Unexpectedly high corneal flap thickness and ectasia after mechanical LASIK

Espessura inesperadamente alta do flap corneano e ectasia após LASIK mecânico

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ABSTRACT

LASIK is a refractive surgical procedure in which a corneal flap is created to expose the corneal stromal bed. Preoperative estimation of corneal flap thickness is necessary to calculate the percentage tissue altered in LASIK, an important quantitative risk factor for ectasia. The objective of this study was to assess flap thickness and calculate percentage tissue altered to check if unexpectedly thicker flaps and higher percentage tissue altered could pose as risk factors of ectasia. Four subjects (eight eyes) were submitted to mechanical LASIK in 2009 and 2010. Pre and postoperative clinical and tomographic data were reviewed. Mean preoperative estimated percentage tissue altered was 39.18±1.31%, which was borderline for increased ectasia risk when considering the limit of 40%. However, when considering the postoperatively measured flap thickness, the actual mean percentage tissue altered turned out to be 45.17 ± 4.13%, which was significantly higher than predicted preoperatively (p=0.002). Unexpectedly higher postoperative percentage tissue altered may be responsible for corneal ectasia after mechanical LASIK.

RESUMO

A LASIK é um procedimento cirúrgico refrativo, no qual um retalho corneano é criado para expor o leito estromal corneano. A estimativa pré-operatória da espessura do retalho corneano é necessária para calcular o percentual de tecido alterado no LASIK, um importante fator de risco quantitativo para ectasia. O objetivo deste estudo foi avaliar a espessura do retalho e calcular o percentual de tecido alterado para verificar se retalhos inesperadamente mais espessos e percentuais de tecido alterado mais altos poderiam representar fatores de risco de ectasia. Quatro indivíduos (oito olhos) foram submetidos à LASIK mecânica em 2009 e 2010. Dados clínicos e tomográficos pré e pós-operatórios foram revisados. A média de percentual de tecido alterado pré-operatória estimada foi de 39,18±1,31%, limítrofe para risco aumentado de ectasia quando considerado o limite de 40%. No entanto, ao considerar a espessura do retalho medida no pós-operatório, o percentual de tecido alterado médio real foi de 45,17±4,13%, ou seja, significativamente maior do que o previsto no pré-operatório (p=0,002). O percentual de tecido alterado pós-operatóriao inesperadamente mais alto pode ser responsável pela ectasia da córnea após LASIK mecânico.

INTRODUCTION

Laser-assisted in-situ keratomileusis (LASIK) is one of the most performed refractive surgery modalities worldwide. This technique creates a flap in the outermost parts of the cornea (epithelium, bowman layer, and anterior stroma) to expose the stromal bed and reshape it with excimer laser using photoablation. The flaps can be created using a mechanical microkeratome or a femtosecond laser.[1]

Although femtosecond laser-assisted LASIK (femto-LASIK) has overcome mechanical LASIK as the preferred technique in the past decade, it is important to consider that for more than 20 years the microkeratome-based technique has been the most popular keratorefractive technique worldwide, and it is still employed in many practices, especially in developing countries. Thus, specific postoperative complications related to this procedure must be acknowledged in the routine of anterior segment surgeons.[2]

Post-LASIK corneal ectasia is a major concern among refractive surgeons and has many risk factors that must be investigated prior to surgery indication, involving corneal curvature, elevation, thickness, and biomechanics. Since the cohesive tensile strength is not uniform throughout the central corneal stroma and the one-third anterior region of the corneal stroma has significantly greater cohesive tensile strength, altering this relevant part of the stroma may induce corneal weakening.[3]

One of the most well-demonstrated quantitative risk factors for ectasia after LASIK is the percentage tissue altered (PTA). It is defined as flap thickness plus ablation depth divided by central corneal thickness. It was demonstrated that ectasia risk significantly increases with a PTA value greater than 35% (with 100% sensitivity) and peaks its maximum combination of sensitivity and specificity when greater than 40%.[4]

In order to successfully assess ectasia risk before performing LASIK, it is necessary to have an accurate estimative of ablation depth and flap thickness. Preoperative underestimation of flap thickness, which may occur when performing mechanical LASIK,[5] will lead to an underestimation of PTA. Higher-than-expected PTA can explain the occurrence of ectasia in patients without increased risk factors in the preoperative evaluation.

In this study, we present a case series of eyes that developed unexplained corneal ectasia after mechanical LASIK, and whose flap thicknesses were measured postoperatively in order to accurately calculate the PTA.

This is a retrospective, non-interventional case series involving four subjects (eight eyes) submitted to mechanical LASIK in 2009 and 2010, at the Department of Ophthalmology and Visual Sciences of the Universidade Federal de São Paulo. Subjects presented unexplained corneal ectasia in one or both eyes after the procedure. Pre and postoperative clinical, topographic and tomographic data were reviewed, and corneal imaging was performed after ectasia diagnosis. The objective was to assess flap thickness and to calculate PTA, in order to check if unexpectedly thicker flaps and higher PTAs could pose as risk factors explaining the occurrence of ectasia. Significance in the difference between estimated and measured flap thickness and PTA was statistically evaluated through t test.

CASE SERIES

Surgical technique

Patients were submitted to clinical and refraction evaluation, as well as to Placido disk-based topography and Scheimpflug corneal profile evaluation prior to surgery. After being considered eligible for corneal refractive procedure, they were submitted to bilateral myopic mechanical LASIK, using Moria microkeratome and Ladar excimer laser platform. Flap thickness was intended to be 160µm. Corneal ablation was either wavefront-optimized or wavefront-guided, with 6.5mm optical zone. In the follow-up, all subjects developed corneal ectasia in one or both eyes. Retrospective assessment of risk factors revealed, through anterior segment optical coherence tomography (AS-OCT), that the corneal flaps were thicker than it was intended, thus making the PTA higher. Post-LASIK corneal ectasia was attributed to this increased, unexpected PTA, which was calculated based on flap thickness plus ablation depth, as informed by the excimer laser platform. Details on each case are given in the following sections, and clinical and refractional data are summarized in table 1.

Case 1

A 29 year-old female mentioned low uncorrected distance visual acuity (UDVA) in both eyes (OU) for the past 6 months. Wavefront-optimized mechanical myopic lasik had been performed 6 years before. Uncorrected distance visual acuity was 20/30+1 on the right eye (OD) and 20/40+1 on the left eye (OS). Refractometry was -0,25 -1,50 x 010º (20/15) OD and -0,50 -1,25 x 150º (20/15) OS. Scheimpflug evaluation evidenced inferior asymmetry with increased posterior elevation in OD, which worsened 8 months later, confirming unilateral corneal ectasia. Flap thickness, assessed through AS-OCT, was 0.18µm OD and 0.15µm OS.

Table 1. Summary of clinical and surgical data of the subjects studied

Case	Age	CCT (µm)	Treatment (SE)	Ablation depth (µm)	Preoperative estimated PTA (%)	Postoperative measured flap thickness (µm)	Postoperative effective PTA (%)	Postoperative ectasia
1 (OD)	29	498	-1.88	28.1	39.65	180	43.67	Yes
1 (OS)	29	504	-2.38	35.6	41.42	150	39.02	No
2 (OD)	34	599	-4.75	82.6	40.50	220	50.52	Yes
2 (OS)	34	612	-4.63	78.8	39.02	200	45.55	Yes
3 (OD)	28	599	-3.63	63.8	37.36	210	45.71	No
3 (OS)	28	601	-3.63	70.5	38.35	236	50.10	Yes
4 (OD)	30	535	-1.50	44.3	38.19	171	40.24	No
4 (OS)	30	526	-1.75	44.8	38.93	200	46.54	Yes

Preoperative estimated percentage tissue altered calculation was based on ablation depth informed by the excimer laser platform + estimated 160µm mechanical flap; postop effective percentage tissue altered was calculated after measuring the effective flap thickness through anterior segment optical coherence tomography.
CCT: Central Corneal Thickness; SE: Spherical equivalent; PTA: percentage tissue altered; OD: right eye; OS: left eye.

Case 2

A 34 year-old female mentioned blurred vision in OD 3 months after being submitted to myopic wavefront-guided mechanical LASIK. Uncorrected distance visual acuity was 20/25 OD and 20/20 OS. Refractometry was -0,25 -0,50 x 015º (20/20) OD and plan (20/20) OS. Serial topographic examination has shown progressive inferior steepening in OD, which had a flap thickness of 220µm. Postoperative topography of OS was also suspect for ectasia, and its flap thickness was 200µm.

Case 3

A 28 year-old female reported worsening of night vision OU 4 months after myopic wavefront-guided mechanical LASIK. Uncorrected distance visual acuity was 30/30 OD and 20/20 OS. Refractometry was -0,75 sphere (20/15-1) OD and plan (20/20) OS. Scheimpflug evaluation was suggestive of inferior ectasia in OS; no evidence of ectasia was found in OD. Anterior segment optical coherence tomography-assessed flap thickness was 210µm and 236µm in OD and OS, respectively.

Case 4

A 30 year-old male reported blurred vision in OS 6 years after being submitted to myopic wavefront-guided mechanical LASIK. Uncorrected distance visual acuity was 20/20-1 OD and 20/60 OS. Refractometry was +0,25-0,50 x 005º (20/15-1) OD and -0,25 -2,00 x 165º (20/25+1) OS. Scheimpflug evaluation evidenced marked inferior steepening in OS; no evidence of ectasia was found in OD. Anterior segment optical coherence tomography was used to evaluate flap thickness, which was 171µm and 200µm in OD and OS, respectively. Exams of this case are reproduced in figures 1 to 3.

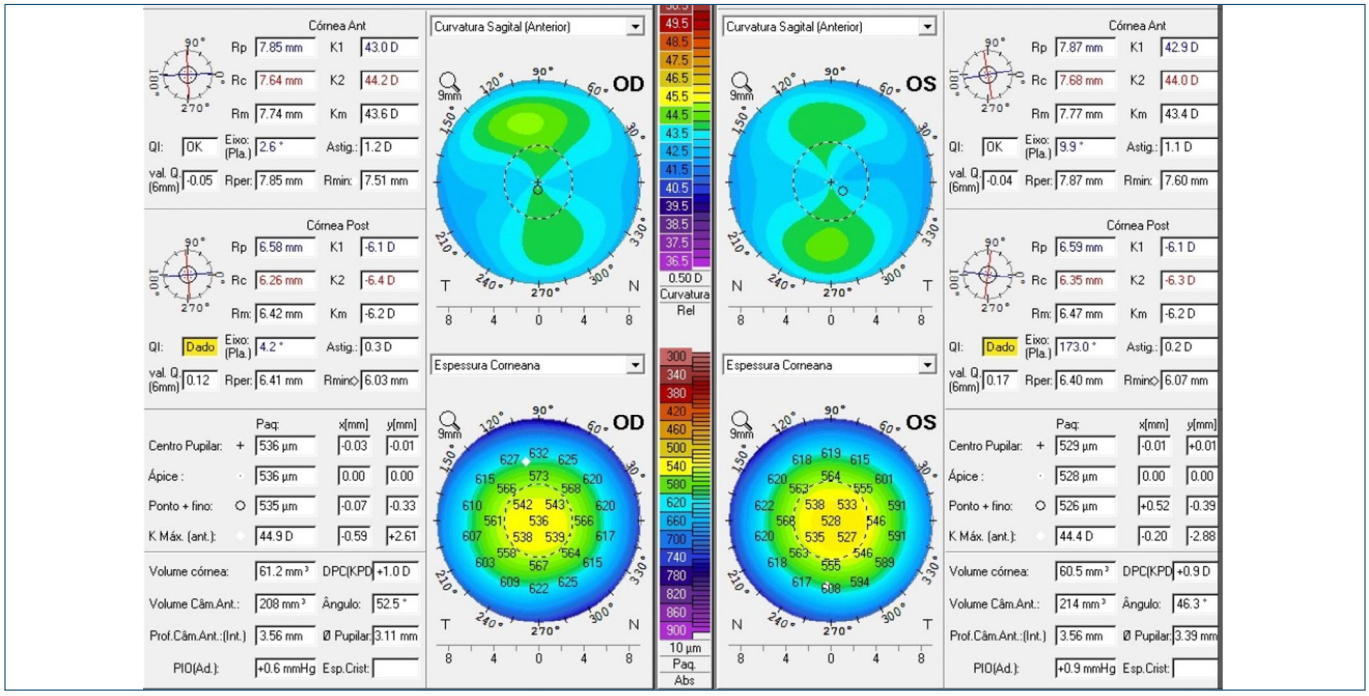

Figure 1. Preoperative corneal Scheimpflug profile of case 4. There were no contraindications for LASIK in both eyes.

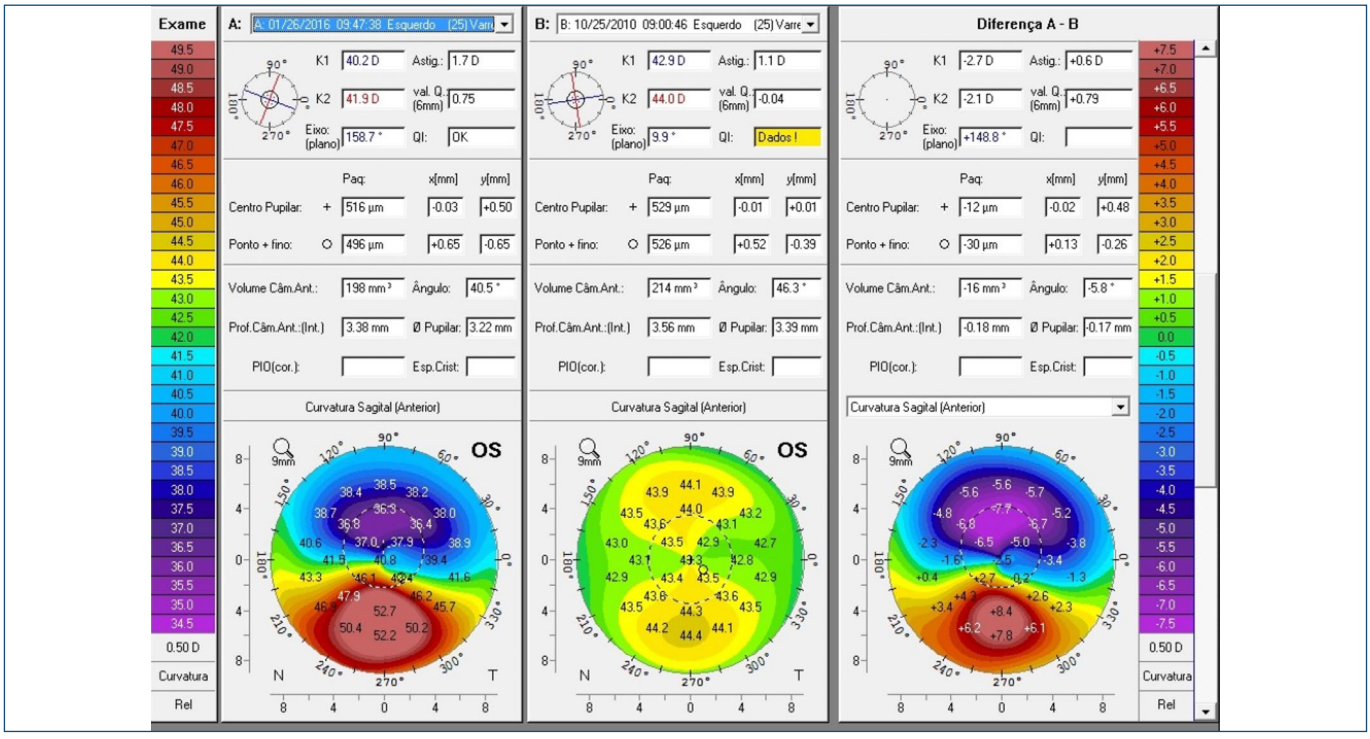

Figure 2. Left eye anterior sagittal curvature of case 4, 1 month and 6 years after surgery. Differential map evidence marked corneal ectasia. No ectasia was found in the right eye.

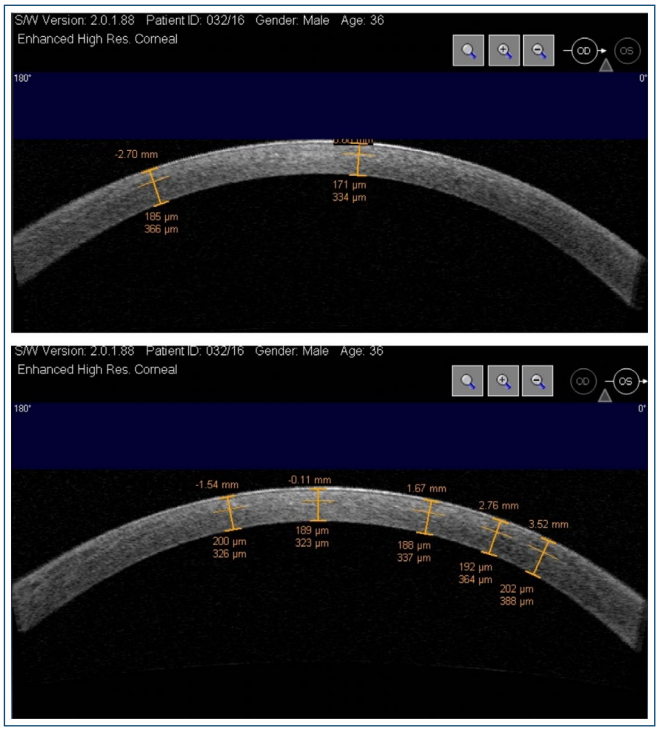

Figure 3. Postoperative anterior segment optical coherence tomography (case 4). Flap was thicker than the expected 160µm in both eyes, especially in the left eye.

DISCUSSION

Corneal ectasia, defined as a progressive corneal steepening, stromal thinning, and decrease in visual acuity, is one of the most serious complications of laser vision correction (LVC) procedures and can present as early as 1 week or as late as several years after the refractive procedure. Post-LASIK ectasia incidence appears to have down-trended, due to increased preoperative screening measures and risk assessment. However, cases of idiopathic ectasia remain a focus of research within the field of refractive surgery.[6]

The lack of predictability of microkeratome-created flap thickness was well demonstrated in several studies, with a variable gap between predicted and AS-OCT-assessed thickness, which could reach as much as 40µm, according to some studies.[7-9] In this case series, all corneal flaps were intended to have a 160µm thickness; however, the measured mean postoperative thickness was 195.7 ± 27.8µm. That means these flaps were significantly thicker than expected (p=0.003).

This gap between estimated and effective flap thickness compromises the PTA calculation. In this case series, mean preoperative estimated PTA was 39.18±1.31%, which was borderline for increased ectasia risk, when considering the limit of 40%. However, when considering the effective flap thickness via postoperative corneal imaging, the actual mean PTA turned out to be 45.17±4.13%, which was significantly higher than predicted preoperatively (p=0.002).

In this study, subjects who developed corneal ectasia were retrospectively re-assessed for risk factors potentially identifiable in topographic and tomographic/

Scheimpflug evaluation, such as corneal asymmetry, increased asphericity, irregular astigmatism, low pachimetry, and increased anterior and posterior elevation. All of these parameters were found to be acceptable and did not impose a contraindication for LASIK. When it comes to the preoperative PTA estimation, two eyes were found to have preoperative estimated PTA higher than 40%; it is important, however, to consider that these subjects were operated before the establishment of low PTA as a hallmark for LASIK safety, so this data were not considered at the time of the surgery indication. Therefore, the increased mechanical flap thickness found after surgery was considered to be responsible for a corresponding increase in PTA, which was pointed as the main factor for the observed corneal ectasias.

In mechanical LASIK, corneal flaps may be thicker than expected, and this underestimates preoperative PTA calculation. Unexpectedly higher postoperative PTA may be responsible for corneal ectasia after mechanical LASIK. This must be considered by refractive surgeons when evaluating unexplained post-mechanical LASIK ectasias, and when indicating mechanical LASIK in eyes with preoperative estimated borderline PTA.

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