LASIK RESULTS OF INTRALASE FEMTOSECOND LASER TO CORRECT MYOPIA: EFFICACY, SECURITY AND PREDICTABILITY

RESULTADOS DE LASIK REALIZADO CON LÁSER DE FEMTOSEGUNDO (INTRALASE) PARA CORRECCIÓN DE MIOPÍA: EFICACIA, PREDICTIBILIDAD Y SEGURIDAD

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ABSTRACT

Purpose: To evaluate LASIK results obtained with the IntraLase femtosecond laser to correct myopia.

Methods: This was a prospective, single masked observer study. Flaps were created with the IntraLase femtosecond laser (FS). All laser procedures were performed by the same surgeon using the Technolas 217 excimer laser (Bausch & Lomb). We have analysed the uncorrected visual acuity (UCVA) at 1 day, 1 week, 1 month and 3 months after surgery and best spectacle-corrected visual acuity (BSCVA) after 3 months.

Results: 485 eyes with myopia were treated and their results evaluated. The mean preoperative sphere was of –3.9 D (SD 2.0) and a mean astigmatism of –0.9 D (SD 0.9) with BSCVA 1.1 (SD 0.1). The UCVA results were 0.94 (SD 0.1) at the first day postoperatively visit, 0.96 (SD 0.1) at first week, 1.00 (SD 0.1) at one month and 1.00 (SD 0.2) at 3 months. The refractive error at 3 months was -0.02 D (SD 0.3) and -0.1 D (SD 0.3) of myopia and...

RESUMEN

Objetivo: Evaluar los resultados refractivos del LASIK utilizando láser de femtosegundo (Intralase) para tallar el colgajo corneal, en la corrección de miopía.

Métodos: Se trata de un estudio prospectivo, observador enmascarado. Los colgajos fueron tallados con láser de femtosegundo (IntraLase). Todos los procedimientos láser fueron realizados por el mismo cirujano utilizando el láser Technolas 217 (Bausch & Lomb). Se evaluó la agudeza visual sin corrección (AVsc) al primer día, semana, primer y tercer mes después de la cirugía, así como la agudeza visual mejor corregida (AVCC) a los tres meses de la cirugía.

Resultados: Evaluamos los resultados refractivos de LASIK en 485 ojos miopes. El defecto refractivo previo era de –3,9 D (DE 2,0) esfera y de –0,9 (DE 0,9) cilindro con una AVCC inicial de 1,1 (DE 0,1). Los resultados de la AVsc fueron de 0,94 (DE 0,1) al primer día postoperatorio, 0,96 (DE 0,1) a la...
INTRODUCTION

The Laser In Situ Keratomileusis (LASIK) technique is the preferred surgical process for the correction of refractive error (1) thanks to its rapid visual recovery and minimal post-operative discomfort. This is due, in large part, to the creation of a corneal flap that is created through a mechanical microkeratome which in turn raises various concerns, like exactitude and the reproducibility of its thickness, in addition to subsequent complications derived from the creation of the flap (2). The exactitude and prediction of the thickness of the flap have been evaluated in the vast majority of the available mechanical keratomes (3-5), together with the refractive results obtained by LASIK using these microkeratomes.

Despite all the good results obtained, technical innovations have been sought to equal or improve the refractive results and the creation of the flap, thus avoiding most of the complications.

The IntraLase or Femtosecond (FS) laser is the first major alternative to a mechanical keratome that has been commercially introduced for the creation of the flap during LASIK (6).

In published studies, a potential reduction has been shown in surgical complications associated with the creation of the flap, such as flaps in the form of buttonholes, incomplete flaps, and DLK, as well as a high degree of exactitude and previsibility in the parameters of the flap (7,8).

Key words: LASIK, IntraLase, results, efficacy, predictability and security.

In this prospective study, we evaluate the efficacy, predictability and security of the LASIK technique using the Femtosecond laser for the creation of the flap in 485 human eyes with a follow-up period of 3 months.

SUBJECTS, MATERIAL AND METHOD

A observer-blind prospective study was performed on a total of 485 eyes subjected to refractive surgery for the correction of myopic gradation defect through the LASIK technique using the Femtosecond Laser (IntraLase) for the creation of the flap.

All patients were subjected to a complete ophthalmological examination that included: subjective refraction and and refraction under cycloplegia, topography with an Orbscan IIZ topographer (Bausch&Lomb, Rochester, NY, USA), contact pachymetry DGH 5100 pachymeter, applanation tonometry, pupillometry measured in mesopic conditions with a Colvard type pupillometer (Oasis) and biomicroscopy.

Following surgery, spontaneous visual acuity (VA) was tested, always by the same examiner, after one day, one week, one and three months, with the results expressed on a decimal scale. For this study moreover the VA results with correction at 3 months were considered.

The initial surgical technique was as follows: cleansing of the skin with povidone iodine, eyelash...
isolation, placement of blepharostat, cleansing with balanced saline solution and marking with gentian violet.

On the IntraLase, the suction ring was subsequently put in place, centered on the cornea, until sufficient suction was achieved. Then the cornea was planaplaned by the planaplanation system, eliminating the entire lachrymal meniscus, performing the flap creation procedure. The raising of the flap was delayed 10 minutes, to avoid possible bubbles appearing on the interface. After this time we proceeded with photoablation, after which the stromal bed was bathed in balanced saline solution and the flap was then recentered in its original location. Subsequently we proceeded to drying with haemostats. We also proceeded to dry the incision with haemostats, and the procedure was concluded after verification of the correct adherence of the flap.

The flap parameters introduced in IntraLase for all patients had a programmed flap thickness of 110 microns, a programmed hinge angle of 50 degrees, and the localization of all the hinges was performed with a superior approach. The laser used for photoablation was in all cases the Technolas 217C from Bausch&Lomb, and the same nomogram was adapted for each patient. All the surgeries were performed by the same surgeon.

As post-operative treatment, EXOCIN (ofloxacin) 1 drop was administered 4 times a day and MAXIDEX (dexamethasone [DCI]) 1 drop 8 times a day was administered during one week prior to suspending treatment.

The statistical analysis was performed using the program: «Statview SE+ graphics»™ (Abacus Concepts Inc., Cupertino, Calif., USA).

RESULTS

A total of 485 eyes have been included in this study. The average age was 33.4 years (SD 6.0) (range 19-52 years). The spherical refraction prior to the operation was -3.9 D (SD 2.0) (range 0 to -11D) and cylindrical refraction -0.9 D (SD 0.9) (range of 0 to -4.75 D). The best corrected visual acuity (BCVA) was an average of 1.1 (SD 0.1) (range of 0.1 to 1.25) (94.85% of the eyes had BCVA > 0.8 and 87.62% BCVA = 1.0). The optical area used was 6.2 mm (SD 0.3) (range of 5.5 to 7 mm).

Efficacy

The evolution of visual acuity uncorrected visual acuity (UVCA) after surgery is shown in Figure 1 while the percentage of eyes that reached UCVA > 0.8 and UCVA ≥ 1 is indicated in Figure 2. The efficacy index was 0.92.

Predictability

Spherical refraction 3 months after surgery was -0.02 D (SD 0.3) and -0.1 D (SD 0.3) for myopia and astigmatism respectively, with which a CVA of

**Fig. 1:** Evolution of uncorrected visual acuity (UCVA) after LASIK with IntraLase the following day, after 7 days, 1 month and 3 months.

**Fig. 2:** Percentage of eyes that reached UCVA >0.8 and UCVA #> 1 (uncorrected visual acuity after LASIK the following day, after 1 week, 1 month and 3 months.)
1.06 was reached. The predictability results at 3 months are indicated in figure 3.

Security

The change in CVA in Snellen lines is shown in Figure 4.

The security index for these patients was 0.97.

The number of repeat treatments needed was of 35 eyes, which is equivalent to 7.2% of the eyes operated on.

No intraoperative (loss of suction) or postoperative complication (diffuse lamellar keratitis) was observed with the flap in any patient, during the initial creation of the flap or its subsequent raising and the excimer treatment. One eye presented an epithelial growth (0.2%), without requiring further surgery for its correction.

DISCUSSION

The recent incorporation of the Femtosecond laser for the creation of the flap in LASIK seems to offer the same safety and efficacy as the microkeratome when it comes to creating the flap, in terms of thickness and dimensions (7.8).

The objective of this study has been to evaluate the efficacy, predictability and safety of LASIK surgery using this new technique of flap creation, in 485 human eyes with myopia and myopic astigmatism.

Our study shows that UCV A improves rapidly, reaching values of 1.0 one month after surgery and maintaining these after three months. At three months post-surgery we have obtained 85.36% of eyes with a UCVA > 0.8 and 69.27% of the eyes presented a UCVA = 1. Thus we find that the postoperative UCVA was similar to BCVA before the operation. The percentage of eyes that reached a UCVA = 1 in the check-up the following day (62.26%) was within the percentages obtained by Kezirian (45%) (8) and Durrie (73%) (9). In the review after one week, 68.66% of the LASIK cases in our study reached UCVA = 1 as opposed to 88% in the paper by Durrie. And this UCVA = 1 was reached at the one-month visit by 67.21% of the LASIK patients opposed to 96% of those of Durrie and 82.1% of Lim (10), while in the revision at 3 months our data (69.27%) is again in line with those obtained in other studies: 67% from Kezirian and 78.6% from Lim. It should be pointed out that in different works, the number of eyes and the initial spherical equivalent as well as the percentage of eyes that reached BCVA = 1 before surgery were different.

The percentage of eyes that deviated less than ±1.00 D of the calculated correction was 96.90% and for ± 0.50 D was of 93.60% at 3 months. Kezirian et al found that 99% of eyes deviated less than ± 1.00 D at 3 months, while for ± 0.50 D this data was 91%. Equally Durrie finds that 90% of eyes deviated from ± 0.50 D.

In our series the average postoperative refracton was -0.02 D (SD 0.3) of myopia and -0.1 D (0.3) for astigmatism at three months, similar to that found by Lim in his work. The scarce value of postopera-
tive refraction that we have found is indicative of the stability of the refractive results.

The refractive stability of this technique has been confirmed by other authors, who didn’t find an important loss of BCVA, meaning that the IntraLase technique has the same security and efficacy as the technique with microkeratome. Thus we find that in the study from Kezirian et al. (8), at three months of the surgery, 2% lose 2 lines, 16% 1 line, while 51% maintain their BCVA and 33% improve 1 line, data very similar to those that Nordan et al. (11) find with a follow-up period of 6 months (3% lose 2 lines, 10% 1 line, 58% maintain their BCVA and 24% improve 1 line). Ratkay-Traub (12) find that, 6 months after LASIK treatment, the percentage of eyes that lost 1 line of BCVA was 6.9%, 41.8% maintained their BCVA, while 27.9% gained 1 line, 13.9% two lines and 9.2% 3 or more. The data obtained in our study confirm these results, with our study showing the highest percentage of eyes that maintain their BCVA after surgery, with a percentage of lines lost within the range found in the papers cited, with the difference that our sample was larger than those of both the other studies.

A percentage of 7.2% of the eyes operated on needed further treatment to correct residual refractive error, a percentage similar to, though somewhat less than, those reported by Farah et al. in a revision of the literature (8.2% to 17.5%) (13) while Hersch et al., in a more recent study, present a 10.5% incidence of secondary surgery (14).

The majority of published articles on IntraLase compare the results of LASIK obtained by the Femtosecond laser with those obtained using conventional microkeratomes (8-10,15). Nordan et al. and Ratkay-Traub present refractive results in LASIK performing the lamellar drilling with a Femtosecond laser; in any case, all these studies present fewer eyes studied than those in this article. Future comparisons are necessary between the results obtained with IntraLase as opposed to those obtained with mechanical Microkeratome, with a larger number of eyes, or similar to that studied here.

Other articles only discuss the flap parameters obtained with IntraLase and its comparison with those obtained with actual microkeratomes, without reflecting the refractive results obtained in both groups (7).

At the time of performing the flap, suction was not lost in any of the 485 eyes, unlike other studies, where suction loss was encountered (11,12).

We have not observed any epithelial invasion of the interface on the border of the flap, save for one eye, without interfering with the central optical zone. Other authors have other types of important complications with this technique such as DLK (15), the presence of bubbles in the anterior chamber (16), severe light sensitivity disorders (17)… In our study none of these complications was present.

Our study shows that LASIK using the Femtosecond laser or IntraLase for the creation of the flap is an effective technique in the correction of myopia, entails a rapid recovery of eyesight, has great predictability and safety and the refractive results obtained are stable for more than a month. To confirm that these favourable conclusions for the Femtosecond laser or IntraLase are related to a greater visual quality, more studies and a longer time frame are necessary to define the role of IntraLase in refractive surgery, even though preliminary studies are expected.

REFERENCE


