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RESEARCH ARTICLE

Evaluation of Intraocular Pressure in Eyes After Femtolasik Surgery

João Leite*[,a], Bruno Ribeiro[a], Ana Carolina Abreu[a], Sílvia Monteiro[a], Ana Figueiredo[a], Rita Reis[a], Isabel Sampaio[a], Maria Céu Pinto[a], Maria João Menéres[a,b]

[a] Department of Ophthalmology, Unidade Local de Saúde de Santo António, E. P. E, Oporto, Portugal
[b] Department of Ophthalmology, Unidade Local de Saúde de Santo António, E. P. E, Oporto, Portugal, [b] ICBAS - Instituto de Ciências Biomédicas Abel Salazar, Oporto, Portugal;

***Corresponding Author:** leite.jmo@gmail.com
Institutional E-mail: u13456@chporto.min-saude.pt

ABSTRACT
Introduction: Femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK) surgery is a surgical procedure performed in the treatment of refractive errors. Given the changes in central corneal thickness, intraocular pressure may be lower and underestimated, which may lead to a late diagnosis of ocular hypertension/glaucoma.
Aims: The aim of this study was to evaluate and compare intraocular pressure, by different methods, before and after FS-LASIK, for correction of myopia or myopic astigmatism.
Methods: Retrospective and observational study, which included eyes undergoing FS-LASIK surgery (November 2020 to November 2022). The intraocular pressure values were measured (preoperatively, on the 1st, 3rd and 6th postoperative month) using contact tonometry (Goldmann applanation tonometry) and non-contact tonometry (by Corvis®ST according to the formulas: pachymetry – Ehlers, Shah, Dresden, Spoerl – and biomechanics – corrected and uncorrected). The intraocular pressure values obtained at 6 months with the different methods were compared with the Goldmann applanation tonometry intraocular pressure values obtained at baseline.
Results: Ninety patients (of a total of 174 eyes) underwent FS-LASIK, with a preoperative spherical equivalent of -3.7±1.7. Preoperatively (mean ± standard deviation) Goldmann applanation tonometry was 15.0±1.9 mmHg; the intraocular pressure values obtained through the Corvis® ST (in mmHg) according pachymetry: Ehlers (13.5±2.6), Shah (14.3±2.3), Dresden (14.5±2.2) and Spoerl (14.5±2.1); and biomechanics: corrected (14.4±1.9) and not corrected (15.3±2.1), respectively. At 6 months postoperatively, all showed statistically significant differences, with the exception of Shah's formula ($p=0.074$); comparing the preoperative Goldmann applanation tonometry with each of the formulas at the end of the follow-up, the Ehlers formula did not present statistically significant differences ($p=0.434$), the Shah formula a value of $p=0.047$ and the others a value of $p<0.001$.
Conclusion: Femtosecond laser-assisted laser in situ keratomileusis surgery underestimates intraocular pressure measurement by contact tonometry. In non-contact tonometry, at 6-month follow-up, the Shah formula appears to be less influenced by this bias. More studies are needed to evaluate the best method to assess I intraocular pressure measurement after FS-LASIK surgery.
Keywords: Intraocular pressure; Goldmann applanation tonometry; CORVIS; FemtoLASIK.

Introduction

Uncorrected refractive error is one of the main causes of visual impairment and the second leading cause of blindness in the world[1]. Myopia is the most common refractive error [2] and its prevalence is expected to increase in such a way that it could affect up to 1 billion people with high myopia by 2050 (7.5 times more than in 2000)[3]. Keratorefractive procedures are very popular in correcting these ametropias, with Laser in situ keratomileusis (LASIK) being the most popular corneal refractive surgery performed in the last decades, with approximately one million myopic patients undergoing LASIK every year [4]. Intraocular pressure (IOP) is the main risk factor for the development and progression of open-angle glaucoma (OAG)[5]. Additionally, myopia, especially for values above 6.00 diopters, is also an important risk factor[6].

The IOP can be evaluated using techniques such as applanation – Goldmann applanation tonometry (GAT) and surface correction (CATS, Reichert, USA)), indentation pneumotonometer (Pneumotonometer, Reichert, USA), both applanation and indentation (Tono-Pen, Reichert, USA), rebound (i-Care, USA), dynamic contour (dynamic contour tonometer (DCT), Pascale, Switzerland) and non-contact type (air breath tonometers such as Corvis ST (CVS, Oculus , Germany) and ocular response analyzer (ORA, Reichert, USA)[7]. GAT is still the gold standard for measuring IOP in normal corneas[4]. Applanation tonometry is based on the Imbert-Fick law[8] which only applies to a sphere with an infinitely thin, perfectly flexible, elastic and dry limiting membrane, neither of which is true in the human eye[7,9]. Some studies report that the IOP measurement through the GAT may be influenced by the central corneal thickness (CCT), corneal curvature, tear film and biomechanical properties of the cornea[5,6,7]. Measurement of IOP by GAT requires a regular spherical ocular surface, providing a correct IOP measurement for corneas of thickness 520µm[6,10].

Femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK) involves the creation of a corneal flap by femtosecond laser and corneal reshaping by excimer laser to remove tissue from the underlying stromal bed. Thus, these changes in corneal morphology and biomechanics may affect IOP measurement by several methods patients[4,5,6,7,11].

After refractive surgery, there is a strong correlation between decreased corneal thickness resulting from refractive ablation and IOP changes[6]. Cacho et all refer that for each ablation of 15 microns, which corresponds approximately to the correction of 1 diopter, the IOP can vary approximately 0.5 mmHg[12], and myopic patients can express an extra decrease in IOP of approximately values of 0.029±0.003 mmHg[6].

The aim of this study was to evaluate and compare IOP before and after FS-LASIK, for the correction of myopia or myopic astigmatism, using different methods and formulas.

Methods

This retrospective and observational study was performed at the Ophthalmology Department Unidade Local de Saúde de Santo António, E. P. E (ULSSA) and comprised all eyes submitted to FS-LASIK surgery for the correction of myopia or myopic astigmatism, between November 2020 and June 2022. This study was carried out according to the principles of the Declaration of Helsinki.

Patients were evaluated preoperatively, at the 1st, 3rd and 6th postoperative month. In each assessment, IOP values were obtained by contact tonometry, through GAT and by non-contact tonometry, using Corvis® ST and the various adjusted formulas: 1) to pachymetry: Ehlers (IOPe), Shah (IOPsh), Dresden (IOPd), Spoerl (IOPsp) formulas; 2) to biomechanics: corrected (bIOP) and not corrected (nIOP). In each evaluation, pachymetry values were also obtained through Pentacam®, Oculus. The IOP values obtained at 6 months with the different methods were compared with the GAT IOP values obtained at baseline.

Eyes with previous ocular surgery, trauma, history of inflammation or correction to hyperopic or hyperopic astigmatism were excluded.

Demographic data such as age, gender and refractive error were recorded. All patients were evaluated according to the preoperative protocol of the refractive surgery section.

After surgery, all patients received topical ofloxacin 3 mg/mL (1 drop, 5 times a day, for 1 week), fluorometholone 10 mg/mL (1 drop, 5 times a day, for 3 weeks) and artificial tear (for 6 months).

Statistical analysis was performed using the SPSS program (SPSS Statistics, version 22.0 for Windows, SPSS Inc., IBM, Somers, NY). Descriptive analysis was performed to calculate the mean and standard deviation (SD). Variables were considered statistically significant with $p<0.05$. A paired sample T-test was used.

Results

In this study, 174 eyes (from 90 patients) were included with a follow-up of 6 months. The demographic information is described in Table 1.

Table 1. Demographic information.

	Total
Eyes, n	174
Patients, n	90
Mean age, years ± SD	31.9 ± 5.4
Gender, %	
Female	60.9
Male	39.1
Preoperative spherical equivalent	-3.7 ± 1.7

In the preoperative period, the mean IOP values obtained by the GAT were 15.0±1.9 mmHg and only the nIOP formula showed higher mean values at baseline (15.3±2.1 mmHg); the remaining formulas showed lower mean IOP values (described in Table 2). Preoperatively, comparing the GAT with the various formulas obtained through Corvis® ST, all formulas showed statistically significant differences ($p<0.05$) with the exception of IOPe formula ($p=0.281$). The mean pachymetry values are also described in Table 2. The IOP evolution during follow-up is described in Figure 1.

At 6 months of follow-up (described in Figure 1 and Table 2), compared to baseline, most formulas had mean IOP values lower than baseline: GAT (decrease of 16.7%), IOPd (decrease of 3.5%), IOPsp (decrease of 15.8%) and biomechanics formulas presented lower values of IOP, being more evident over time, with a decrease in the mean values of 9.7% in bIOP and 22.2% in nIOP. On the other hand, 2 formulas presented IOP values at the 6th month higher than the baseline: IOPe (increase of 12.6%) and IOPsh (increase of 1.4%). Statistical differences are described in Table 3.

Table 2. Evaluation of preoperative and postoperative parameters

Parameter	Preoperative	1st month	3rd month	6th month	Mean difference (6th month vs preoperative)
Contact tonometry					
GAT (mmHg ± SD)	15.0 ± 1.9	13.5 ± 2.2	13.0 ± 1.8	12.6 ± 1.8	-2.4 ± 2.9
Non-contact tonometry					
Pachymetry-adjusted formula:					
Ehlers (mmHg ± SD)	13.5 ± 2.6	16.3 ± 3.2	15.6 ± 2.7	15.3 ± 2.8	1.8 ± 2.4
Shah (mmHg ± SD)	14.3 ± 2.3	15.6 ± 2.7	14.9 ± 2.2	14.6 ± 2.2	0.3 ± 2.0
Dresden (mmHg ± SD)	14.5 ± 2.2	15.1 ± 2.5	14.4 ± 2.0	14.1 ± 1.9	-0.4 ± 1.9
Spoerl (mmHg ± SD)	14.5 ± 2.1	13.3 ± 2.3	12.7 ± 1.8	12.4 ± 1.7	-2.1 ± 1.8
Biomechanics-adjusted formula:					
Corrected (mmHg ± SD)	14.4 ± 1.9	14.1 ± 2.2	13.4 ± 1.8	13.1 ± 1.6	-1.3 ± 1.5
Not corrected (mmHg ± SD)	15.3 ± 2.1	13.0 ± 2.4	12.4 ± 2.0	12.0 ± 1.7	-3.3 ± 1.8
Pachymetry (μm ± SD)	567.7 ± 24.8	502.0 ± 38.3	503.8 ± 34.9	504.0 ± 35.6	-63.7 ± 28.7

SD, standard deviation.

There are only no statistically significant differences between the preoperative and the 6th month of follow-up in the IOPsh formula ($p=0.074$). Comparing the preoperative GAT with each Corvis® formulas at 6th month of follow-up, only Ehlers formula did not present statistically significant differences ($p=0.434$) (described in Table 4).

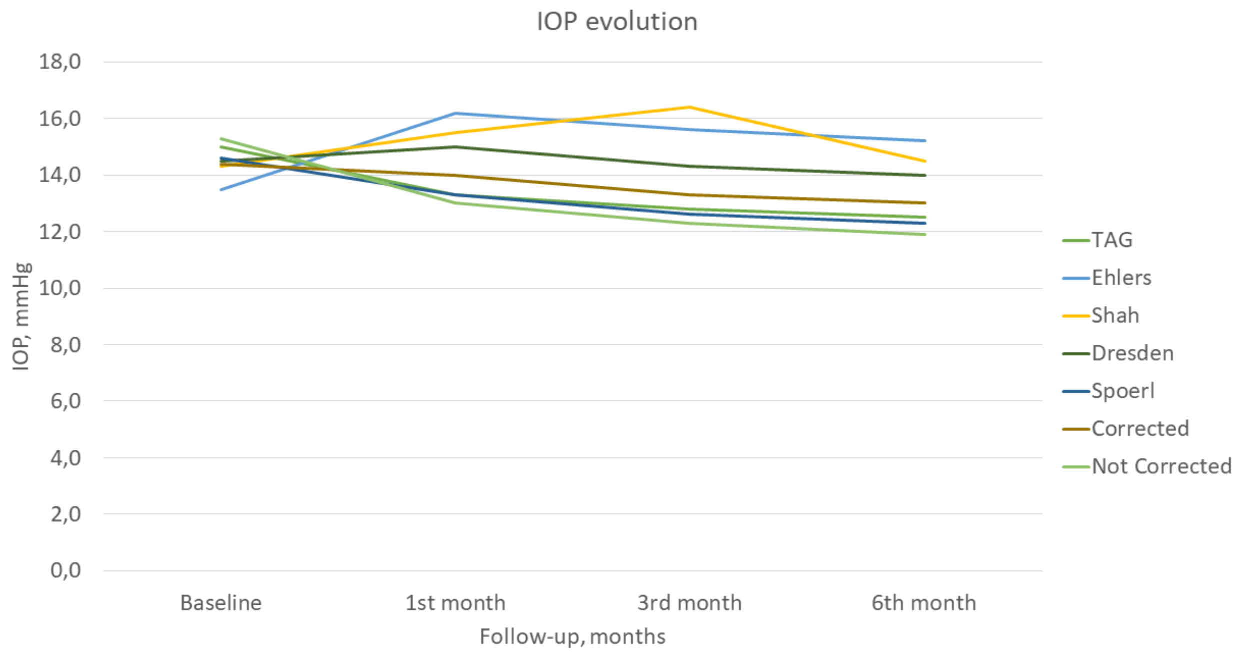

Figure 1. IOP evolution during follow-up.

Table 3. Statistical evaluation.

Parameter	**p-value (preoperative vs. 1st month)**	**p-value (preoperative vs. 3rd month)**	**p-value (preoperative vs 6th month)**
Contact tonometry			
GAT (mmHg ± SD)	p<0.001[1]	p<0.001[1]	p<0.001[1]
Non-contact tonometry			
Pachymetry-adjusted formula:			
Ehlers (mmHg ± SD)	p<0.001[1]	p<0.001[1]	p<0.001[1]
Shah (mmHg ± SD)	p<0.001[1]	p=0.007[1]	p=0.074[1]
Dresden (mmHg ± SD)	p=0.043[1]	p=0.140[1]	p=0.004[1]
Spoerl (mmHg ± SD)	p<0.001[1]	p<0.001[1]	p<0.001[1]
Biomechanics-adjusted formula:			
Corrected (mmHg ± SD)	p<0.001[1]	p<0.001[1]	p<0.001[1]
Not corrected (mmHg ± SD)	p<0.001[1]	p<0.001[1]	p<0.001[1]
Pachymetry (μm ± SD)	p<0.001[1]	p<0.001[1]	p<0.001[1]

SD, standard deviation. 1 – Paired Samples T-test

Table 4. Statistical evaluation: comparison between preoperative GAT and postoperative (6th month) Corvis® formulas.

Parameter	p-value
Non-contact tonometry	
Pachymetry-adjusted formula:	
Ehlers (mmHg ± SD)	p=0.434
Shah (mmHg ± SD)	p=0.047
Dresden (mmHg ± SD)	p<0.001
Spoerl (mmHg ± SD)	p<0.001
Biomechanics-adjusted formula:	
Corrected (mmHg ± SD)	p<0.001
Not corrected (mmHg ± SD)	p<0.001

The average pachymetry value decreases by 11.5% between the pre and the 6th postoperative month.

Preoperatively and during follow-up, there was no IOP greater than 21mmHg in any eye, with no need for treatment for ocular hypertension.

Discussion

Some studies have reported that IOP after LASIK is underestimated[6,10]. IOP reduction after this procedure has been attributed to a reduction in CCT[6,11,10]. However, changes in corneal stiffness after a surgical procedure such as LASIK can be an equally important reason[10]. Thus, trauma to Bowman's layer during flap creation, collagen deposition during flap making, collagen deposition during the healing process, and increased accumulation of water in the stroma due to increased proteoglycans and hyaluronic acid can alter the normal rigidity of the cornea[10,13,14]. So, consequently, decreasing corneal stiffness will make it easier for applanation-type tonometer to flatten the cornea, so less force will be required to flatten the cornea and IOP readings will decrease[4,10].

Clinical studies and experiments in animal models have shown that keratorefractive surgery does not induce a decrease in IOP, suggesting that the reduced IOP measurements recorded after surgery need to be corrected[11,15]. To minimize GAT biases in post LASIK patients, some authors have postulated that non-contact tonometer is more accurate than the GAT[4,16].

The Corvis® ST has recently emerged as a more convenient and faster method to evaluate corneal biomechanics and measure IOP[11]. Only a few studies have compared IOP values before and after corneal refractive surgery, reporting that the IOP obtained with the Corvis® ST is more reliable than the values obtained with other non-contact devices[11]. Some studies report that the biOP proved to be the most stable and accurate parameter after surface ablation or lamellar procedure, in addition to being the one that presents a smaller mean difference in IOP values before and after surgery[7,17,18]. This formula, developed by Joda et al through analysis of clinical data, appears to decrease the influence of corneal elastic modulus (as well as eliminate the effect of corneal thickness) and age on IOP measurements[19,20]. However, other studies (obtained through Pentacam) have shown that the Shah, Ehlers and Dresden correction formulas can be used to correct IOP after LASIK[11,21,22].

In this study, our purpose was to find at the end of follow-up which device and formula would give the closest measurements to preoperative values despite the change in corneal thickness, corneal curvature, and manifest refraction.

In our study, in the preoperative period, the average IOP value obtained by the GAT was 15.0mmHg. Except for the nIOP formula, all the other analyzed formulas presented IOP values below the GAT value. The GAT obtained one of the highest mean decreases comparing the preoperative period with the end of the follow-up (mean decrease of 2.4 mmHg). This decrease is in line with the literature although it is higher than the expected value (decrease of 0.5 mmHg for each diopter ablated). This value has just been surpassed by the decrease in the values obtained by nIOP (mean decrease of 3.3 mmHg).

The GAT was accepted as the reference standard for IOP measurements, and this value is significantly affected by the thickness and curvature of the cornea. Thus, Ang et al, in a study comparing three tonometer, concluded that the GAT showed that the lowest mean IOP values in the postoperative period led to the greatest difference in IOP measurements before and after surgery [7]. Shafiq also reported the influence of CCT on IOP measurements with GAT in normal subjects, concluding that CCT was significantly correlated with intraocular pressure in that a thicker cornea overestimates IOP and a thinner cornea underestimates IOP [23]. In our work, we noticed that there was an underestimation of IOP after FS-LASIK, mainly due to the reduction of CCT and eventually due to the biomechanical alteration of the cornea. This is congruent with the literature and also validates our results.

During the follow-up, mainly in the 1st month postoperative period, we noticed an IOP fluctuation, which can be related to the use of corticosteroids in the postoperative period, corroborating the literature[11].

At the end of follow-up, except for the IOPe and IOPsh formulas, all remaining formulas obtained through the Corvis® ST showed a decrease in the mean IOP values comparing to the preoperative period.

Variations in IOPsh and IOPd are small, although IOPsh is the only one whose values at the 6th month of follow-up do not present statistically significant differences with baseline. Since at the end of the follow-up the IOPe and IOPsp formulas deviate further from the baseline value, these formulas may not be reliable.

Our study demonstrates that biOP presents a profile of IOP drop during follow-up (mean of 13.1 mmHg in the 6th month) that follows the GAT values (mean of 12.6 mmHg in the 6th month), instead of the formulas IOPe (mean 15.3 mmHg in the 6th month), IOPsh (mean 14.6 mmHg in the 6th month) or IOPd (mean 14.1 mmHg in the 6th month), which present values at the end of the follow-up that are closer to the preoperative GAT (mean of 15.0 mmHg). In addition, there was less difference (<1mmHg) between preoperative and postoperative IOP measurements in the IOPsh and IOPd formulas.

In this aspect, there is a difference with the literature: it has been reported that the biOP had the best level of agreement with the preoperative GAT and the smallest percentage difference in the measurement of the preoperative and postoperative IOP, suggesting that may be least affected in post-surgery IOP measurements[7,11]. Thus, although the biOP formula is considered a better alternative for measuring IOP through the GAT in eyes after FS-LASIK surgery, there may be some confounding factors, requiring further comparative studies between the various formulas until some formula is considered standard in clinical decision.

This study has some limitations: it was a retrospective study with a relatively small sample size, limited only to FS-LASIK surgery for correction of myopia or myopic astigmatism. In addition, IOP measurements were taken once, without controlling for diurnal IOP variability and intraobserver and interobserver variability.

Conclusion

After this study, it seems to us that the Shah and Ehlers formulas are the formulas that most closely resemble preoperative IOP values, obtained through GAT preoperatively.

The formula adjusted to biomechanics obtained using Corvis® ST, instead of what has been described in the literature, presents a descending IOP profile after a FS-LASIK surgical procedure, similar to GAT measurement postoperatively, requiring further comparative studies.

Furthermore, in future work, it would be important to include other types of keratorefractive procedures as well as to consider the biomechanical properties of the cornea.

Statement of Ethics

The study was conducted under the tenets of the National Council of Ethics for the Life Sciences and the Declaration of Helsinki and its latest amendment (Brazil, 2013).
Ethical approval is not required for this study in accordance with the local IRB (Departamento de Ensino, Formação e Investigação of Unidade Local de Saúde de Santo António, E. P. E).
All patients signed an informed consent form.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Study design: João Leite; Data acquisition: João Leite and Bruno Ribeiro; Data analysis: João Leite and Bruno Ribeiro; Critical interpretation of data: Ana Carolina Abreu, Sílvia Monteiro, Ana Figueiredo, Rita Reis, Isabel Sampaio, Maria Céu Pinto, Maria João Menéres; Manuscript drafting: João Leite and Bruno Ribeiro; Manuscript critical review: Ana Carolina Abreu, Sílvia Monteiro, Ana Figueiredo, Rita Reis, Isabel Sampaio, Maria Céu Pinto, Maria João Menéres.

Data Availability Statement

The clinical data that support the findings of this clinical case are available in the electronic hospital register of CHUdSA. All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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