Original article

Post-lasik corneal ectasia in patients with significant differences in keratometry readings between both eyes

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ABSTRACT

Objectives: A study is made on the incidence of corneal ectasia after laser in situ keratomileusis (LASIK) in patients with large differences in mean keratometry (MK) readings between both eyes (OU). Visual outcomes were also evaluated.
Methods: The medical records of 164,603 patients (315,259 eyes) who underwent LASIK from January 2003 to December 2011 were reviewed in order to identify patients with a difference in MK of ≥1.25 D between OU. The main outcome measures were incidence of ectasia after LASIK, and visual outcome.
Results: A total of 35 eyes that met the inclusion criteria were found. Functional and visual results were those expected for myopia studies. After a minimum follow-up of 2 years, no corneal ectasia was found in 3 eyes (2 patients).
Conclusions: The possibility of finding a patient with an asymmetry in MK and normal topography is low (0.021%), and it does not seem to be a contraindication of LASIK. Although no corneal ectasia was found in this case series, and as it is a potentially sight-threatening complication, patients with very different MK between OU should be studied carefully before undergoing LASIK.

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**Ectasia corneal post-LASIK en pacientes con diferencias significativas en las lecturas queratométricas de ambos ojos**

**Resumen**

**Objetivos:** Investigar la incidencia de ectasia corneal tras queratomeileusis in situ asistida por láser excimer (LASIK) en pacientes con diferencias significativas en la lectura queratométrica media (KM) entre ambos ojos (AO). Además se evalúan los resultados visuales.

**Métodos:** Se han revisado las historias clínicas de 164.603 pacientes (315.259 ojos) intervenidos con LASIK de enero de 2003 a diciembre de 2011 para identificar pacientes con una diferencia de KM ≥ 1,25 D entre AO. Además de este criterio, debían ser pacientes miopes con topografía corneal normal. Las principales variables de estudio fueron la incidencia de ectasia tras LASIK y el resultado visual.

**Resultados:** Un total de 35 ojos de 20 pacientes cumplieron con los criterios de inclusión y exclusión. Los resultados funcionales y visuales fueron los esperados para las refracciones estudiadas. No se encontraron ectasias en la serie estudiada tras un seguimiento mínimo de 2 años.

**Conclusiones:** La posibilidad de encontrar en un paciente asimetría de KM y topografía normales pequeña (0,021%) y no parece ser una contraindicación para realizar LASIK. A pesar de no encontrarse ectasias en la serie estudiada, ya que esta es una complicación potencialmente grave para la visión, los pacientes con elevadas diferencias en la KM entre AO deben ser estudiados cuidadosamente antes de ser intervenidos mediante LASIK.

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**Introducción**

Laser excimer (LASIK) assisted keratomeileusis provides fast visual acuity recovery with low incidence of complications. However, corneal ectasia can appear, mainly after the treatment of high myopic refractive errors, high manifested astigmatisms, high corneal curvature, thin corneal pachymetry and irregular astigmatisms.\(^1\)\(^,\)\(^2\) As only 50% of post-LASIK keratectasia appear in the first year after surgery, this complication must be analyzed in a longer term.\(^3\) The objective of this study is to assess the incidence of corneal ectasia and long-term visual and refractive results after LASIK in patients with a mean central keratometry reading difference (KM) between both eyes (BE) of ≥ 1.25 diopters (D).

As the frequency of corneal ectasia (and that of other post-LASIK complications) is low, analyzing long series of a single institution can provide more data on clinically relevant parameters and enable more efficient management of said complications. A series of a single institution provides incidence data in an environment in which many of the possible variables are controlled due to compliance with action protocols for surgeons and patients before, during and after surgery. Likewise, as the incidence of keratectasia is low, a large sample is required to obtain relevant conclusions and these samples are very difficult to find in a single center.\(^4\)

This study presents a broad series of patients with significant differences in KM between BE, with all the procedures being carried out in the same institution using the same microkeratome. A retrospective review of cases was carried out to provide information on the incidence of ectasia and risk factors in order to improve knowledge on said entity.

**Métodos**

A review of 35 eyes of 22 patients in a series of patients consecutively operated in our institution between 2003 and 2011. Said series comprised over 30,000 annual refractive procedures in 19 centers carried out by 84 surgeons.

The inclusion criteria were: myopic refractive error (defined as negative spherical equivalent [SE]), normal presurgery corneal topographic and KM difference ≥ 1.25 D between BE, measured by means of an autorefractor keratometer and confirmed (at least 1.00 D) by means of Orbscan II device (Bausch & Lomb, Claremont, California, USA).

The exclusion criteria included hypermetropia (positive SE), insufficient follow-up (<2 years) and abnormal presurgery corneal topography. All the patients exhibited stable refraction at least in the year prior to the procedure. None referred significant ocular or systemic disease or family history involving keratoconus.

The pre- and post-surgery examinations included uncorrected distant visual acuity (UDVA), corrected distant visual acuity (CDVA), refraction, cycloplegic refraction, slitlamp biomicroscopy assessment, intraocular pressure, indirect ophthalmoscopy, keratometry, and pachymetry Orbscan II corneal topography. Emmetropia was sought in all cases. To obtain the average post-surgery CDVA, the Snellen visual acuities were converted to their log-MAR equivalents to calculate the final mean visual acuity. The corneal ectasia diagnostic was based on topographic findings. The statistical analysis of data was performed using SPSS for Windows (version 17.0. SPSS Inc., Chicago, USA).

Data collection complied with national data protection laws. No special informed consent was included due to the retrospective nature of the study.
Surgical technique

After a complete presurgery ophthalmological study following a standard protocol to confirm that patients were candidates for corneal refractive surgery, informed consent was obtained in writing signed by all patients. All the interventions were carried out according to standard protocols. The patients were instructed to carry out adequate palpebral hygiene starting 3 days before the operation. The microkeratome was manual linear Moria LSK-One (Microtech Inc., Moria, France). The same blade was used in BE of the same patient. The corneal lenticule was always carved first in the left eye and then in the right one, while laser ablation was carried out first in the right and then in the left eye utilizing a Technolas excimer laser (217C and 217-Z-100; Bausch & Lomb, Claremont, California, USA) or Mel 80 (Carl Zeiss Meditec Inc., Jena, Germany). After surgery, a topical combination of 3 mg/ml tobramycin and 1 mg/ml dexamethasone was prescribed (Tobradex, Alcon, Barcelona, Spain) 4 times a day for one week as well as preservative-free artificial tears. All patients were assessed in the first 24 h, after one week and 3 months. Only the patients who visited the practice after 2 years were included in the study.

The variables included in the study were corneal ectasia incidence and visual results, including UDVA and CDVA (in the last available visit).

Functional and refractive results

Predictability was defined as the percentage of eyes with a post-surgery SE of ±1.00 D. Indicators for measuring visual results were the efficacy index (post-surgery CUVA/presurgery CDVA) and safety index (post-surgery CDVA/presurgery CDVA).

Results

During the period of the study, 315,259 LASIK procedures were performed in 164,603 patients. Overall, 35 eyes (20 patients) fulfilled the inclusion and exclusion criteria (0.021%). The mean age was of 36.00 ± 15.55 years (range 25–61 years) (Table 1). The functional and refractive results are shown in Figs. 1–5 and in Tables 2 and 3.

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Table 1 – Presurgery data.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of eyes</td>
<td>35</td>
</tr>
<tr>
<td>Patients</td>
<td>20</td>
</tr>
<tr>
<td>Male/female</td>
<td>12/8</td>
</tr>
<tr>
<td>Age (years)</td>
<td>36.00 ± 15.55 (25–61)</td>
</tr>
<tr>
<td>Sphere (D)</td>
<td>−1.75 ± 2.77 (+3.75 to −7.00)</td>
</tr>
<tr>
<td>Astigmatism (D)</td>
<td>−1.77 ± 1.40 (−0.25 to −5.25)</td>
</tr>
<tr>
<td>SE (D)</td>
<td>−4.18 ± 3.01 (−0.25 to −14.50)</td>
</tr>
<tr>
<td>KM (D)</td>
<td>4.43 ± 1.96 (40.50–48.25)</td>
</tr>
<tr>
<td>KM difference between BE</td>
<td>1.76 ± 0.54 (1.25–3.00)</td>
</tr>
<tr>
<td>KM difference between BE</td>
<td>1.47 ± 0.39 (1.00–2.40)</td>
</tr>
<tr>
<td>(Orbscan) (D)</td>
<td></td>
</tr>
<tr>
<td>CDVA (log-MAR)</td>
<td>0.06 ± 0.11 (0–0.52)</td>
</tr>
<tr>
<td>Presurgery pachymetry (µm)</td>
<td>560.66 ± 30.07 (509–623)</td>
</tr>
<tr>
<td>Anterior elevation (EA) (µm)</td>
<td>11.10 ± 3.35 (6.00–17.00)</td>
</tr>
<tr>
<td>Anterior BFS (BFSA) (D)</td>
<td>43.07 ± 1.62 (41.10–46.60)</td>
</tr>
<tr>
<td>Anterior ratio (EA/BFSA)</td>
<td>0.27 ± 0.07 (0.15–0.39)</td>
</tr>
<tr>
<td>Posterior elevation (PE) (µm)</td>
<td>29.00 ± 10.39 (13.00–47.00)</td>
</tr>
<tr>
<td>Posterior BFS (BFSP) (D)</td>
<td>52.84 ± 4.09 (43.20–59.00)</td>
</tr>
<tr>
<td>Posterior ratio (PE/BFSP)</td>
<td>0.55 ± 0.20 (0.30–0.89)</td>
</tr>
<tr>
<td>I-S</td>
<td>0.74 ± 1.20 (−1.18–2.88)</td>
</tr>
</tbody>
</table>

Values expressed as mean ± standard deviation (range).

BFS, best fit sphere (Orbscan); BFSA, best fit sphere anterior; BFSP, best fit sphere posterior; CDVA, corrected distant visual acuity; D, diopters; EA, elevation of anterior face (Orbscan); SE, spherical equivalent; PE, posterior face elevation (Orbscan); I-S, KM inferior-superior corneal morphology index; mean keratometry; UDVA, uncorrected distant visual acuity.

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Table 2 – Intra-surgery data.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of eyes</td>
<td>35</td>
</tr>
<tr>
<td>Lenticule thickness (µm)</td>
<td>90.06 ± 16.90 (65–130)</td>
</tr>
<tr>
<td>Ablation (µm)</td>
<td>80.77 ± 39.70 (69–154)</td>
</tr>
<tr>
<td>Residual stromal bed (µm)</td>
<td>389.83 ± 50.91 (319–490)</td>
</tr>
<tr>
<td>Post-surgery corneal thickness (µm)</td>
<td>478.34 ± 52.13 (404–581)</td>
</tr>
</tbody>
</table>

Values expressed as mean ± standard deviation (range).

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Fig. 1 – Uncorrected distant visual acuity (UDVA).

Fig. 2 – Change in corrected distant visual acuity (CDVA).
The mean follow-up was of 4.90 ± 1.95 years (range 2.01–8.78 years). No intra-surgery (for example, poorly carved lenticules or epithelial defects) or post-surgery (diffuse lamellar keratitis, epithelial growth, infection or epithelial recovery) complications appeared. None of the patients were identified as having corneal ectasia.

**Discussion**

The ectasia risk factors include pre-existing keratoconus (or frustrated keratoconus, i.e., eyes exhibiting ectasia characteristics without clinical evidence,1 poor residual stromal corneal bed, thin pre-surgery corneal thickness, elevated ablations, large ablation diameter, young age (<30 years) and high myopia.12,6,7 Many described cases exhibited topographic or clinical evidence of frustrated keratoconus, manifested keratoconus or pellucid marginal degeneration.8,9. Due to the diversity of risk factors, scoring systems have been proposed to predict post-LASIK ectasia.6,10

Some authors believe there is a group of factors that produce an aggregate risk of ectasia but without defining specific critical values.11-14 In 2005, the group of reference refractive surgeons established consensus to conclude that "the decision of performing LASIK must take into account the clinic case globally".7

All the patients of this case were studied at least 2 years after the operation. Follow-up length is essential, particularly after LASIK, because corneal ectasia only appears in the first year in 50% of the cases.1 In one of the most rigorous studies published to date, the mean time of appearance of post-LASIK ectasia was of 16.3 months.1 Even though no ectasia were found in this series, it must be mentioned that 3 eyes of patients were excluded due to abnormal presurgery topographs and, even though ectasia hadn’t developed at the time, it could develop in the future.

In this study, the minimum residual stromal post-surgery bed was of 389 μm, confirmed with intra-surgery ultrasound pachymetry. Some authors postulate that the most important risk factors are residual bed and presurgery topograph.15 Usually surgeons plan on leaving a minimum residual after ablation of at least 250 μm.16 However, ectasia may appear in patients without obvious risk factors.17

Rao et al.18 suggested that the elevation of the anterior and posterior corneal faces in the Orbscan topograph could...
be related with the possibility of post-LASIK keratectasia. Said data were analyzed in the patients of this study.

The obtained functional and refractive results are similar to those found in the literature, taking into account that the treated myopic spherical equivalent range is very broad, ranging from slight to advanced myopia. Accordingly, 63% of the study patients achieved uncorrected vision of 20/20 or greater, 83% exhibited between +1.00 and −1.00 D of the preoperative refraction and 5.7% lost 2 or more CDVA lines. In clinical studies by the Food and Drug Administration (FDA) of USA, these numbers are in the range of 67–86%, 94–100% and 2.15%, respectively when the treated myopia was slight (under −6.00 D). When myopia was between −6.00 and −12.00 D, the numbers get worse in the FDA studies up to 26–71%, 41–96% and 0–4.5%, respectively.19,20

When a patient exhibits a high KM difference between BF, we must not consider that this excludes LASIK although we must study in depth the global clinic case and discard corneal topography anomalies.

**Conflict of interests**

No conflict of interests has been declared by the authors.

**References**