

Comparison of the Effect of Removing Bandage Contact Lens on the Days 3 and 5 Following Photorefractive Keratectomy

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Abstract

AIM: To compare the outcomes of removing bandage contact lens (BCL) on days 3 and 5 after photorefractive keratectomy (PRK).

Methods: One hundred patients underwent PRK (totally 200 eyes) were enrolled in the present study. The subjects were assigned to two groups. BCL removal was performed in group 1 on the day 3 after PRK from the right eye, but the removal in the group 2 was performed 5 days after the surgery from the left eye. Then, data obtained from both groups were compared. To evaluate complications, the subjects underwent slit-lamp examination in all visits.

Results: Filamentary keratitis (FK) was observed in one eye in both groups. The frequency of haze was higher in group 1; however, it was not significant between two group. Using mixed model analysis, significant differences were observed in the rate of complications as well as pain and eye discomfort scores between the groups (P <0.05). No major complication was reported.

Conclusion: Majority of post PRK corneal epithelial defect is healed on day 3. However, keeping BCL for 5 days postoperatively, instead of the three days produces slightly lower rate of total complication.

Keywords: Photorefractive keratectomy; Bandage contact lens; Filamentary keratitis; Recurrent corneal erosion; Corneal haze

INTRODUCTION

Photorefractive keratectomy (PRK) since 1983 is performed as an effective, safe and reasonable method to treat low to moderate myopia ¹⁻⁶. Additionally, in case of refractive errors resulted from thin corneas, laser in situ keratomileusis (LASIK) cannot be performed for patients with mildly topographic irregularities and epithelial basement membrane disease; but PRK can be performed safely ⁷⁻⁸. Nevertheless, corneal haze,

epithelial healing irregularity and pain accompanies as most notable adverse effects of PRK ⁹⁻¹⁰. PRK is a flawless technique with low complication rate performed for more than 20 years ¹¹. However, it is not very popular due to its slower rehabilitation and discomfort ¹¹⁻¹⁵

To overcome the pitfalls, BCL is introduced; it protects the abraded cornea, and reduces eyelid irritation and pain. BCLs accelerate visual recovery due to faster relief of lesions and reepithelialization ¹¹⁻¹⁶ Gas permeable, silicon hydrogel contact lenses are nowadays attached after PRK on the eye until epithelial defect is healed that usually occurs around day four ^{17,18}

Previous study demonstrated that long-term attachment of BCL accelerates visual recovery and reduces postoperative complications, however, it assumed increase the risk of keratitis. Furthermore, the authors experience showed that majority of post PRK corneal epithelial defect were repaired on the third day. So, we hypothesized that sooner removal of BCL may yield to the lower risk of keratitis. The present study aimed at comparing the outcomes of removing BCLs on the days 3 and 5 after PRK.

METHODS

In the current prospective, contralateral eye study, a total of 100 consecutive eligible adult patients (200 eyes) undergoing elective myopic PRK at Baqiyatallah Hospital, affiliated to Baqiyatallah University of Medical Sciences, Tehran, Iran from Januarys to August 2018 were enrolled. The inclusion criterion was: receiving the diagnosis of refraction stability at least one year prior to the study. The exclusion criteria were:

myopia >8 D, astigmatism >4 D, keratometry >48D, corneal thickness <480 m, and the mesopic pupil size >6 mm, or any degree of hyperopia. Patients with keratoconus, herpes keratitis, corneal dystrophy, glaucoma, cataract, blepharitis, uveitis, pregnancy, dry eyes, diabetes mellitus, keloid formation, autoimmune disease, and immune deficiency was also excluded. Subject who failed to stop wearing their BCLs for minimum 5 days (soft lenses) or two weeks (gas-permeable lenses) before perioperative assessments were also excluded.

The study was based on Helsinki's principles, and ethical approval was obtained by the Ethics Committee in Human Research at Baqiyatallah University of Medical Sciences. All subjects were asked to sign the informed consent form. A complete preoperative eye examination including uncorrected distance visual acuity (UDVA), corrected visual acuity (CDVA), manifest and cycloplegic refractions, slit-lamp examination of the anterior segment and the fundus, and applanation tonometry was performed for all patients.

Surgical procedure

after PRK, respectively

PRK procedure in all the subjects was performed by the same surgeon (SHD). Povidone iodine was used to clean lids and lashes. After scrubbing and draping the lids, a speculum was positioned to open the lids. One drop of tetracaine 0.5% anesthesia droplets (Sina Darou Company) was instilled into the eye to be treated. In addition, cornea was treated with 20% ethyl alcohol for 15 seconds by placing a 9-mm well on it and then was rinsed with balanced salt solution to be prepared for epithelium peel-off.

Subsequently, laser was delivered with ablation profile of the software by Technolas 217Z excimer laser (Bausch&Lomb). The optical zone varied 6.5 to 7 mm; relyingon age, K reading, pupil size and refractive error, transition zone was determined for each patient using a nomogram. The stromal surface was treated with Mitomycin C .02% for 30 seconds and then washed with 50 ml saline. Senofilcon A (Acuvue ®; Johnson and Johnson Vision Care, Inc., Jacksonville, USA) high-water content bandage contact lenses were placed over both eyes after instilling the drop Topical Diclofenac 0.1% every six hours for 24 h, betamethasone drops 4 times daily, chloramphenicol drops 4 times daily, and artificial

0.1% every six hours for 24 h, betamethasone drops 4 times daily, chloramphenicol drops 4 times daily, and artificial tears (preservative free) every 2 hours were administered after surgery. After one week, chloramphenicol drops were stopped but betamethasone drops continued for 1 month and then fluorometholone 0.1% drops was started every six hours, then tapered for two months.

The slit-lamp examination was utilized on the days 1, 3, and 5 as well as 1, 3 and 6 months after the surgery to explore any signs of epithelial defects, corneal clarity, filamentary keratitis, etc. A questionnaire was also completed for each patient regarding the eye discomfort and pain. To determine the degree of pain, visual analogue scale (VAS) was employed. Discharge, epiphora, foreign body sensation, photophobia, and blurred vision were assessed as ocular discomfort using a scale from 0 (no complaint) to 10 (the worst possible complaint).

An interviewer who was blind to groupings helped the patients to complete questionnaires. On the day 3 (after confirming the relief of the epithelial defect), subjects were divided into two 100-eye groups using non-randomized number table. BCLs were removed on the day 3 ;groups 1 ,in right eye and day 5 ;groups 2 for left eye

The patient was excluded if the epithelium recovery was not completed yet. Subjects recompleted the pain and discomfort questionnaire 5 days after surgery. Visual acuity [Corrected Distance Visual Acuity and Uncorrected

Distance Visual Acuity] was tested one and three months after the procedure using Snellen chart and the results were converted to Log MAR scale the main outcome measure was early postoperative complication including filamentary keratitis, recurrent corneal erosion, and corneal haze occurring within six months of the surgery.

Sample size calculation and statistical analysis

In the current study based on 80% the study power, 1.4 SD, and 0.05 confidence interval, the minimum sample size was determined 50. Nevertheless, 100 subjects were enrolled in the study in order to increase the study power. Data were analyzed using SPSS version 20. Chi- squared test was utilized to compare the descriptive data between the groups. The scores and data were also compared using the Mann-Whitney test. Both eyes of each patient were included. The level of significance was <0.05.

RESULTS

In the current study 200 eyes of 100 patients underwent PRK. Ablation depth <100 µm was similar in all patients. Corneal healing was reported in all subjects on the day 3 after operation. The mean age of the study subjects were 28.96±6.39 years. The groups had no significant difference on the day 1 after PRK in terms of pain score, level of epiphora, blurred vision, photophobia, and foreign body sensation(not shown in table). On the day five after PRK, the group 2 had lower mean scores in photophobia score, level of epiphora, and blurred vision; the difference between the groups were not significant

Means of pain score and foreign body sensation were significantly lower in group 2 (Tables 1).

reported complications were completely resolved within six months.

=0.30); however, after three months, a slightly significant difference was observed (P=0.09) (Table 2). Likewise, there was no statistically significant difference in the one and three-month postoperative CDVA between groups (see table 2). Filamentary keratitis (FK) and recurrent corneal erosion (RCE) were observed in one eye (1%) and corneal haze in two (2%) eyes in group1 after six months of surgery. RCE was not observed (0%), but FK and corneal haze were reported in one (1%) eye in Group 2. The groups had a significant difference in the frequency of complications (P=0.04) (Table 3). However, with proper management, the

The groups had no significant differences in the Log MAR means of UDVA one month after surgery (P

DISCUSSION

It was the first prospective, contralateral eye study on the comparison of the outcomes of removing BCL at two different time points after PRK. Three-month post-surgery results were slightly more satisfactory in Group 2 in which BCL was kept for a longer run.

The corneal epithelium has six layers that normally epithelial wounds healing occurs around four days after PRK, which prolongs the complete recovery.^{20,21}

On the other hand, restored epithelium is protected by BCL, which accelerates epithelial relief and anchoring to beneath layers, and facilitates formation of a smoother epithelial surface, which lead to visual recovery. ^{19,20} Hence, it can be concluded that faster and better visual recovery may be associated with delayed BCL removal.

In this study, there was a significantly lower frequency of complications in group 2 (P=0.04). FK was observed in ablative refractive surgeries that mostly occur in dry eye condition²². Epithelial damage is the main cause of FK, which leads to the detachment of epithelium from the underlying membrane that focal regions deposition of detached epithelium forms fine filaments. ²³ So it is recommended to apply BCLs to treat FK because BCL stops this cycle. Hence, long-term use of BCL helps the attachment of newly-formed epithelium and reduced FK rate.

In group 2, the frequency of corneal haze was lower, although the difference was insignificant. Different factors affect opacity of subepithelial cornea. Results of a rabbit model study on PRK showed that the procedure may lead to corneal haze due to irregularity and defect in epithelium. ²⁴ .The crucial role of basement membrane integrity in prevention from subepithelial corneal haze was also confirmed in a study by Stramer et al., ²⁵ since TGF b is released from defective epithelium, which triggers the generation of keratinocytes in the stromal layer and finally leads to haze.

Also, according to the results of different studies, epithelial debridement techniques trigger epithelial healing and postoperative haze formation in various manners. Mechanical removal is a technique that causes irregularity in stromal surface, while epithelium is still remained in place that roughs stromal bed for restoration of epithelium. This technique prolongs epithelial relief, which alters extracellular matrix and

cellular density followed by tissue opacity and haze. ²⁸ In contrast, stroma and epithelium were separated using diluted alcohol, which causes no damage to the stromal surface, reduces inflammation and alteration in the cells, and helps epithelial regeneration. Ultrastructural studies of the application of alcohol for debridement in the eye confirms this finding. ³¹

In the present study, Senofilcon A (Acuvue ®; Johnson and Johnson Vision Care, Inc., Jacksonville, USA), high water content bandage contact lenses, were utilized. Using these lenses facilitates nutrition and oxygen delivery to cornea. BCL use helps relieve in cornea and enables modified reepithelialization. It can be used comfortably for a long run. It also prevents irritation and micro traumas, which lead to micro-epithelial defects and haze.

The same BCL type and method of debridement were utilized for the current study subjects, hence, lower postoperative complications in group 2 may be associated with the better epithelial integrity, which is rooted in the removal of BCL after 3 days.

Although LASIK was the commonest surgery for correction of myopia, PRK is preferred in some cases with thin cornea or risk of exposure to trauma. Post-PRK complications are significantly lower, which makes it as a safe and efficient technique with faster visual recovery. Studies show epithelium debridement with alcohol yields to a complete epithelial layer and corneal healing. Although dry eye and stem cell damage are more frequent using PRK, the difference is insignificant. Use of Mitomycin C and debridement of epithelium with alcohol reduces haze and time to

recover vision. ^{30,32} However, prolonged BCL use play a major role in the reduction of time to recovery, since the group 2 in the current study had less complications and achieved complete visual recovery within one month after PRK.

In this study the inclusion criterion was same. Surgeries and follow-ups were performed by the same surgeon. Ablation depth <100 µm, excimer laser machine, duration of MMC application, and postoperative protocol were similar. However, there was some limitation in our study as follows: first and foremost, epithelial defect size and healing velocity was not checked with image analysis software; the gold standard that might be more reliable. Secondly, grouping was not performed on a random basis and patients chose the procedure they preferred. Even so, several advantages such as: a longer follow-up (at least six months), high number of patients included in our study in comparison to previous studies, stability of vision after six months and finally no reports pertaining adverse events in patient associated with any treatment method, could warrant comprehensively

evaluation of our outcomes.

In conclusion, results in this prospective non-randomized clinical trial suggests that majority of post PRK corneal epithelial defect is healed on day 3. However, keeping BCL for 5 days postoperatively, instead of the three days produces slightly lower rate of total complication.

DECLARATIONS

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Consent for publication

Not Applicable

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Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available since all relevant data are included in the manuscript. The datasets are available from the corresponding author on reasonable request.

Authors' contributions

AA, KJ and SHD were responsible for the conception and design of the study. SAM acquired the data. KJ,SAM and MN analyzed and interpreted the data. SAM wrote the draft. SHD,MN and KJ revised the manuscript critically. All authors have read and approved the final manuscript.

Ethics approval

The research protocol was in accordance with the Helsinki's Declaration and approved by the Ethics Committee in Human Research at Hospital Research Center.

Animal Research (Ethics)

Not Applicable

Consent to participate

Informed consent to participate in the study was obtained from all participants

Competing interests

The authors declare that they have no competing interests.

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- **Table 1:** Means of pain score and eye discomfort after BCL removal.
- Table 2: Postoperative results of bandage contact lens removal on the 3rd versus fifth day after PRK
- Table 3: Post-operative complications