

Fluency of laser and surgical downtime, loss of fixation, as factors related to the precision refractive

Fluência do laser e tempo de parada cirúrgica, por perda de fixação, como fatores relacionados à precisão refracional

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ABSTRACT

Objective: To evaluate the correlation of flow and stopping time intraoperative loss of attachment factors as hypertension or hipocorreções of refractive errors after Lasik. **Methods:** The age ranged between 19 and 61 years (mean= 31.27 ± 9.99). The minimum follow-up period was 90 days. Individuals with: corneal topography preoperative maximum keratometry greater than 46.5D or presence of irregularities, corneal curvature postoperative simulated smaller 36.0D, pupils more 6mm; corneal thickness smaller 500 µm; Myopia more -8.0, hyperopia more +5.0DE and astigmatism more -4.0DC. The laser was used with Esir Schwind Eye-Tracking and 350Hz scanning spot of 0.8 mm. The microkeratome used was the Moria M2 with programming 130µm thick. **Results:** The visual acuity logMAR preoperative correction ranged from 0.40 to 0 (mean= 0.23 ± 0.69) and postoperative uncorrected 0.40-0 (x= 0.30 ± 0, 68). The Median= 0 logMAR for both time points (p= 0.424). For spherical equivalent before and after surgery, we found an obvious difference, with the pre (mean= -4.09 ± 2.83) and post (mean= -0.04 ± 0.38). The Median was -4.75 in the pre and zero postoperatively (p <0.0001). Sixty-nine cases (78.3%) were plano ± 0.25. Fluency minimum= 0.513 mJ/cm² and maximum= 0.581 mJ/cm² (mean= 0.545 ± 0.01), no correlation (r = -0.03266, 95% CI -0.241 to 0.178, p = 0.762) between the flow and spherical equivalent (mean = -0.04 ± 0.38) in eyes operated. The minimal downtime during surgery was 02 seconds and maximum was 12 seconds (mean= 4.90 ± 3.47). Making a correlation (r = 0.08865, 95% CI = -0.123 to 0.293, p = 0.411) between the postoperative spherical equivalent and downtime during surgery, not perceived differences. **Conclusion:** There was no correlation between the fluency of the laser during surgery and downtime due to loss of fixation with hipocorreções in hyper-or post-Lasik ametropia.

Keywords: Keratomileusis, laser in situ; Refractive erros; Visual acuity

RESUMO

Objetivo: Avaliar a correlação da fluência e o tempo de parada transoperatória por perda de fixação, como fatores de hiper ou hipocorreções das ametropias pós-Lasik. **Métodos:** A idade variou entre 19 e 61 anos com média de 31,27 ± 9,99. O tempo mínimo de acompanhamento pós-operatório foi de 90 dias. Foram excluídos indivíduos com topografia corneana pré-operatória com ceratometria máxima maior que 46,5D ou presença de irregularidades; ceratometria média pós-operatória simulada menor que 36,0D; pupilas maiores que 6mm; paquimetria menor que 500 µm; miopia maior que -8,0DE, hipermetropia maior que +5,0DE e astigmatismo maior que -4,0DC. O laser utilizado foi o Esiris Schwind com Eye-Tracking de 350Hz e scanning spot de 0,8 mm. O microcerátomo utilizado foi o M2 da Moria com programação de 130µm de espessura. **Resultados:** A acuidade visual logMAR pré-operatória com correção variou de 0,40 a 0 com média de 0,23 ± 0,69; a pós-operatória sem correção foi de 0,40 a 0 com média de 0,30 ± 0,68. A mediana foi de 0 logMAR para os dois momentos (p=0,424). No equivalente esférico pré e pós-operatório, notou-se uma óbvia diferença (p< 0,0001), no pré-operatório com média de -4,09 ± 2,83 e o pós com média de -0,04 ± 0,38. A mediana foi de -4,75 no pré e de 0 no pós-operatório. Sessenta e nove casos (78,3%) ficaram plano ± 0,25. A fluência mínima foi de 0,513 mJ/cm² e a máxima de 0,581 mJ/cm² com média de 0,545 ± 0,01, não se percebendo correlação (r= -0,03266; IC 95% -0,241 a 0,178; p= 0,762) entre a fluência e o equivalente esférico final (média= -0,04 ± 0,38) nos olhos operados. O tempo mínimo de parada transoperatória foi de dois segundos e o máximo de 12 segundos com média de 4,90 ± 3,47. Fazendo-se uma correlação (r= 0,08865; IC 95%= -0,123 a 0,293; p= 0,411) entre o equivalente esférico pós-operatório e o tempo de parada transoperatória, não se percebeu diferenças. **Conclusão:** Não houve correlação entre a fluência do laser e o tempo de parada transoperatória por perda de fixação, com hiper ou hipocorreções nas ametropias pós-Lasik.

Descritores: Ceratomileuse assistida por Excimer laser in situ; Erros de refração; Acuidade visual

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Work conducted at the Ophthalmology Reference Centre, Ceará School of Ophthalmology, Fortaleza/CE, Brazil. Data collected at VISIONLASER.

O autor declara não haver conflitos de interesse

Received for publication: 8/11/2011 - Accepted for publication: 20/01/2013

INTRODUCTION

The Laser was created in 1960, and its first medical use in the area of ophthalmology occurred in the same decade⁽¹⁾. Pallikaris was the first to promote the removal of corneal stromal tissue with excimer laser to correct refractive errors⁽²⁾.

The use of excimer laser to correct myopia, hyperopia and astigmatism evolved in recent years, mainly due to the technological advancement of devices.

Laser-assisted in situ keratomileusis (LASIK) is still the most widely used technique; it is a painless, safe, and accurate method for treating refractive errors with quick recovery⁽³⁻⁵⁾. By preserving epithelial integrity in the central region of the cornea, it promotes a milder wound healing reaction. The healing response triggered by the laser and the creation of a flap are important to the safety and efficacy of the procedure. However, it is a significantly complex event⁽⁶⁾.

The literature reports great refractive stability from the 3rd month after surgery⁽⁷⁻⁹⁾. However, do intraoperative factors such as daily variations in laser fluence and interruptions during laser application due to loss of fixation influence the refractive outcome?

The aim of this study was to evaluate the correlation of laser fluence and intraoperative stopping time due to loss of fixation with over- or undercorrection of refractive errors after LASIK.

METHODS

We reviewed the medical records of 83 patients in a reference service in the city of Fortaleza, Brazil, in 2009, in order to assess the refractive accuracy of excimer laser in correcting myopia, hyperopia and astigmatism.

The study's protocol was approved by the Research Ethics Committee of the Integrated Faculty of Ceará (Of. No. 214/10).

Of the 83 medical records, 47 (56.6%) were considered eligible according to the aims of the study. We examined data such as gender, age, pre- and postoperative spherical equivalent (SE) and visual acuity (VA), preoperative corneal topography and pachymetry, laser fluence (mJ/cm²), and intraoperative stopping time due to loss of fixation.

A total of 88 eyes were evaluated among the 47 medical records, of which 31 (65.9%) were female and 16 (34.1%) were male. Patient age ranged between 19 and 61 years with a median of 29 years.

Preoperative refraction was assessed under cycloplegia after refractive stabilisation for at least three years. The refractive outcome was then evaluated 90 days after surgery.

Exclusion criteria for surgery included: a) Pre-operative corneal topography showing maximum keratometry higher than 46.5D or areas with irregularities; b) Average simulated postoperative keratometry lower than 36.0D; c) Pupils larger than 6mm; d) Pachymetry under 500 micrometres; e) Myopia greater than -8.0D, hyperopia greater than +5.0D, and astigmatism greater than -4.0D; f) Eyes in which, during the loss in fixation, the stromal bed had to be wiped.

The study used an Esiris Schwind laser with 350Hz eye-tracking and a 0.8 mm scanning spot. For the laser to operate within the desired standards of accuracy, a fluence of 0.555 nn, ranging from 0.495 to 0.605 nn, was considered adequate. A Moria M2 microkeratome with a 130µm head was used to create the flap. For myopia alone and myopia associated astigmatism a

Table 1

Nomogram for correction of refractive errors for the Esiris Schwind device

Hyperopia	Real diopter x 30.0%
Astigmatism	Real diopter x 25.0%
-1.00 to -2.00	Real diopter x 20.0%
-2.25 to -3.00	Real diopter x 15.0%
-3.25 to -4.00	Real diopter x 10.0%
-4.25 to -5.00	Real diopter x 5%
-5.25 to -6.00	Real diopter
-6.25 to -7.00	Real diopter x -5.0%
-7.25 to -8.00	Real diopter x -10.0%
-8.25 to -9.00	Real diopter x -20.0%

6-mm optical zone was used with a 1.25-mm transition zone (total ablation zone, 8.5 mm). For hyperopia alone and hyperopia associated astigmatism a 6.25-mm optical zone was used with a 1-mm transition zone (total ablation zone, 8.25 mm).

The operations were performed by a single surgeon who used the same intraoperative criteria for all eyes. After the blepharostat was placed, four markings were done in the corneal surface with gentian violet: a lower, an upper and two lateral marks. After creating the flap (with a medial pedicle), the upper and lower fornices were cleaned with a Merocel sponge to remove the excess liquid and then raised. After lifting the flap the stromal bed was dried with a Merocel sponge only once and then the laser was applied. The flap was then repositioned and the interface was cleaned with sterile ringer lactate using an appropriate cannula mounted on a 5ml syringe. Finally, the edge of the flap was dried with a Merocel sponge and a bandage contact lens was placed, being removed the next day.

A local nomogram was developed for the correction of refractive errors, initially based on existing nomograms for same device used in other regions of Brazil (Table 1). In the presence of astigmatism of spherical diopter, a 30.0% correction of the hyperopic effect of astigmatism was used.

Even though the literature shows no significant changes in pachymetry with age^(10,11), thus maintaining stromal hydration, at the end of the calculation for myopia and hyperopia 0.75 was subtracted in patients over 40 years, as we observed overcorrection upon improving the nomogram.

Postoperatively, antibiotic eye drops (4th generation quinolone) associated with prednisolone 1.0% were used. Artificial tears were prescribed only in cases of foreign body sensation or postoperative dryness.

Data were analyzed with SPSS version 15.0. To check for normal distribution of continuous data the Shapiro-Wilk test was used. In continuous data with non-normal distribution, the Wilcoxon test for paired samples was used. Bivariate correlation was used to assess the association between continuous variables. We adopted a significance level (p) of 0.05.

RESULTS

The minimum follow-up period was 90 days and the maximum was 402 days (median, 143 days). The minimum preoperative pachymetry was 500µm and the maximum was 629µm (mean, 547.23 ± 30.91). Regarding the mean preoperative keratometry, a minimum of 40.0D and a maximum 45.0D were observed (mean, 42.74 ± 1.25 D).

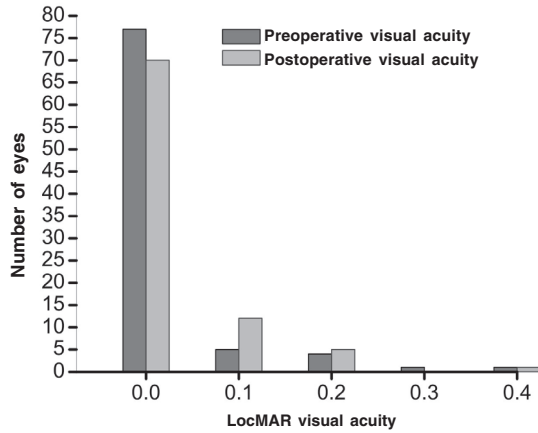


Figure 1 - Pre- and postoperative logMAR visual acuity in eyes submitted to LASIK

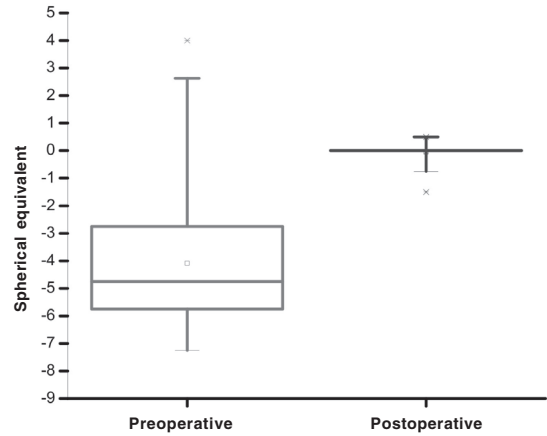


Figure 2 - Pre- and postoperative spherical equivalent in patients submitted to LASIK

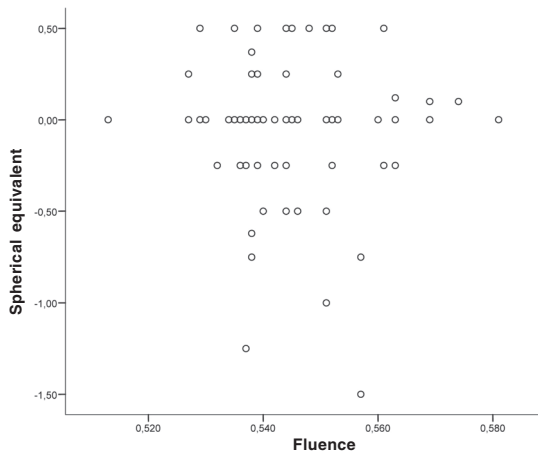


Figure 3 - Fluence of Isiris Schwind excimer laser (mJ/cm²) versus final spherical equivalent (SE) in each eye

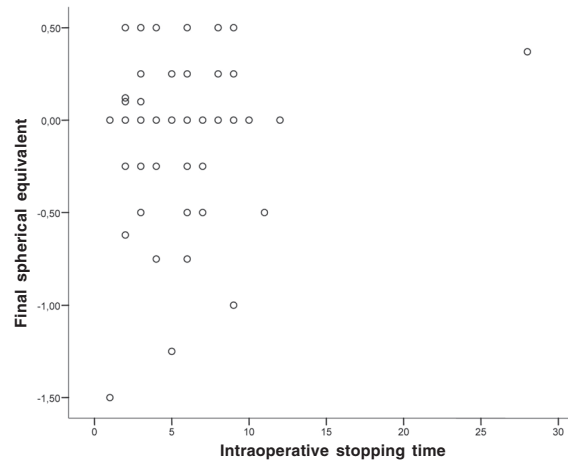


Figure 4 - Correlation between intraoperative stopping time due to loss of fixation and final spherical equivalent (SE) in each eye

The preoperative corrected logMAR VA ranged from 0.40 to 0, with an average of 0.23 ± 0.69 . The postoperative values ranged from 0.40 to 0, with an average of 0.30 ± 0.68 (Figure 1). The median logMAR was 0 for both time points, with no statistically-significant differences ($p = 0.424$).

Regarding pre- and postoperative SE, a clear difference was noted between the two time points ($p < 0.0001$), with mean values of -4.09 ± 2.83 and -0.04 ± 0.38 , respectively (Figure 2). Postoperatively, three (3.4%) cases showed undercorrection between -1.50 and -1.00, seven (7.9%) showed undercorrection between -0.75 and -0.50 and nine (10.2%) showed overcorrection of +0.50. The remaining 69 (78.3%) cases had a SE of 0 ± 0.25 .

The minimum observed fluence was 0.513 mJ/cm^2 and the maximum was 0.581 mJ/cm^2 (mean, 0.545 ± 0.012). Figure 3 shows that there was no correlation ($r = -0.03266$, 95% CI, -0.241 to 0.178, $p = 0.762$) between fluence and final SE (mean, -0.04 ± 0.38).

The minimum intraoperative stopping time due to loss of fixation was 2 seconds and the maximum was 12 seconds (median, 4.0 seconds). No correlation was found between postoperative SE and intraoperative stopping time ($r = 0.08865$, 95% CI, -0.123 to 0.293, $p = 0.411$) (Figure 4).

DISCUSSION

The literature reports refractive stabilisation 90 days after refractive surgery^(7,12,13,14). In our study, the minimum follow-up period was 90 days and the maximum was 402 days (median, 142 days) with no observed regression, even in cases of hyperopia. The cases of undercorrection (23.9%) were observed since the first days after surgery and thus were not considered as cases of regression.

According to the literature, the loss of lines of vision is more frequent in cases of myopia of moderate to high degree^(7,12). Despite the use of a centering mechanism (eye tracking)⁽¹⁵⁾, slight decentration may occur, predisposing to the loss of lines of vision. Decentration can occur in up to 6.5% of cases^(4,7,12) and may induce irregular astigmatism⁽¹⁶⁾. The experience of the surgeon and cooperation by the patient can help prevent decentration⁽¹⁸⁾. In our study, even though no statistical difference was found between preoperative corrected and postoperative uncorrected VA ($p = 0.483$), there was a trend towards a lower postoperative VA: 87.5% of eyes had a corrected VA of 0 LogMAR preoperatively, compared with 79.5% postoperatively; this was more common in hyperopic eyes (6.4%). Another factor that

contributed to the loss of lines of vision were striae, which were observed in 3.0% of operated eyes.

As in other studies^(18,19), a line of vision was gained in 11.5% of eyes compared to preoperative corrected VA. This was more common in myopic eyes, regardless of the degree of myopia. Laser devices have evolved significantly in recent years, and spot size has been decreasing in size, thus increasing the accuracy of the procedure and improving visual quality.

Despite the significant accuracy of laser devices, potential candidates should be informed about the possibility of under- or overcorrection. Despite the procedure's irreversibility, small adjustments can be made from the third month after surgery by elevating the corneal disc and performing photoablation of the cornea^(7,20,21). In our study, as was previously reported in the literature^(7,12,13,18,19), the correction of refractive errors of any type and magnitude proved accurate, provided adjustment was made using a nomogram (Table 1). Comparing the spherical equivalent pre- and postoperatively, a clear difference can be noted between the two time points ($p = 0.000$), with mean values of -4.09 and -0.04 , respectively.

Laser fluence reflects the amount of energy per area in a single pulse and it has a direct relationship with the amount of ablated stromal tissue⁽²²⁾. If the fluence is higher than the recommended value, overcorrection can occur; if it is lower, undercorrection is expected. In our study, despite daily fluctuations in fluence (minimum of 0.513 and maximum of 0.581 mJ/cm²), no correlation was found between fluence and final SE ($r = -0.03266$, 95% CI, -0.241 to 0.178 , $p = 0.762$) (Figure 3).

The hydrated corneal stroma has more separated lamellae, and water uptake is done by its constituent proteoglycans. Such a rearrangement, with intrinsic modification of the extracellular matrix, can alter the rate of corneal ablation, with loss of energy due to water destruction. On the other hand, dehydration makes the lamellae more compact, which can potentiate the treatment⁽²³⁾. Thus, intraoperative interruptions due to loss of fixation, with a greater exposure of the stromal bed to the environment, would lead to dryness and consequent overcorrection. In our study, the minimum intraoperative stopping time was 2 seconds and the maximum was 12 seconds. As shown in Figure 4, no correlation was found between postoperative SE and intraoperative stopping time ($r = 0.08865$, 95% CI = -0.123 to 0.293 , $p = 0.411$).

This study involved a specific brand of laser device, and the results should be restricted to the studied model.

CONCLUSION

No correlation was found between variations in laser fluence or intraoperative stopping time due to loss of fixation and over- or undercorrection of refractive errors after LASIK treatment.

Acknowledgements: Dr. André Messias (USP- FMRP)

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