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Original research

Comparison of bandage contact lens removal on the fourth versus seventh post-operative 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 post-operative day, while in Group 2, BCL was removed on the 7th post-operative 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 Log MAR UDVA and 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 post-operative day yields faster visual rehabilitation and lower rate of post-operative complications with no increase in eye pain, discomfort or infection.

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

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

Abbreviations and acronyms: BCL, bandage contact lens; CDVA, corrected distance visual acuity; FK, filamentary keratitis; LASIK, laser in situ keratomileusis; PRK, photo refractive keratectomy; RCE, recurrent corneal erosion; UDVA, uncorrected distance visual acuity; VAS, visual analogue score.

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

Conflicts of interest: No conflicting relationship exists for any author.

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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 post-operative 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 BCL have been employed, BCL by protecting the abraded cornea, diminishes the mechanical irritation of the eye lid and reduces level of post-operative 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 post-operative 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 48D, 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, post-operative medications were the same. Patients received topical Diclofenac 0.1% every 6 h for 24 h 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 post-operative 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 post-operatively to evaluate the epithelial defect, corneal clarity, the presence of filamentary keratitis 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 post-operative 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 post-operative day, the patient would be excluded from the trial. On the seventh day, the same questionnaire about post-operative 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 post-operative complication including Filamentary Keratitis, Recurrent Corneal erosion, 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 post-operative 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.

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