) is the most frequent postoperative complication of photorefractive keratectomy, its incidence varying, according to the degree of myopia, from 2.4 to 52 %. Undercorrections are easier to retreat by excimer laser, and two thirds of patients retreated end up with a near-perfect correction.

Photorefractive keratectomy can induce regular or irregular astigmatism, the first type occurring in 4 to 15 % of cases, the second, which is evident during the healing period, disappearing after a few weeks or months. Additionally, regression of the refractive effect of the keratectomy can occur in the months following the operation. The extent of this effect varies according to the degree of myopia.

Myopes have the advantage, prior to laser treatment, of being able to see near without corrective lenses with less effort than individuals with normal vision. When myopia is corrected by keratectomy, this advantage is lost, and, in some cases, the laser-treated myope will achieve clear distant vision as expected but will have to wear glasses for near vision, which he did not have to do previously.

Several authors have reported a surface elevation, or island, in the centre of the ablation zone following photorefractive keratectomy in their patients. The island can lead to a decrease in vision quality, ghost images and diplopia. In most cases, it resolves spontaneously, although a central island persists after 6 to 12 months in less than 2 % of patients. Furthermore, the new, posttreatment corneal topography can cause optical aberrations, which can impair visual performance.

Good laser beam centration is essential for a successful keratectomy. Significant decentration (greater than 1 mm) occurs in approximately 2 to 8 % of cases and can cause glare, halos (i.e. shimmering blur circles around lights at night), ghost images and diplopia.

Although satisfied with their surgery, many patients complain of a decrease in the quality of their vision, especially at night. Recent studies have begun to show that some patients experience a loss of contrast sensitivity (decreased vision in conditions of suboptimal lighting), but the cause of this phenomenon is still not very clear. During the first few postoperative months, most patients also see halos at night. After 12 months, about one fourth of these patients still experience this problem, which can constitute a source of dissatisfaction.

The various adverse effects and complications of photorefractive keratectomy, such as haze, laser beam decentration and the induction of astigmatism, can lead to a loss of visual acuity, i.e. a loss of fine detail vision. A significant loss of visual acuity can occur in

0 to 5 % of cases of low myopia, depending on the study. In cases of high myopia, this figure is higher (9 to 21 %).

#### *Other Possible Effects: Research in Progress*

In a keratectomy, the laser beam removes only very superficial layers of corneal tissue. Recent research suggests, however, that a keratectomy can nonetheless cause damage to the deeper corneal layers. This question remains controversial, but it is possible that, in the long term, such endothelial damage affects corneal hydration and transparency in certain predisposed patients. It will not be possible to verify this hypothesis until after several years of observing patients who have undergone the procedure.

#### *Patient Satisfaction*

Very few studies have examined the question of patient satisfaction. The few data available concern patients who had a low degree of myopia or astigmatism. Three to six months after the operation, more than 90 % of them said they were satisfied or very satisfied.

In one study on vision quality after photorefractive keratectomy, about 55 % of the patients noted an improvement after three months and 15 % a deterioration. After two years, 25 % reported an improvement and 20 % a deterioration. In another study, more than 90 % of the patients stopped wearing glasses or contact lenses three months after the operation.

The most frequent complaint (in more than half of cases) is decreased night vision, which very often interferes with night driving. The problem of halo or glare occurs in 45 to 70 % of cases, followed by decreased fine detail vision and the need for glasses for near vision. The severity of these symptoms tends to diminish with time, but they do not disappear completely.

#### *Financial Costs*

According to one study, at \$2,000 per eye, the cost of excimer laser treatment is equal to that of using daily wear contact lenses for 10 years. Compared over a period of 20 years, the excimer laser is less expensive than daily or extended-wear contact lenses, but glasses are still the least expensive modality of refractive correction. However, after a 20-year period, most laser-treated patients will develop presbyopia, which will require an appropriate optical correction. Lastly, with time, the cost of excimer laser treatment will probably come down.

#### *The Practice in Québec*

Five types of excimer laser are available in Québec, and there are a total of 15 instruments, nine of which are in Montréal. This works out to one laser per 300,000 population.

In 1995, the *Collège des médecins du Québec* proposed guidelines for excimer laser surgery. Its report discusses ethical issues, sets out patient selection criteria, proposes advertising and record-keeping standards, explains certain aspects of quality professional practice, and provides a sample informed consent form.

Except in very specific and limited cases, refractive surgery is not an insured service, since it is performed essentially for esthetic reasons, as refraction problems are, at the present time, adequately corrected with glasses or contact lenses.

### *Conclusion*

Since 1988, hundreds of thousands of people worldwide have undergone photorefractive keratectomy, and this number can be expected to grow steadily, given that a quarter of the world's population is myopic. This technology has thus undergone very rapid diffusion, even if this type of excimer laser refractive surgery is still, in several respects, at the experimental stage. Different countries have or are considering adopting regulations requiring that excimer lasers be approved before they can be marketed, such approval being or to be based on the assessment of experimental prototypes.

Our assessment of photorefractive keratectomy indicates that it can successfully correct myopia and astigmatism and that a very large percentage of patients say they are very satisfied with the procedure. However, a significant proportion also experience adverse effects, such as night glare. Many patients, especially among those who are highly myopic, will not achieve the desired correction, and some will even experience a decrease in best corrected visual acuity. Lastly, recent studies suggest that damage can be caused to the deep corneal layers, and it is still not known if it can eventually lead to vision problems.

Like other health technology assessment agencies or panels of experts, we conclude that excimer laser photorefractive keratectomy does not constitute a medical necessity. It is an irreversible procedure associated with certain risks and is usually performed for mainly esthetic reasons. Anyone considering excimer laser surgery to correct his myopia or astigmatism should compare it with glasses or contact lenses, for these alternatives are extremely effective and are not associated with the complications observed with photorefractive keratectomy.

We consider excimer laser photorefractive keratectomy for the treatment of myopia and astigmatism to be an innovative technology, that is, a technology that has passed the experimental stage and whose efficacy has been established, but about which there are some important questions that are still unanswered. Specifically, for patients with higher degrees of myopia (about -6.00 diopters or more), our knowledge is less complete than for patients with lower degrees of myopia.

Different aspects of photorefractive keratectomy should be the subject of thorough assessments or research in clinics and at universities, such as short- and long-term patient satisfaction, the effect of the procedure on the eye's optics and on vision quality, the surgical indications for and limitations of the technique in high myopes, and the long-term effects on the eye and vision, including the effects on the deeper corneal layers. Excimer

laser photoablation is, in fact, one of the research sectors of the *Réseau en santé visuelle du Québec*, which was created in 1995. Lastly, the example of this technology shows that all new technologies, as long as they are said to be experimental or innovative, would need to be subjected to a systematic assessment before they are disseminated on a larger scale.