



Original research

Comparison of bandage contact lens removal on the fourth versus seventh postoperative day after photorefractive keratectomy: A randomized clinical trial

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Abstract

Purpose: To compare the outcomes of bandage contact lens (BCL) removal on the fourth versus seventh post-operative day following photorefractive keratectomy (PRK).

Methods: This study recruited eyes of patients who underwent PRK surgery. The patients were randomly assigned to 2 groups. In Group 1 BCL was removed on the 4th postoperative day, while in Group 2, BCL was removed on the 7th postoperative day. After BCL removal, patients were asked to express their pain score and eye discomfort. At one and three months follow-up examinations, visual acuity scale was assessed. Slit-lamp examination was performed in all visits to evaluate complications.

Results: 260 eyes of 130 patients underwent PRK. The age and sex ratio were not significantly different between the two groups. One month after the surgery, the logMAR uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were significantly lower in Group 2 (P value = 0.016, 0.001 respectively), however, the UDVA and CDVA were not significantly different after 3 months (P > 0.05). In Group 1, filamentary keratitis (FK) was observed in 10 (7.6%) eyes, 6 (4.61%) eyes were diagnosed with recurrent corneal erosion (RCE) and corneal haze was detected in 3 (2.3%) eyes. However, in Group 2, RCE was observed in 4 (2.3%) and FK was noted in 4 (3.07%) eyes. No haze was seen in Group 2. The difference in rate of complications was statistically significant (14.6% and 6.1% in Groups 1 and 2, respectively, P = 0.02). Pain and eye discomfort scores were not significantly different (P > 0.05). There was no major complications including infectious keratitis in either groups.

Conclusion: Following PRK surgery, BCL removal on the seventh postoperative day yields faster visual rehabilitation and lower rate of postoperative complications with no increase in eye pain, discomfort or infection.

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

The present study was performed at Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran.

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Introduction

Over the last decade, significant developments have been made to improve corneal refractive surgery outcome,^{1–6} and Laser in situ keratomileusis (LASIK) has emerged as the most popular refractive procedure. Nevertheless, serious complications including corneal ectasia, epithelial ingrowth, and flap-related complications have been reported.^{7–10} On the other

hand, Photorefractive Keratectomy (PRK) is a flapless, well-established technique with a low rate of complications which has been performed for over 20 years.¹¹ However, due to slower visual rehabilitation and more postoperative discomfort, its popularity has declined.^{2,5,11–15} Therefore, to obtain the best results with the least rate of complications, new approaches such as using bandage contact lens (BCL) have been employed, BCL by protecting the abraded cornea, diminishes the mechanical irritation of the eye lid and reduces level of postoperative pain. It also facilitates faster reepithelialization and improved wound healing which contribute to earlier visual rehabilitation and more favorable results.^{2,11–17}

Nowadays, silicon hydrogen contact lenses with high oxygen permeability are utilized after PRK and are often removed after the epithelial defect is healed.¹⁸ The healing process occurs around the fourth postoperative day.^{18,19} It is assumed that a delay in contact lens removal contributes to a higher risk of infection; however with prophylactic use of topical antibiotics, BCL could be held longer which may provide more stable and enhanced epithelial healing and less discomfort.

In this study, we aim to test this hypothesis that delayed BCL removal may yield better outcomes in terms of visual recovery and post-operative complications.

Methods

This single-center, double masked controlled trial was performed at Farabi Eye Hospital, a tertiary and academic eye center, affiliated with Tehran University of Medical Sciences, Tehran, Iran from July 2014 to September 2014. Adult patients undergoing elective myopic PRK surgery were recruited. The patients were eligible to be enrolled in our trial if they had documented refraction stability of at least one year. Subjects with myopia more than -8 D, astigmatism more than 4 D, keratometry more than 48 D, corneal thickness less than 480 μ , and the mesopic pupil size larger than 6 mm or any degree of hyperopia were excluded. Patients with keratoconus, herpes keratitis, corneal dystrophy, glaucoma, cataract, blepharitis, uveitis, pregnancy, past medical history of dry eyes, diabetes mellitus, keloid formation, autoimmune disease, and immune deficiency were not included. Overall 260 eyes of 130 patients were enrolled in the study.

The present study adhered to the tenets of the Declaration of Helsinki. All aspects of the trial were approved by the ethics committee and Institutional Review Board of Farabi Eye Hospital and Tehran University of Medical Sciences and registered in the Iranian trial registration website (registration number = IRCT2013061613567N3). An informed consent was signed by the study participants.

Surgical procedure

All PRK procedures were performed by a single surgeon (MM). Prior to laser ablation, topical tetracaine 0.5% was instilled in each eye. Following alcohol 20% solution application, a standard 8.5 mm epithelial defect was made with a hockey spatula. Stromal ablation was completed by Technolas

217-Z excimer laser (Bausch & Lomb). Mitomycin C 0.02% was left on the stromal surface for 30 s and was rinsed with 50 ml of saline solution. After applying one eye drop of chloramphenicol, a BCL [Comflicon A silicon 52%, water content 48%, contact lenses with base curve of 8.6 mm, Diameter of 14 mm, Dk = 128 (Biofinity, Cooper vision care, USA FDA approved for seven days constant wear)] were placed over both eyes.

In all subjects, postoperative medications were the same. Patients received topical Diclofenac 0.1% every 6 hrs for 24 hrs after the surgery. Betamethasone 0.1% was applied four times a day for a month and was tapered later. Chloramphenicol 0.1% was prescribed until the contact lens was removed. Patients were visited by the same surgeon (MM) on the 1st, 4th and 7th postoperative day and also 1, 3, and 6 months following the operation. Slit-lamp examination was performed on first, fourth, and seventh day after surgery and then one and three months postoperatively to evaluate the epithelial defect, corneal clarity, the presence of filamentary keratitis (FK) and other complications. Patients also completed a questionnaire (Noor Eye Hospital questionnaire) about the eye discomfort and pain. Visual analogue score (VAS) was employed to determine degree of pain, in which 0 means no pain at all and 10 means the worst pain a patient has ever experienced. Ocular discomfort including discharge, epiphora, foreign body sensation, photophobia, and blurred vision was assessed on a scale of zero to ten in which zero indicated no complaint at all and ten the worst possible complaint. Patients were asked to score each eye separately. An interviewer who was blinded to the cases, assisted in completing the questionnaire. On the fourth day (after it was confirmed that the epithelial defect was healed), according to random number table, subjects were divided into two even groups (each group included 130 eyes). In Group 1, BCL was removed on the fourth postoperative day and in the second group, BCL was removed seven days after the surgery in both eyes. If the epithelium was not healed by the 4th postoperative day, the patient would be excluded from the trial. On the seventh day, the same questionnaire about postoperative pain and discomfort was completed by the patients. In the following visits, in the first and third month after the procedure, visual acuity [Corrected distance visual acuity (CDVA) and uncorrected distance visual acuity (UDVA)] were assessed by means of Snellen chart and then converted to logMAR scale. The main outcome measure was early postoperative complication including FK, recurrent corneal erosion (RCE), and corneal haze which occurred in 6 months following the procedure.

Sample size calculation and statistical analysis

To obtain a statically significant difference in the main outcome measure (Early postoperative complications) between the two groups, with a power of 80%, SD of 1.4, and confidence interval of 0.05, a sample size of at least 60 was calculated with the following formula. However, we enrolled 130 cases to increase the power of the study.

$$n = \frac{2\left(\mathbf{Z1} - \frac{\mathbf{a}}{2} + \mathbf{Z1} - \mathbf{B}\right) * 2 (\mathbf{S1} - \mathbf{S2}) * 2}{(\mu - \mu)^2}$$

Statistical analysis was performed by means of SPSS for Windows software (version 20, SPSS, Inc). To compare the descriptive data between the two groups, chi square test (χ^2) was used. Mann Whitney test was utilized to compare the score and other quantitative data. All data were presented in mean \pm SD. Both eyes of each patients were included. P values < 0.05 were considered significant.

Results

PRK surgery was performed on 260 eyes of 130 patients which were divided into two equal groups. Ablation depth < 100 micron were the same in all patients. All patients had corneal healing on the 4th postoperative day, and all cases were included. The mean age of patients in Groups 1 and 2 was 28.91 ± 6.83 and 27.7 ± 6.38 years old, respectively (P = 0.13). Female-to-male (F/M) ratios were not significantly different between the two groups (Group 1; F/M = 0.64, Group 2; F/M = 0.60 P = 0.52).

On the first postoperative day, there was no significant difference in means of pain score, level of epiphora, blurred vision, photophobia, and foreign body sensation between the two groups. On the seventh day after surgery, means of pain score, level of epiphora and blurred vision were lower in Group 2; however, the difference was not statistically significant (Tables 1 and 2).

One month after the surgery, the logMAR UDVA and CDVA means were significantly lower in Group 2 (P value = 0.016, 0.001, respectively); however, the UDVA and CDVA were not significantly different after 3 months (P = 0.1) (Figs. 1 and 2).

In the 6 month follow-up, in Group 1, FK was observed in 10 (7.6%) eyes, 6 (4.61%) eyes were diagnosed with RCE and

Table 1
Means of pain score and discomfort on the first postoperative day.

	Group 1	Group 2	P value
Pain score	5.42 \pm 3.20	5.86 \pm 3.36	0.20
Photophobia	6.39 \pm 2.92	6.56 \pm 2.95	0.54
Epiphora	6.10 \pm 3.29	5.86 \pm 3.85	0.84
Foreign body sensation	5.39 \pm 3.30	5.6 \pm 3.38	0.58
Blurred vision	5.56 \pm 2.89	5.3 \pm 3.17	0.46

Table 2
Means of pain score and eye discomfort after bandage contact lens (BCL) removal.

	Group 1	Group 2	P value
Pain score	2.92 \pm 2.84	2.35 \pm 2.71	0.07
Photophobia	5.07 \pm 2.60	5.34 \pm 3.02	0.40
Epiphora	2.15 \pm 2.66	1.85 \pm 2.56	0.20
Foreign body sensation	2.50 \pm 2.97	2.78 \pm 2.75	0.21
Blurred vision	4.77 \pm 2.36	4.42 \pm 2.22	0.17

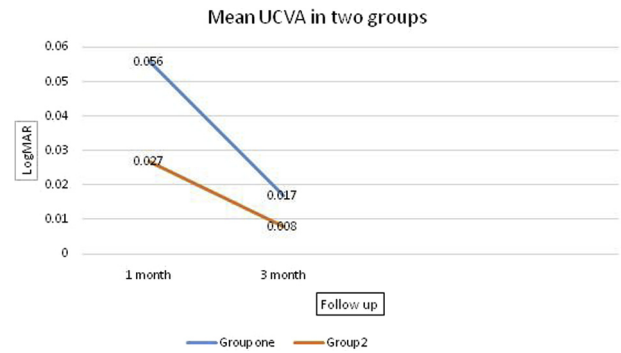


Fig. 1. Means of uncorrected distant visual acuity (UDVA) in the two studied groups.

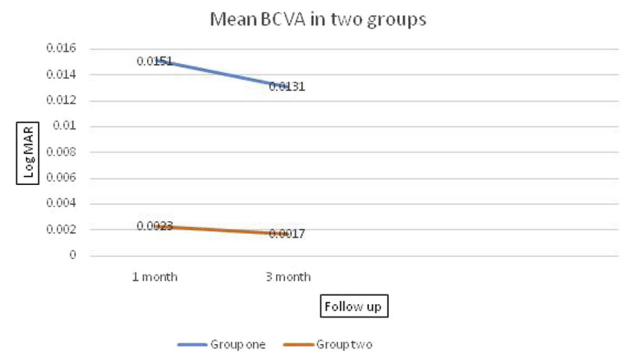


Fig. 2. Means of corrected distant visual acuity (CDVA) in the two studied groups.

corneal haze was detected in 3 (2.3%) eyes. However, in Group 2, RCE was observed in 4 (3.07%), and FK was noted in 4 (3.07%) eyes. No haze was seen in Group 2. The difference in rate of complications was statistically significant (14.6% and 6.1% in Group 1 and 2, respectively, P = 0.02) (Table 3). All complications resolved within the six months with proper management.

Discussion

To the best of the author's knowledge, this is the first prospective randomized controlled clinical trial with an appropriate sample size which compared the outcomes of early versus delayed removal of BCL after PRK. Our findings demonstrated that both UDVA and CDVA at one month follow-up were significantly better in Group 2 with delayed BCL removal. It implies that delayed removal of BCL yields faster and better visual rehabilitation.

Table 3
Postoperative complications.

	Group 1 (N/%)	Group 2 (N/%)	P value
FK ^a	10 (7.6%)	4 (3.07%)	0.09
RCE ^b	6 (4.61%)	4 (3.07%)	0.51
Corneal haze	3 (2.3%)	0 (0%)	0.08
Total	19 (14.6%)	8 (6.1%)	0.02

^a FK: filamentary keratitis.

^b RCE: recurrent corneal erosion.

As already known, the corneal epithelium consists of six layers and although epithelial defect heals around the fourth postoperative-day, the complete healing process prolongs.^{20,21} BCL, by protecting the fragile newly-formed epithelium, provides enhanced epithelial healing, improves anchoring to the underlying layers and yields a smoother epithelial surface that could contribute to earlier visual recovery.^{19,20}

Regarding complications, the overall rate was significantly lower in Group 2 (P value = 0.02). FK which is characterized by fine filaments of epithelial cells and mucus attached to the corneal epithelium, is highly associated with dry eye condition and is considered a complication of ablative refractive surgeries.²² FK occurs as a result of epithelial damage which gives rise to epithelial detachment from the underlying basement membrane. The focal regions of detached epithelium become the receptor sites for epithelial cells and mucus which eventually form fine filaments.²³ BCL has been proposed as one of the various treatment options for FK. Since BCL acts as a barrier and prevents the shearing influence of the eyelid, it halts this vicious cycle. Therefore, by keeping BCL for a longer period of time which helps better attachment of newly formed epithelium, the rate of FK may be reduced.

In Group 2, no corneal haze was detected. However, the difference was not statistically significant. Several factors have been proposed to have an impact upon inducing subepithelial corneal opacity. On an experimental study on rabbits, it has been suggested that surface irregularity and epithelial defect are associated with corneal haze formation after PRK.²⁴ Stramer et al²⁵ also supported the crucial role of basement membrane integrity in preventing sub epithelial corneal haze, since defective epithelium releases TGF β which triggers keratocyte generation in the stromal layer, and haze is considered to be associated with an increased number of wound healing keratocytes.^{25,26} Previous studies confirm that different techniques in epithelial debridement have diverse impacts on epithelial healing and postoperative haze formation.^{27–29} Mechanical removal technique delivers an irregular stromal surface with retained islands of epithelium which give rise to a rough stromal bed for epithelial regeneration. This results in delayed and defective epithelial healing which is the main culprit of alteration in extracellular matrix and cellular density which subsequently leads to loss of tissue transparency and haze formation.²⁸ In contrast, epithelial debridement with diluted alcohol separates stroma and epithelium without trauma to the stromal surface.³⁰ Therefore, the favorable environment for epithelial growth with less inflammation and cellular alteration is obtained.²⁰ Ultra structural studies on eyes which underwent alcohol solution debridement confirmed this idea and showed an intact epithelial layer.³¹

In this study, we used third generation BCL (Comflicone A) which has high oxygen permeability (Dk = 128) and more water content (48%) simultaneously. This feature is of utmost importance, since it enables delivery of more nutrients and oxygen to the corneal surface, and more water content is associated with less discomfort.^{18,21,32,33} Thus, it modifies corneal healing and enables modified reepithelialization. Furthermore,

the mentioned BCL has a higher water content which makes it more comfortable for a longer period of time and prevents the mechanical irritation and micro trauma that would consequently lead in micro-epithelial defect and later haze formation. Since the same BCL and same debridement method were used in all the participants, the key factor in reducing postoperative complications may be explained by the better epithelial integrity in Group 2 which had delayed BCL removal.

This study had several limitations. We acknowledge that physiologic responses in different individuals vary; however the mean age, sexual ratio, and inclusion criteria between the two groups were not different, and all patients were operated and followed by the same surgeon. Ablation depth <100 micron, excimer laser machine, duration of mitomycin C application and postoperative protocol were similar. Another limitation of our study was that we did not obtain any data on epithelial defect size on the 2nd and 3rd postoperative days.

Although LASIK is the most common refractive surgery, some ophthalmologists consider PRK the method of choice in individuals who have a thin cornea or an active lifestyle prone to trauma.^{11,14} LASIK involves creating a corneal flap which entails intraoperative complications. Furthermore, corneal ectasia, high rate of dry eye, and flap-related complications are the major shortcomings of LASIK.^{7–10} Therefore, great enthusiasm has been shown in reducing post PRK complications and consequently making PRK a safe and efficient procedure with fast visual recovery.¹⁴ Previous studies showed that epithelium removal with alcohol is associated with a complete epithelial layer and intact desmosomes and hemidesmosomes which permits corneal healing. Although the rate of dry eye and stem cell damage is higher with this technique, the difference is not statically significant.²⁷ Administration of mitomycin C and epithelial debridement with alcohol solution aided in reducing haze and visual recovery time.^{30,32} However, delayed removal of BCL played the most important role in the latter findings, since our second group had superior outcomes regarding complications and visual recovery at one month, postoperatively.

In conclusion, for the first time, we showed that by keeping BCL for one week postoperatively, instead of the traditional four days, faster visual rehabilitation and lower rate of total complications are obtained.

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