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Excimer laser refractive surgery: a review

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Summary

Refractive errors are very common on general population, and currently all of them respond acceptably well to surgical correction within a certain magnitude range. As more and more patients are drawn to that idea the influence of those procedures will increase. Photorefractive laser surgery has become one of the most used alternatives. Corneal reshaping is achieved in photorefractive surgery using excimer laser tissue ablation to modify the shape of this organ. Photorefractive keratectomy (PRK) and laser assisted in-situ keratomileusis (LASIK) are photorefractive techniques. In this paper, using MEDLINE to find the bibliography and then analyzing it, the historical background was reviewed and an overview of the current clinical and research status of the refractive surgery is provided. Moreover our current LASIK surgical criteria and technique are shown *[Galvis V, Tello A, Aparicio JP. Excimer laser refractive surgery: a review. MedUNAB 2007; 10: 99-105].*

Key words: Excimer, Laser, Refractive surgery, LASIK.

Resumen

Los defectos refractivos son muy comunes en la población general, y actualmente todos responden aceptablemente bien a la corrección quirúrgica dentro de cierto rango de magnitud. A medida que más pacientes son atraídos por esta idea, la influencia de estos procedimientos se incrementará. La cirugía fotorrefractiva con láser se ha convertido en una de las alternativas más empleadas. El cambio de la forma de la córnea se logra en cirugía fotorrefractiva por medio de la ablación de tejido con un excimer láser. La queratectomía fotorrefractiva (PRK por sus siglas en inglés) y la queratomileusis asistida con excimer láser (LASIK por sus siglas en inglés) son técnicas fotorrefractivas. En este artículo, empleando MEDLINE para encontrar la bibliografía y luego analizándola, se revisó la historia de la cirugía refractiva. Mostramos asimismo un panorama general del estado actual, clínico e investigativo, de la cirugía refractiva. Además indicamos nuestros criterios quirúrgicos vigentes en LASIK así como nuestra técnica quirúrgica actual en este procedimiento. *[Galvis V, Tello A, Aparicio JP. Cirugía refractiva con excimer laser: una revisión. MedUNAB 2007; 10: 99-105].*

Palabras clave: Excimer, Laser, Cirugía refractiva, LASIK.

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Introduction and historical background

Since vision is one of the senses which bring more information about the environment to the brain, and its malfunction noticeably affects quality of life, visual alteration and blindness have been always a crucial concem for humankind. However, initial studies of refractive errors only began in the sixteenth century when Leonardo da Vinci began to reflect their possible causes.[1,2] More than three centuries later, following the development of physiologic optics and methods of achieving objective measurements of ocular parameters, alternatives of correction of those natural ammetropias and for post-cataract surgery refractive errors were proposed. In 1869, Snellen published an article proposing the use of corneal incisions across a steepest meridian to correct astigmatism.[3] Schiotz in 1885 published the firsts reference to a partially successful keratotomy made in a postoperative cataract patient.[4] It was followed by the publication of two series of cases independently by Bates and Lucciola[5, 6] but it was Lans, in 1898, who investigated the effects of corneal relaxing incisions to correct refractive errors in a more methodical way and described corneal steepening by use of thermal cauterization on rabbit corneas.[7, 8] Lans in his article about non penetrating incisions estalished much of the basic principles of the radial and astigmatic keratotomies.

In the XX century, Sato in Japan, in the 1930s, observed corneal flattening in keratoconus eyes with previous steep and thin corneas, which developed hydrops (rupture of the Descemet membrane with subsequent hydration of the stroma) and thought that breaks in Descemet's membrane might play a role in that flattening, so he attempted to treat keratoconus creating breaks in Descemet's membrane with posterior incisions.[9] Later he experimentally developed a model with both anterior and posterior corneal incisions to treat myopia, and transferred it directly to humans.[10] In that time the importance of the corneal endothelium integrity in maintaining the corneal transparency, currently a well known principle, had not been discovered. Eventually, due to the endothelial damage, his patients developed bullous keratopathy.[11, 12]

Several decades later, Fyodorov developed an anterior approach for the radial keratotomy which became popular worldwide.[23] The rationale of this approach was based in that the incisions made the peripheral cornea to become steeper, making the central cornea flatter (figure 1). However radial keratotomy has shown long term instability and lower degree of predictability than excimer laser surgery and because of that nowadays is considered an obsolete procedure.[14]

Parallel to the development of incisional techniques in Russia, since the 1950s, Barraquer had been working in Colombia in techniques based on the principles of his "Law of thickness" that is: to flatten the cornea tissue must be removed from the central cornea or added to the peripheral cornea, and to make the cornea steeper tissue must be subtracted from the periphery or added to the center.[15] If we want to correct a myopia, which has the focus in front of the macula, we need to subtract dioptric power from the cornea, moving the focus posteriorly to the retina. For hyperopic cases it is needed to increase the dioptric power of the cornea, moving the focus anteriorly. Following those principles he developed the myopic keratomileusis (subtracting tissue) and the keratophakia (adding tissue) for hyperopia, giving birth to a new era in refractive surgery: the lamellar refractive surgery.[16] Initially he developed a manual microkeratome to cut a corneal free cap, which he freezed and lathed using a contact lens lathe and then sutured back in the stromal bed. Later, in 1987, Ruiz in Bogotá, developed the automated microkeratome and designed the automated lamellar keratectomy (ALK).[17, 18] The usage of an automated microkeratome provided a way to get more reproducible corneal flaps, avoiding the necessity of freezing the corneal tissue and made the popularity of those techniques increased.

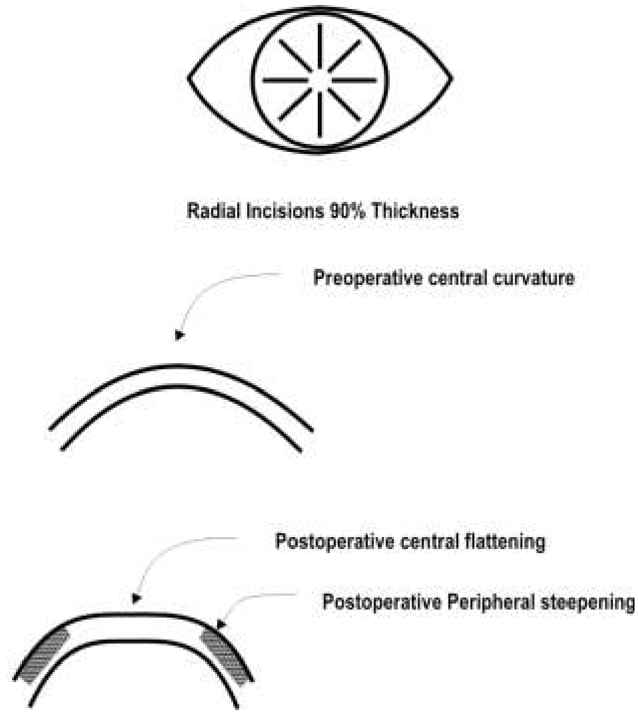

Figure 1. Radial keratotomy: the peripheral cornea becomes steeper, making the central cornea flatter. Radial keratotomy has shown long term instability and lower degree of predictability and nowadays is considered an obsolete procedure.

In regard to Excimer laser, it was originaly used for etching silicone computer chips in the 1970s. Laser stands for Light Amplification by stimulated Emission of Radiation, i.e. a coherent narrow beam of light (of a very small band of wavelengths) that has very high energy originated by radiation. This condition contrasts with common light sources, such as the incandescent light bulb, which emit incoherent photons in almost all directions, usually over a wide spectrum of wavelengths.The word "excimer" is a contraction of "excited dimer," a dimer being a diatomic molecule of an inert gas whose halogen atoms are bound in the highly charged (excited) state, temporary and unstably. This condition is achieved when exposing the gas to a high voltage electric current. This diatomic molecule emits highly energized photons of ultraviolet light as it separates and returns to the ground state, in this way generating the laser (figure 2). Seemingly, in an independent way two physicists (Taboada,[21] working at Brooks Air Force Base in San Antonio -U.S.A.- in 1979, and then Srinivasan,[22] at IBM's T.J. Watson Research Center in 1982) saw the potential of the Excimer laser in interacting with biological tissue. Trokel and Srinivasan in 1983, reported using the process of ablative photodecomposition with the ultraviolet (193 nm wavelength) argon fluoride (ArF) excimer laser to remove corneal tissue in a series freshly enucleated cow eyes, showing that adjacent tissue suffered no thermal damage and the stromal lamellae adjacent to the incision showed no evidence of disorganization.[22] Initially the laser was used to experimentally replicate the radial keratotomy incisions,[23] but on the other hand, since 1.986 an engineer, Munnerlyn, who had been studying about the direct reshaping of cornea's central optical zone using tissue ablation on an extensive area, coined the term "photorefractive keratectomy", which consists in scraping off the corneal epithelium

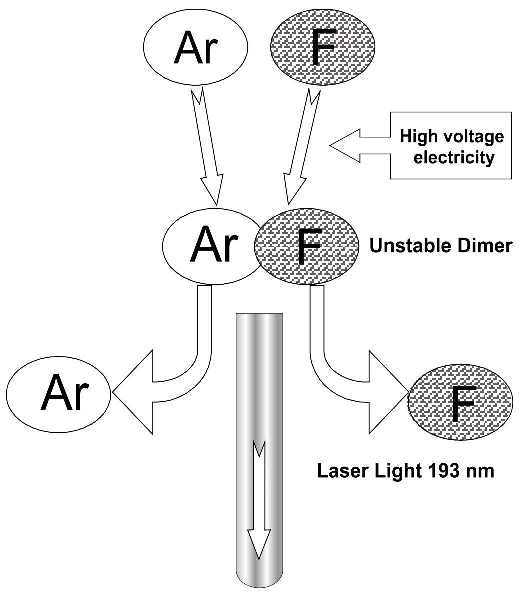

Figure 2. A dimer is a diatomic molecule of an inert gas whose halogen atoms are bound temporary and unstably when exposing the gas to a high voltage electric current. This Diatomic molecule emits Highly energized Photons of ultraviolet light as it separates and returns to the ground state, in this way generating the Laser.

and applying the laser on the Bowman´s membrane.[24] In 1988 he published an article showing the principles of photorefractive keratectomy (PRK) and his famous formula, based on geometric equations for changing the surface curvature, assuming the cornea as spherical in shape, which was the base for calculations of tissue subtraction in refractive surgery.[25]

Marguerite McDonald using excimer systems designed by Munnerlyn conducted the first tissue removal experiments on monkeys,[26] later in blind human eyes[27] and finally, under an FDA investigational device exemption, performed the first PRK on a sighted eye in 1987.[28]

The combination of these laser technologies and the lamellar procedures, which had been developed in Colombia, was done by Pallikaris in Greece who, in 1990, published the results of combining the principles of the laser PRK and those of the lamellar ALK surgery of Barraquer and Ruiz, and described what he called the laser in situ keratomileusis (LASIK).[19,20] By performing the laser ablation under a corneal flap containing epithelium, Bowman´s membrane and superficial stroma, he could make the healing process faster and more predictable.[29] Another technique developed almost simultaneously by Buratto, in Italy, included performing the ablation in the undersurface of a free corneal disc,[30] but the Pallikaris technique had superior features which allowed it to spread all over the world.

The LASIK technique has been kept basically unchanged during the last 17 years, but laser technologies has evolved a lot. Moreover the way to create the corneal flap currently includes in addition to the use of mechanical microkeratomes, the alternative of employing the femtosecond (ultra fast) laser which, according to some studies, could be more predictable in terms of flap regularity and safety[31] and may diminish the re-treatment rate.[32] However, other studies have not shown significant differences in the visual outcomes between mechanical microkeratomes and creation of the flap using the femtosecond laser.[33]

Lasik predictability factors

Current safety and efficacy. Refractive surgery procedures have progressively increased their efficacy and safety, and that in turn has caused patients' expectations to grow. All the factors that may influence in the final visual outcome are being intensively analyzed. In terms of safety and efficacy several studies have proven that LASIK is better than PRK,[34] although surface ablation using new techniques, like laser epithelial keratomileusis (LASEK)[35,36] and Epi-LASIK,[37,38] has shown to have similar outcomes. LASEK is a variation of PRK, a trephine is used to mark a rounded area of epithelium that then is exposed to a diluted alcohol solution so that it loosens the edges of the epithelium, and the epithelial layer is lifted and folded back using a spatula. Epi-LASIK has a similar principle, but uses a device similar to a microkeratome, in order to create just an epithelial sheet without including corneal stroma. Although, for standard cases LASIK is still the preferred procedure, as it has been during the past 17 years, those new surface procedures are gaining popularity for special cases, as in patients with thin corneas.[39, 40] The risk of complications has always been low in LASIK, but it is significantly less and results are better in currently applied techniques than some years ago due to advances in the surgical technique, better selection of candidates, improvements in the microkeratomes and in laser's performance (including better eye-tracking systems and improved ablation profiles) and the advent of the clinical use of wave-front customized ablations.[40-42]

Factors influencing early refractive outcomes. Excimer laser surgery is a subtraction procedure, i.e. it removes corneal tissue in order to change the power of the cornea. It follows the principles of the Barraquer's "Law of thickness",[15] i.e. it removes central tissue to correct myopia and removes peripheral tissue to correct hyperopia. The change in the refractive power of the cornea is based in mathematical calculations and the fundamental model was developed by Munnerlyn who stated that the depth of the ablation (in microns) per diopter of refractive change is equal to the square of the optical ablation zone measured in millimeters, divided by three.[25] This formula, modified according with empirical experience (which gave birth to the so called refractive surgery nomograms) has been relatively successful in correcting refractive errors for the majority of patients treated up to date. However, in this formula the cornea is modeled as a sphere and its behavior considered as if it was a piece of plastic being sculpted.[43,44] Currently different lasers use slightly different formulas and ablation patterns.[45] Several patterns have been designed and laser beam profiles have also suffered changes during the last years, passing from a broad beam to a smaller diameter, higher speed flying spot, usually with a gaussian profile in an intent to get a smoother corneal surface following the ablation. Last generation systems like MEL-80® (Carl Zeiss - Germany) that we are currently using have this feature.

Moreover, not only the visual acuity, but also the quality of vision has become more important in modern refractive surgery results, and in modern patient's satisfaction, so it was a necessity to develop aberration-reducing ablation profiles. When measuring a refractive error the examiner can take in account not only the so called "low order" aberrations, i.e. the spherical and cylindrical errors (like myopia, hyperopia and astigmatism), but also the so called "higher order" aberrations, which includes the spherical aberration, coma and others of less clinical significance. The use of wavefront-guided customized ablations has shown promising results. To measure these aberrations the aberrometers are employed. The WASCA® aberrometer, which is linked to the MEL-80® system, is the one with the higher resolution available,[46] and let us quantify these aberrations and then to input that information into the laser to treat them. This is very important in cases of distorted corneas, as those with previous surgery.

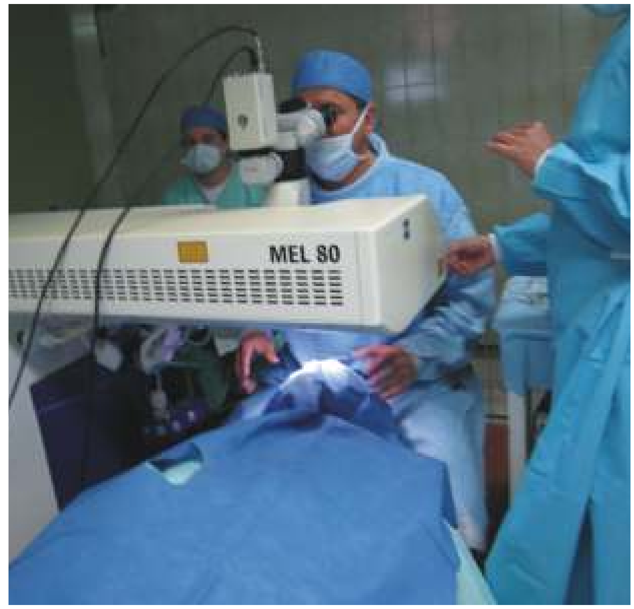

Figure 3. The MEL 80® excimer laser system possesses a 0.7 mm flying spot beam, with a pulse frequency of 250 Hz, permitting an optimized beam fluence/shot distribution pattern. In addition it has an active dual eye tracker system to assure centration.

Currently we are using the MEL 80® laser system (figure 3). This equipment features a 0.7 mm diameter flying spot beam, which can be used to translate any designed ablation pattern onto the cornea. Its pulse frequency is 250Hz, permitting an optimized beam fluence/shot distribution pattern in order to avoid overheating of the corneal tissue. Since the treatment must be centered in the visual axis, and kept in that centration along the whole treatment period (usually less that one minute), it is necessary to employ an active eye tracker system. MEL 80® has a dual (pupil and limbus) tracker, with a high acquisition frame rate (250 Hz) and short feedback time (6 ms). As explained before, it also offers the options of standard treatments or, based on ocular wavefront data, using a high resolution aberrometer (WASCA®). Moreover in highly aberrated corneas the high resolution topography system (ATLAS®) capture the data from the cornea and a specialized software program (CRS-MASTER®), analyzes the best fit toric surface for that cornea in order to regularize it. This is the topography smooth option, also available with the MEL 80® system.[47]

Patient selection

Adequate patient selection is critical in excimer laser refractive surgery. Several characteristics may make a patient not

Figure 4. The automated microkeratome contains an oscillating blade that will perform a lamellar cut of 130 to 160 microns.

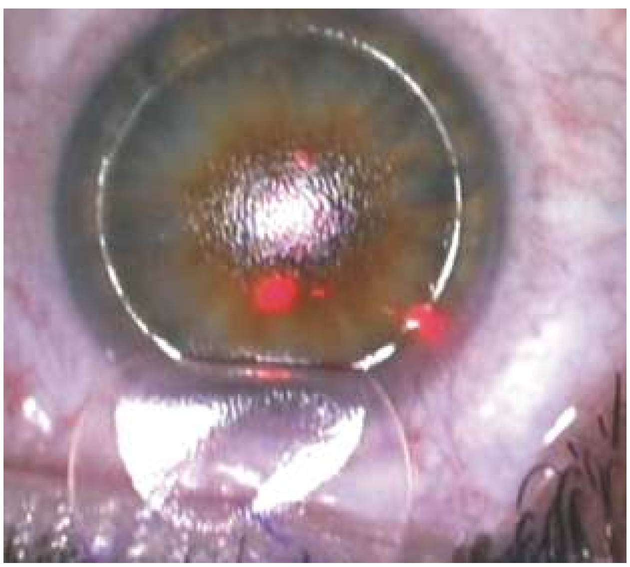

Figure 5. The corneal flap created with the microkeratome is folded back, and on the exposed stroma the laser is applied.

a good case for LASIK, so it is crucial to determine who is suitable for surgery and, more importantly, who is not. Every day it is more evident that patients with keratoconus are not good candidates for LASIK, so every effort must be done to discover them. Currently it is known that high refractive errors have a higher incidence of under or overcorrections, and late regression of the defect. [50]

Long term stability of modern LASIK seems to be related with preoperative refractive error magnitude. A study in moderate myopic patients (mean preoperative spherical equivalent -4.85 diopters) showed that 5 years postoperatively 60% of eyes were within plus or minus 0.5 D of attempted correction with 83% within plus or minus 1.0 D; 89% of eyes had a vision of 6/12 or better at 5 years. Best spectacle corrected visual acuity (BSCVA) was unchanged

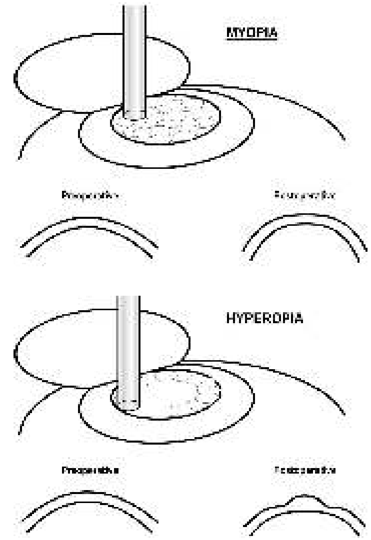

Figure 6. The laser removes tissue to change the shape of the anterior surface of the cornea, according to the pattern designed by the computer: in the central area to flatten the cornea and correct myopia and in the peripheral area to make the central cornea steeper and correct hyperopia.

or improved in 51%. No eye lost more than one line of BSCVA. Overall, there was regression towards myopia with a mean change in refraction of -0.5 D over the 5 years. As expected, severely myopic patients regressed more with a mean change of -1.06 D.[48]

In hyperopia the stability behavior is similar having poor long-term stability in cases higher than +4.50 or +5.00 D, although the most recent technologies show better results.[49]

Using the current technology our indications for LASIK are:

- Myopia between -0.50 and around -7.00 D (occasionally in myopias up to 9.00 D if cornea thickness is enough to leave a undisturbed posterior thickness thicker than 250 microns, using an optical zone of at least 6.00 mm).
- Hyperopia up to + 5.00 D. In cases up to + 6.50 D the patients is warned about the possibility of regression.
- Astigmatisms: cylinders up to 6.00 D.

In cases with higher refractive errors we are offering our patients the alternative of intraocular phakic lenses or refractive phacoemulsification of the crystalline lens and implantation of an intraocular lens in the posterior chamber, according to the patient's age.

Surgical technique

After using a lid speculum to hold the eyelids, and using anesthetic eye drops, some reference marks are made in the cornea. Then the suction ring of the microkeratome is applied to the eye which will hold it firmly while passing the microkeratome´s head. This head contains an oscillating blade that will perform a lamellar cut of 130 to 160 microns thick (figure 4), creating a corneal flap, which remains attached to the eye by a hinge. The flap is folded back, and laser energy is applied on the exposed stroma, after treatment centration and activation of the eye tracker system (figure 5). The laser will remove the tissue to change the shape of the anterior surface of the cornea, according to the pattern designed by the computer (figure 6). The flap is replaced with no need for stitching, and it will re-attach due to attractive forces of the corneal tissue. The whole procedure takes about 15 minutes for both eyes. Usually vision will be blurred for several hours, but will improve over the next day.

The possibility of having a full correction of the refractive error varies according with the amount and the kind of previous ammetropia, but in general in our experience it is between 92 and 97%.

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