Original article

Long-term results of lasik refractive error correction after penetrating keratoplasty in patients with keratoconus

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Objective: To evaluate the long term results of Lasik for residual refractive errors (RE) after penetrating keratoplasty (PKP) for keratoconus (KC).

Design: Retrospective cohort.

Method: Records of 14 consecutive patients (19 eyes) who had Lasik after PKP for KC were retrospectively reviewed. In all eyes with refractive stability and suture removed before Lasik, far distance Visual Acuity with (AVCC) and without correction (AVSC), spherical equivalent (EE), refractive (Ast) and keratometric (dK) astigmatism were analyzed pre- and post-operatively before and after one year of follow up. Data were analyzed using Shapiro–Wilk normality test, Student t test and Mann–Whitney test. A p-value of <0.05 was considered statistically significant.

Results: The mean follow-up time was 3.16 months for the follow-up before one year postoperative and 5.8 years for the follow-up after one year postoperative. The best spectacle corrected visual acuity of 0.11 LogMAR (DE 0.07) before Lasik remained stable throughout the study. The SE decreased from $-2.6$ (DE $3.53$) to $-0.36$ D (DE $1.33$) ($p<.05$) for the follow-up before one year postoperative and $-1.28$ D (DE $1.63$) ($p=.07$) for the follow-up after one year postop. The refractive cylinder was reduced from $-3.43$ (DE $1.35$) preoperative to $-1.37$ D (DE $1.24$) ($p<.05$) and $-3.21$ D (DE $2.29$) ($p=.36$) in the long term after one year of follow-up.

Conclusions: Lasik refractive results regress one year after the operation; therefore it is not an effective long-term surgical refractive procedure for residual refractive errors after PKP for KC.

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Resultados a largo plazo de lasik para ametropía residual en queratoplastia penetrante en pacientes con queratocono

Resumen

Objetivo: Evaluar la efectividad a largo plazo del Lasik en la corrección de ametropías residuales a la queratoplastia (QP) en pacientes con queratocono (QC).

Diseño: Cohorte retrospectiva.

Métodos: Análisis retrospectivo de fichas clínicas de 19 ojos (14 pacientes) operados de Lasik post-QP por QC. En todos los ojos, con estabilidad refractiva y remoción de suturas previas al Lasik, se evaluaron y compararon los siguientes resultados pre- y post-Lasik, de antes de un año de seguimiento y después de un año de seguimiento: agudeza visual corregida (AVCC) y sin corrección (AVSC), equivalente esférico (EE), astigmatismo refractivo (Ast.) y queratомétrico (dK). Los datos fueron analizados con test de normalidad Shapiro-Wilk, t de Student y Mann-Whitney para grupos independientes. Se consideró significativo un valor p < 0.05.

Resultados: Tiempo promedio de seguimiento post-Lasik fue de 3,16 meses (DE 3,8) para grupo antes de un año de seguimiento y 5,8 años (DE 2,4) para grupo después de un año de seguimiento. La AVCC 0,11 LogMAR (DE 0,07) pre Lasik, se mantuvo estable en ambos grupos, mientras que el EE disminuyó de –2,6 (DE 3,53) pre Lasik a –0,36 D (1,33) (p < 0.05) en el grupo antes de un año de seguimiento y a –1,28 D (1,63) (p = 0,07) en el grupo después de un año de seguimiento. El Ast. bajó de –3,43 (DE 1,35) a –1,37 D (1,24) (p < 0.05) a corto plazo antes del año, para aumentar a –3,21 D (DE 2,29) (p = 0,36) después del año postoperatorio.

Conclusión: Los resultados refractivos del Lasik desaparecen después del año, por lo tanto no es una cirugía refractiva efectiva a largo plazo para corregir los ER residuales en QP después del QC.

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Introducción

Even though in the past few years a number of new therapeutic alternatives for managing keratoconus have appeared (cross-linking, intra-stromal rings), a still significant number of patients end up with keratoplasty, either penetrating (PK) or ideally deep lamellar keratoplasty (DLK). Visual rehabilitation after PK continues to be a challenge due to the high level of residual astigmatism and ametropia occurring in an important percentage of patients. Management of post-PK residual ametropia would have a special characteristic in patients with keratoconus (KC) because in this condition the receiving cornea has a less stable structure due to its altered biomechanics. After PK, slight to moderate residual ametropia generally respond positively to the use of contact lenses. However, many patients are not able to use these lenses due to handling difficulties, intolerance or discomfort. Several surgical techniques have been applied to resolve the refractive problem in these cases. Of these, relaxing limbar incisions, astigmatic keratotomy and the use of sutures have demonstrated very low predictability and slow and insufficient and results. Photorefractive keratotomy (PRK), with or without mitomycin, has also been attempted but insufficient correction, high stromal haze rates or corneal scars have set it aside as a first choice for this group of patients. Subsequently, LASIK has demonstrated slightly better results in this group of patients, with shorter recovery times and slower corneal haze risk but with complications related to the flap and the disappearance of the refractive defect. The small number of available clinical reports on the use of LASIK in this group of patients suggest good results in the short and medium term and PK has been defined as a safe and effective alternative by most of said reports. Unfortunately, most published papers do not include follow-up periods over 12 months and there is sufficient clinical evidence to consider that post-LASIK stability criteria in the long-term are not the same in a patient with KC. Accordingly, the objective of this work is to present and assess the authors’ long-term post-LASIK experience in patients with KC.

Métodos

A retrospective cohort study with the objective of analyzing the efficacy and safety of LASIK in managing residual ametropia in patients with KC treated with PK. Of patients with KC treated with PK between 1999 and 2011, we selected eyes treated with LASIK for correcting residual ametropia. Nineteen eyes corresponding to 14 patients fulfilled the inclusion criteria, i.e., contact lens intolerance and refractive graft stability (defined as a change under 0.50 D sphere, 1.00 D cylinder or 10° in the axis in a one-year period). The study excluded patients who exhibited PK with follow-up under one year or incomplete data when LASIK was performed. All PK and LASIK procedures were carried out by the same surgeon utilizing the same surgical technique. The PK technique was standard: trephination of the donor corneal button 0.25 mm above the
trephination of the receiving cornea, mixed sutures of 8 separated stitches with nylon 10-0, performing final adjustments according to qualitative keratotomy at the end of the surgery. None of the patients exhibited significant postoperative complications (filtration/flattening, cataract, infection, rejection or endophthalmitis). After achieving refractive stability and withdrawing all the sutures, LASIK surgery was performed on all patients under informed consent. The LASIK technique was performed with a Hansatome microkeratome (Bausch & Lomb Hansatome™, California, United States) in the preparation of a 9.5 mm diameter flap and an Excimer NIDEK EC-5000 laser (Aichi, Japan) for stromal photoablation at the same time.

In said 19 eyes, pIVA visual acuity with correction (UCVA) and without correction (UCVA), SE, Ast and dK were taken before LASIK surgery and in the successive postoperative checkups up to the last follow-up visit. Preoperation data were compared with postoperation data before and after one-year post-LASIK. The results were analyzed with the STATIA 10 application, utilizing the Shapiro–Wilk normality test, the T for student test and the Mann–Whitney nonparametric test for independent groups. A value of $p < 0.05$ was considered as significant.

Results

The average age of patients was 28.1 years when PK was carried out and the time elapsed between PK and LASIK was an average of 6 years (range 19 months to 9 years). The average diameter of PK was 7.64 mm (SD 0.48) (Table 1). The mean follow-up results for under one-year postoperation were of 3.16 months (SD 3.8), while for the patients above one year follow-up post-LASIK was of 5.8 years (SD 2.4). Prior to LASIK, the average UCVA were 0.56 LogMAR (SD 0.36), CVA 0.11 LogMAR (SD 0.07), SE –2.6 (SD 3.53), Ast –3.43D (SD 1.35) and dK 3.84 D (SD 2.78) (Tables 2 and 3). With the exception of CVA = 0.11 LogMAR (SD 0.11), all the average results before one year postop were significantly better ($p < 0.05$) than preoperative levels: UCVA 0.19 LogMAR (SD 0.13), SE –0.36 D, Ast –1.37 D and dK –1.83 D. Comparing preoperative levels with results at one year postoperative, the differences were not significant: UCVA 0.37 LogMAR (SD 0.5), CVA 0.10 (SD 0.16); $p = 0.47$. SE –1.28 D (SD 1.63) ($p = 0.07$), Ast –3.21 D (SD 2.29) ($p = 0.36$) and dK –2.97 D (SD 2.90) ($p = 0.20$). After the first year, 3 patients lost one or more lines of UCVA while only one lost CVA with the passage of time (Table 3).

Discussion

Until now, published studies have confirmed the safety and effectiveness of LASIK in patients with PK, most with follow-up periods under one year and only some reports have identified better predictability in cylinder correction. On the other hand, even though many of the papers mentioned included some patients with KC diagnostic, none studied this group of patients exclusively. It should be noted that Malecha and Holland published a series of 20 eyes of which 74% exhibited KC diagnostic and found good results. However, only 2 patients were followed up during 12 months whereas the rest were followed up less than 7 months. As far as the authors know, the publication by Lima et al. is the only study that includes exclusively KC patients treated with PK and operated with a LASIK for residual ametropia. This series of 27 cases demonstrated the effectiveness and safety of LASIK although, here again, only with one year evolution in this group of patients.

The present work agrees with the majority of previously published papers in terms of safety and effectiveness of the LASIK technique in patients with PK for KC at one-year follow-up. However, follow-up after the year demonstrates a regression of the effect, which seems unusual for these eyes with KC, establishing a relevant difference to be considered in the refractive defect management of this group of patients. It should be pointed out that some results of LASIK in PK which remain stable in the long term are in studies of patients operated with PK, most of them for causes other than KC.

The stability of LASIK has been defined on the basis of varying criteria. In general, it is accepted that stability is achieved 3–6 months after the procedure. In the present study, long-term post-LASIK refractive instability could be explained due to the construction of the flap that includes receptor corneal tissue which, together with the typical biomechanical alteration of KC, leads to an unexpected and unforeseeable refractive response similar to that of an ectatic cornea with altered biomechanics. Another possibility is that this refractive regression is due to the natural evolution of the disease, although the SD change observed in the present study was an average of 0.92 D, significantly higher than

### Table 1 – Description of the sample.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Average</th>
<th>Range</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>PK diameter in mm</td>
<td>7.64</td>
<td>7–8</td>
<td>0.48</td>
</tr>
<tr>
<td>Age at PK in years</td>
<td>28</td>
<td>15–44</td>
<td>7.5</td>
</tr>
<tr>
<td>PK time in months</td>
<td>5.8</td>
<td>1.6–9</td>
<td>2.4</td>
</tr>
<tr>
<td>Early postop in months</td>
<td>3.2</td>
<td>1–8</td>
<td>3.8</td>
</tr>
<tr>
<td>Long postop term in years</td>
<td>4.5</td>
<td>1.2–10.5</td>
<td>4.3</td>
</tr>
</tbody>
</table>

### Table 2 – Refractive results-effectiveness.

<table>
<thead>
<tr>
<th></th>
<th>Preoperative (SD)</th>
<th>Under one year postoperative (SD)</th>
<th>Over one year postoperative (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esf</td>
<td>–0.88 (3.76)</td>
<td>0.33 (0.90)</td>
<td>0.32 (1.78)</td>
</tr>
<tr>
<td>SE</td>
<td>–2.60 (3.53)</td>
<td>–0.36 (1.33)</td>
<td>–1.28 (1.63)</td>
</tr>
<tr>
<td>Cil</td>
<td>–3.43 (1.35)</td>
<td>–1.37 (1.24)</td>
<td>–3.21 (2.29)</td>
</tr>
<tr>
<td>ΔK</td>
<td>–3.84 (2.78)</td>
<td>–1.83 (0.66)</td>
<td>–2.97 (2.90)</td>
</tr>
</tbody>
</table>

* $p < 0.05$.

### Table 3 – Visual results-safety of the intervention.

<table>
<thead>
<tr>
<th></th>
<th>Preop (SD)</th>
<th>Under one year postoperative (SD)</th>
<th>Over one year postoperative (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LogMAR UCVA</td>
<td>0.56 (0.36)</td>
<td>0.19 (0.13)</td>
<td>0.37 (0.50)</td>
</tr>
<tr>
<td>Pierde UCVA</td>
<td>0/19</td>
<td></td>
<td>3/19 (15.8%)</td>
</tr>
<tr>
<td>LogMAR CVA</td>
<td>0.11 (0.07)</td>
<td>0.11 (0.11)</td>
<td>0.10 (0.16)</td>
</tr>
<tr>
<td>Pierde CVA</td>
<td>0/19</td>
<td></td>
<td>1/19 (5.3%)</td>
</tr>
</tbody>
</table>

* $p < 0.05$. 
expected in accordance to the described natural history for this condition.\textsuperscript{20} It must be recalled that Patel described a relapse of KC in PK of 6% at 5 years.\textsuperscript{21}

A factor yet to be assessed is the application of cross-linking prior to LASIK or surface ablation. However, it is known that PRK in this group of patients entails high risk of developing corneal opacity, on the one hand due to the need of significant stromal ablation to correct large ametropia, and on the other due to greater cicatrizations in patients operated with PK, already having cicatrical fibroblasts in their stroma.\textsuperscript{22}

A recently published series of 47 cases has reported encouraging results in the use of PRK associated to MMC for treating this group of patients with low levels of corneal opacity and stability with 12 months evolution. It is yet to be demonstrated whether a possible solution to the post-Excimer laser refractive stability problem for correcting high ametropia and astigmatism in keratoplasty for KC could be the use of cross-linking prior to treatment.\textsuperscript{23}

Studies with larger number of cases and follow-up in Lasik post-PK in KC, as well as new treatment combinations, should elucidate whether the options discussed above or others will provides the safety, efficacy and stability necessary to be adopted as the first and definitive choice in the management of these ametropiae.

Conflict of interests

No conflict of interests was declared by the authors.

References