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Research Article

Long-term Results of LASIK Refractive Error Correction after Penetrating Keratoplasty in Patients with Keratoconus

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Abstract

Purpose: To analyze the long term results of LASIK for residual refractive errors (RE) after penetrating keratoplasty (PK) 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 (BCVA) and without correction (UCVA), spherical equivalent (SE) and refractive (Ast) and keratometric (dK) astigmatism were compared pre and postoperatively, before and after one year of post Lasik follow up (groups A and B respectively). Data were analyzed using Shapiro-Wilk normality test, t-student test and Mann-Whitney test. A P-value of <0.05 was considered statistically significant.

Results: The average follow-up time was 3.16 months for the group A and 5.8 years for the group B. Best spectacle corrected visual acuity of 0.11 LogMAR (SD 0.07) before LASIK remained stable along all the study. The SE decreased from -2.6 (SD 3.53) to -0.36 D (SD 1.33) (p< 0.05) in group A and -1.28 D (SD 1.63) (p=0.07) in group B. The refractive cylinder was reduced from -3.43 (SD 1.35) preoperative to -1.37 D (SD 1.24) (p< 0.05) and -3.21 D (SD2.29) (p=0.36) in the long term.

Conclusions: LASIK refractive results regress one year postop, therefore it is not an effective surgical long-term refractive procedure for residual refractive errors after PKP for KC.

Keywords: *Keratoconus, LASIK; Penetrating keratoplasty; Refractive error*

Introduction

Although in recent years have added several therapeutic alternatives new for the management of keratoconus (cross linking, intrastromal rings), still a significant number of patients eventually reach a keratoplasty, penetrating (PKP) or ideally deep lamellar keratoplasty (DALK), the subsequent visual rehabilitation PKP. It remains a challenge due to high levels of astigmatism and residual ametropy in a significant percentage of patients [1]. The management of residual ametropy after PKP has a special character in patients with KC because in this condition the recipient cornea has a less stable structure due to their altered biomechanics. After a PKP slight to moderate residual ametropies can be managed with the use of optical lenses and higher ametropies generally have a good response to the use of contact lenses [2]. However, many patients are unable to wear contact lenses, either by difficulty in handling, intolerance or discomfort [1]. Various surgical techniques have been tried to solve the refractive problem in these cases. Of these, limbal relaxing incisions, astigmatic keratotomy, and the use of sutures have shown a very low predictability and slow and insufficient final results [3]. It has also been tested Refractive Photo keratectomy (PRK), with or without mitomycin, showing an insufficient correction, high incidence of stromal haze or corneal scarring, which has been shelved as a first alternative for this group of patients [3]. Later, LASIK has shown somewhat better results in this group of patients presenting shorter recovery time and less risk of corneal haze, but with the main complication problems

related to the flap and regression of refractive error [3]. The few clinical reports available about the use of LASIK in this group of patients generally suggests good results in the short and medium term, and has been rated as a safe and effective alternative for most of the reports [4-10]. Unfortunately most of the published works have no greater follow-up than 12 months and there is sufficient clinical evidence to consider that the criteria for post LASIK long-term stability, would not be the same in a patient with KC. Therefore, the objective of our work is to present and evaluate our long-term post LASIK PKP experience in patients with KC.

Methods

Retrospective cohort study was performed in order to analyze the efficacy and safety of LASIK in the management of residual ametropia in patients undergoing PKP because of KC. Of the patients undergoing PKP for KC between 1999 and 2011, those eyes undergoing LASIK for correction of residual ametropia were selected. Nineteen eyes corresponding to 14 patients met the inclusion criteria of intolerance to contact lenses and refractive stability graft (defined as a minor change to 0.50 D of sphere, 1.00 D of cylinder or 10° on the shaft in a period of one year). Patients who had PKP with less than one year of follow-up or incomplete record at the time of Lasik were excluded from the study. All LASIK procedures PKP and were performed by the same surgeon using the same surgical technique. The technique was the standard PKP: donor corneal button trephination of 0.25 mm greater than recipient trephination, mixed suture with 8 interruptedsutures and running 10-0 Nylon, performing a final qualitative adjustment according to the intraoperative keratoscopy. None of the patients had significant postoperative complications (filtration / crushing, cataract, infection, rejection or endophthalmitis). LASIK surgery was performed to all patients once achieved refractive stability and sutures removed, under their informed consent.For the LASIK technique, aHansatome® microkeratomewas used for making the 9.5 mm flap diameter and Excimer Laser NIDEK EC-5000® for stromal photoablation.

In these 19 eyes appropriated UCVA and BCVA, SE, Ast and dK, , was consigned, prior to LASIK surgery and during their postoperative controls until last follow-up. Preoperative data were compared with postoperative data,before and after one year of follow-up post Lasik (Groups A and B respectively). The results were analyzed using STATA 10 software, using Shapiro-Wilk normality test, *t*-Student test and nonparametric Mann-Whitney test for independent groups. It was considered as significant difference $p< 0.05$.

Results

The average age of patients was 28.1 years at the time of PK and the time between PKP and LASIK averaged 6 years (range 19 months to 9 years). The average diameter of the QP was 7.64 mm (SD 0.48) (Table N 1). Group A had a mean of 3.16 months (SD 3.8), while Group B 5.8 years (SD 2.4) after LASIK. Prior to LASIK AVSC average values were LogMAR 0.56 (SD 0.36), AVcc LogMAR 0.11 (SD 0.07), the EE -2.6 (SD 3.53), Ast -3.43 (SD 1.35) and dK 3.84 (SD 2.78); (Table N 2). All average VA postop. results from Group A were significantly better than the preop: UCVA LogMAR 0.19 (95% CI 0.16 to 0.23; $p <0.05$), AV cc 0.11 (SD 0.11) LogMAR, EE -0.36 D ($p< 0.05$), Ast -1.37 D ($p< 0.05$) and -1.83 D dK ($p< 0.05$), BCVA remained stable, when Group B was compared with preoperativethe results were: UCVA LogMAR 0.39 (95% CI 0.33 to 0.45; $p< 0.05$), AVcc 0.10 (95% CI from 0.06 to 0.15; $p = 0.47$), EE -1.28 D ($p = 0.07$), Ast of -3.21 D ($p = 0.36$) and -2.97 D dK ($p = 0.20$). After the first year two patients lost one or more lines of UCVA while BCVA remained without significant change over time (Table 3).

	Average	Range	SD
PKPDiameter	7.64 mm	7 - 8 mm	0.48
Age at PKP	28 years	15 - 44 years	7.5
Time at PKP	5.8 years	1.6 - 9 years	2.4
EarlyPostop.	3.2 months	1 - 8 months	3.8
Long TermPostop.	4.5 years	1.2 -10.5 years	4.3

Table 1: *Description of the sample.*

	Preop (SD)	Group A (SD)	Group B (SD)
Sphere	-0.88 (3.76)	0.33 (0.90)	0.32 (1.78)
SE	-2.60 (3.53)	-0.36 (1.33)*	-1.28 (1.63)
Cyl	-3.43 (1.35)	-1.37 (1.24)*	-3.21 (2.29)
ΔK	-3.84 (2.78)	-1.83 (0.66)*	-2.97 (2.90)

Table 2: *Refractive results - effectiveness.*

	Preop	Postop	Long Term
LogMARUCVA	0.56 (SD 0.36)	0.19 (SD 0.13) *	0.37 (SD 0.50)
Lost UCVA		0/19	3/19 (15.8%)
LogMARBCVA	0.11 (SD 0.07)	0.11 (SD 0.11)	0.10 (SD 0.16)
Lost BCVA		0/19	1/19 (5.3%)

Table 3: *Visual Results - safety of the intervention.*

Discussion

So far the various published studies have supported the safety and effectiveness of LASIK in patients with PKP, most of them with minor follow-up to one year [11-15] and only a few reports have identified less predictability correction cylinder [16]. Moreover while many of the aforementioned works include some patients diagnosed with KC, none of them studied exclusively this group of patients. It should be noted that Malecha and Holland, presented a series of 20 eyes among which 74% had been diagnosed with KC and found good results, however only 2 patients were all with a follow-up less than 7 months [17]. To our knowledge the publication of Lima *et al.* is the only study including KC patients undergoing PKP and LASIK surgery for residual refractive error. This series of 27 cases demonstrated the effectiveness and safety of LASIK but again a year of follow-up in this group of patients [18].

Our work is consistent with most previously published in terms of safety and effectiveness of LASIK technique in patients with PKP for KC at one year follow-up. However, after year of follow-up, allows us to identify a regression effect, what we think is unprecedented for these eyes with KC establishing a relevant difference to consider in managing the refractive defect of this group of patients. It should be noted that some long-term stable LASIK results, are PKP studies mostly operated by causes other than KC [10,14].

LASIK stability has been defined according to various criteria. In general, it is accepted that it is reached within 3 to 6 months after the procedure [19]. In our study post Lasik long term refractive instability, could be explained by the construction of the flap including corneal tissue receptor, which together with the own altered biomechanics of KC leads to an unexpected and unpredictable refractive response, typical of anectatic cornea with altered biomechanics. Another possibility is that this refractive regression is due to the natural evolution of the disease, although the change of EE observed in our study averaged 0.92 D, which is much higher than expected according to the natural history described for this condition [20]. Also it must remember that Patel describes a 6 % recurrence of the KC in PKP at 5 years [21].

One factor still to evaluate would be the use of cross-linking prior to LASIK or surface ablation. However, it is known that the PRK in this patient carries a high risk of developing corneal opacity, firstly because of the need for significant stromal ablation to correct high ametropy, and secondly because of the increased scarring in PKP operated patients, already with scarring fibroblasts in the stroma [22]. A series of 47 cases recently published, have yielded encouraging results in the use of MMC associated PRK for the treatment of these patients with low levels of corneal opacity and stability to 12 months duration. Also it remains to be shown, whether a possible solution to the problem of refractive stability after excimer laser to correct vision defects and high astigmatism in keratoplasty for KC, could be the use of cross-linking prior to the Laser treatment [23].

Conclusion

Studies with higher number of cases and LASIK follow-up post PKP in KC, as well as new treatment combinations must determine whether these or other options have the safety, efficacy and stability necessary to be considered as the first and final alternative in handling these postoperative ametropies.

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