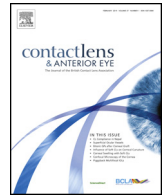




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# Contact Lens & Anterior Eye

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## Comparison of Lotrafilcon B and Balafilcon A silicone hydrogel bandage contact lenses in reducing pain and discomfort after photorefractive keratectomy: A contralateral eye study



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### ABSTRACT

**Purpose:** To assess the effect of two silicone hydrogel contact lenses with high oxygen permeability in patients having photorefractive keratectomy (PRK).

**Setting:** Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran.

**Methods:** Sixty patients (120 eyes) who had bilateral PRK were enrolled in this double blind clinical trial. Each patient was fitted with a Lotrafilcon B (Air Optix® AQUA, Ciba Vision, Duluth, GA, USA) lens in one eye and a Balafilcon A (PureVision™ Bausch & Lomb, Rochester, NY, USA) lens in the fellow eye. Patients' responses to a subjective questionnaire in terms of pain, foreign body sensation, photophobia, blurred vision and epiphora were evaluated on the first and third postoperative days.

**Results:** Mean pain score for Lotrafilcon B and Balafilcon A contact lenses was  $4.43 \pm 3.18$  vs.  $5.45 \pm 3.37$  on the first postoperative day and  $3.43 \pm 3.23$  vs.  $3.88 \pm 3.01$  on the third postoperative day. However, the difference was only significant in the first 24 h after surgery ( $P=0.032$ ). Foreign body sensation was clinically higher with Balafilcon A contact lens ( $5.0 \pm 3.47$  vs.  $4.08 \pm 3.34$  on day 1 and  $4.98 \pm 3.52$  vs.  $3.55 \pm 3.20$  on day 3) and the difference was statistically significant on the first and the third postoperative days ( $P=0.042$  and  $0.002$ , respectively). There was no statistically significant difference between two contact lenses in terms of photophobia, epiphora and blurred vision ( $P>0.05$ ).

**Conclusion:** The Lotrafilcon B lens resulted in significantly less postoperative pain and discomfort after PRK, especially in the first 24 h after PRK.

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### 1. Introduction

Ablative refractive surgery with excimer laser is an effective way to correct refractive errors including myopia and hyperopia [1]. Surface ablation techniques including photorefractive keratectomy (PRK), laser-assisted subepithelial keratectomy (LASEK) and epithelial laser in situ keratomileusis (epi-LASEK) have gained popularity in recent years. Although LASIK is the most common refractive surgery performed, [2] in certain situations such as in patients with thin corneas and those participating in contact sports who are more susceptible to trauma and flap dislocation, PRK is the

preferred method [3]. However, PRK has many drawbacks including postoperative pain and delayed visual recovery [4].

Postoperative pain is usually more prominent in the first 24 h and peaks about 3–4 h after the surgery [5]. Different approaches for management of postoperative pain have been used, including topical anesthetics, topical non-steroidal anti-inflammatory drugs and bandage contact lenses [6]. In 1996, Cherry found that the additive effect of all three methods was most effective in managing pain after PRK [7]. Mohammadpour et al. stated that preemptive administration of topical diclofenac significantly reduces postoperative pain in the first 24 h after PRK [5].

Bandage contact lenses (BCLs) were introduced about 40 years ago and were mainly used for protective purposes after corneal injuries, but their therapeutic role became more prominent with the evolution of refractive surgery [8]. BCLs act by protecting the cornea, relieving pain and accelerating the healing process [9,10].

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Faster corneal reepithelialization results in a more rapid recovery, less corneal haze and infection [11] and faster visual recovery. Conventional non-silicone contact lenses are widely used as bandage contact lenses, but their low oxygen permeability increases corneal swelling during extended wear [12]. Silicone hydrogel contact lenses have a very high gas permeability, which reduces complications related to corneal hypoxia and improves wound healing and epithelial regeneration after refractive surgery [13–16]. Comparison of silicone and non-silicone hydrogel contact lenses after LASEK has shown better corneal epithelial status with silicone hydrogel contact lenses [17].

Several silicone hydrogel contact lenses have been introduced in recent years. Two commonly used BCLs are Lotrafilcon B and Balafilcon A. These silicone hydrogel contact lenses have been approved by Food & Drug Administration (FDA) for continuous wear after refractive surgery (6 days and 30 days for Lotrafilcon B and Balafilcon A lenses, respectively) [14,18]. Different comparisons have been made among commercially available lenses, but no study has directly compared Lotrafilcon B and Balafilcon A. The aim of this study is to evaluate the efficacy of these silicone hydrogel lenses in reducing pain and ocular discomfort after PRK.

## 2. Patients and methods

### 2.1. Study design

This double-blind clinical trial evaluated the effect of Lotrafilcon B and Balafilcon A silicone hydrogel contact lenses in reducing pain and discomfort after PRK. It enrolled 60 patients (120 eyes) who had bilateral PRK for correction of myopia and astigmatism at Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran, from October 2013 to December 2013. The details of the study and possible risks were explained to each patient and a written consent form was signed.

Patients were included in this study if they met the following criteria: age 19 years or older, myopic refractive error of 8.00 diopters (D) or less and/or astigmatism of 3.00 diopters (D) or less, refraction stability of at least 1 year duration, less than 1.00 diopters difference in refractive error between two eyes, central corneal thickness 480  $\mu\text{m}$  or thicker, residual stromal bed thickness at least 420  $\mu\text{m}$  and corrected distance visual acuity (CDVA)  $\geq$  20/20.

Exclusion criteria included a history of refractive or cataract surgery, keratoconus, a history of glaucoma, CDVA less than 20/20, irregular astigmatism, bleeding disorders, collagen vascular diseases, diabetic retinopathy, autoimmune diseases, immunodeficiency, and a history of keloid formation. Recruited patients were excluded from the final statistical analysis if they experienced significant trauma to the eye, displaced a contact lens or were refitted with a contact lens.

### 3. Surgical technique

The same surgeon (M.M) performed all PRK procedures. Topical tetracaine 0.5% was applied 2 times in 10 min before excimer laser application. Using an 8.5 mm well, a standardized epithelial defect was created into which 20% alcohol was instilled and left for 20 s. After the alcohol was rinsed from the eye with 50 cc of a balanced salt solution (BSS), the epithelial layer was removed with a hockey spatula. Then, using a Technolas 217-Z excimer laser (Bausch & Lomb), stromal ablation was performed. Mitomycin C was applied for 30 s and irrigated using 50 cc of BSS.

After the surgery, one eye of each patient was randomly and through coin flipping fitted with a Lotrafilcon B (Air Optix® AQUA, Ciba Vision, Duluth, GA, USA) lens and the fellow eye with a Balafilcon A (PureVision™ Bausch & Lomb, Rochester, NY, USA) lens. The

**Table 1**  
Contact lens characteristics.

Parameter	Air Optix AQUA	Pure Vision
Manufacturer	Ciba Vision	Bausch & Lomb
Material	Lotrafilcon B	Balafilcon A
Dk/t	110	99
Water content (%)	33	36
Diameter (mm)	14.2	14.0
Back vertex power (D)	−0.00	−0.00
Back optic zone radius (mm)	8.60	8.60

characteristics of fitted lenses are summarized in Table 1. Patients and examiner were masked to which type of bandage contact lens was in which eye. The same surgeon evaluated the fit of the bandage contact lenses using slitlamp biomicroscopy.

### 4. Postoperative protocol

The postoperative medication regimen was the same for both eyes and included betamethasone and chloramphenicol eye drops four times daily. Betamethasone was administered four times daily for 3 weeks and then changed to fluorometholone 0.1% which was used four times daily and then tapered over 2 months. Chloramphenicol was discontinued 5 days after surgery. For pain control, patients were given Diclofenac 0.1% eye drop four times daily for 2 days and oral acetaminophen 325 mg, 1–2 tablets every 6 h as needed.

All patients were examined 1 and 3 days postoperatively. On each examination, a questionnaire regarding subjective pain and ocular discomfort was given to patients. Patients were asked to assess the level of pain and ocular discomfort including foreign body sensation, photophobia, blurred vision and epiphora using a verbal numerical rating scale of 0–10 (0 = no pain and discomfort; 10 = highest level of pain and discomfort). A trained examiner recorded the subjective pain and discomfort scores. Both the examiner and patient were masked to which kind of lens was in each eye.

### 5. Statistical analysis

Statistical analysis was performed using SPSS for windows software (version 18.0, SPSS, Inc.). Paired sample *t* test was used to compare paired-eye variables. Data are expressed as the mean  $\pm$  SD. *P* value of  $\leq$ 0.05 was considered significant.

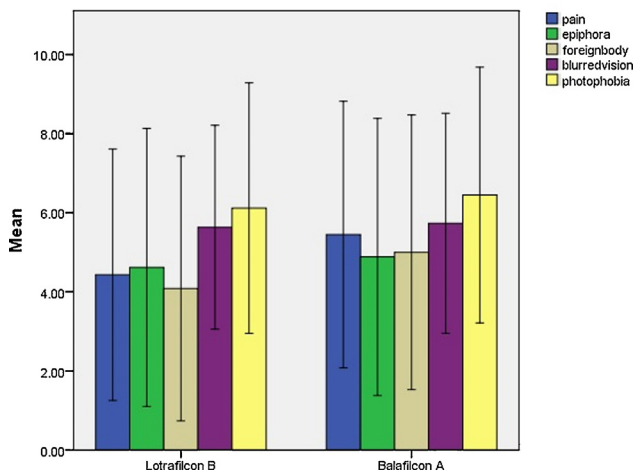
### 6. Results

One hundred twenty eyes of 60 patients who fulfilled the criteria and had PRK for correction of low to moderate myopia/astigmatism were analyzed. The mean age of 18 men (30%) and 42 women (70%) was 27.9 years (range 19–47 years).

Pain scores were clinically higher in the eyes fitted with Balafilcon A contact lens on both postoperative visits. On the first postoperative day, the mean pain score in Balafilcon A group was 5.45 and 4.43 in the Lotrafilcon B group and the difference was statistically significant ( $P=0.032$ ) (Fig. 1). Mean pain scores on the third postoperative day were 3.88 and 3.43 for Balafilcon A and Lotrafilcon B lenses, respectively. However, the difference was not statistically significant ( $P=0.163$ ).

There was not a significant difference between two lenses in levels of photophobia and blurred vision. However, patients reported more blurred vision in the eyes fitted with Balafilcon A lens on the third postoperative day.

Foreign body sensation was significantly less in eyes fitted with Lotrafilcon B lens, both on the first and third postoperative days ( $P=0.042$  and 0.002, respectively). Patients reported more epiphora



**Fig. 1.** Mean pain and ocular discomfort on the first postoperative day. The error bars represent  $\pm 1$  SD.

in eyes with Balafilcon A lens, which was statistically significant on the third postoperative day ( $P=0.042$ ).

## 7. Discussion

Silicone hydrogel soft contact lenses were developed about 10 years ago. These lenses are 5–6 times more oxygen permeable than conventional hydrogel soft contact lenses [19] and have been widely used for extended wear. Studies have shown that silicone hydrogel contact lenses reduce subjective responses more dramatically compared to non-silicone contact lenses and help cornea heal faster [17,20,21]. In addition, no significant difference has been shown between them regarding visual acuity, rate of reepithelialization and contrast sensitivity [15,21]. Given the burden of subjective symptoms such as pain and ocular discomfort and BCLs' difference in alleviating them, the efficacy of two commonly used BCLs Lotrafilcon B and Balafilcon A, which were not previously compared in any study, in reducing pain and discomfort after PRK were compared. In order to add strength to the study and eliminate the effect of environmental factors and difference between patients in terms of pain threshold, each patient was fitted with both types of lenses. Therefore, the effect of interindividual variance in pain threshold was negated and patient bias was kept to a minimum.

Lotrafilcon B silicone hydrogel contact lens has been approved by FDA for 6 days of continuous wear. In a study performed by Grentzelos et al., which compared Lotrafilcon B and Lotrafilcon A contact lenses, no difference was found in subjective measurements and corneal reepithelialization between two lenses [14]. Balafilcon A, another approved BCL, has been compared to other commercially available BCL Galyfilcon A after LASEK in two studies. Both studies indicated similar clinical performance for two lenses, although Galyfilcon A was associated with more patient comfort and deposit resistance [15,22].

In the present study, patients reported significantly less pain in eyes fitted with Lotrafilcon B contact lens in the first 24 h after the surgery (4.43 vs. 5.45,  $P=0.032$ ). This may be due to the difference in mechanical characteristics, particularly stiffness of the lens materials [15] and higher oxygen permeability coefficient ( $Dk/t$ ) of Lotrafilcon B contact lens. It has been suggested that larger epithelial defects are associated with higher levels of pain due to greater nerve ending exposure [14]. However, in this study epithelial defect size was not measured postoperatively. In addition, patients reported higher levels of foreign body sensation with Balafilcon A contact lens. The reason is that Balafilcon A lens is thicker

and has a bigger tensile modulus compared to Lotrafilcon B lens. In similar studies which compared Balafilcon A with other BCLs, patients also reported less comfort with this lens and subjective measures were significantly worse [15,22].

The results also demonstrated that more patients complained of blurred vision in the eyes fitted with Balafilcon A lens. In addition, subjective visual acuity was worse on the third postoperative day compared to the first postoperative day in Balafilcon A group. Plasma oxidation surface treatment of Balafilcon A contact lens reduces its resistance to deposition and results in accumulation of more debris. This problem becomes worse with time and this may be considered as a potential cause for more blurred vision on the third postoperative day. A similar study also found that subjective vision was worse on the third postoperative day and their explanation was that epithelial healing occurs at the center of the cornea at this time and deteriorates visual acuity [14].

In terms of photophobia and epiphora, there was not a statistically significant difference between two lenses. However, patients reported significantly lower epiphora with Lotrafilcon B lens on the third postoperative day. This may be due to accumulation of more debris on Balafilcon A lens on the third postoperative day, which results in the development of inflammatory response and epiphora.

In conclusion, this study found that silicone hydrogel contact lenses can be used effectively after refractive surgery and demonstrated that Lotrafilcon B contact lens better improves postoperative pain and ocular discomfort, especially on the first postoperative day after PRK.

## Financial disclosure

No author has a financial or proprietary interest in any material or method mentioned.

## References

- [1] McDonald MB, Deitz MR, Freantz JM, Kraff MC, Krueger RR, Salz JJ, et al. Photorefractive keratectomy for low-to-moderate myopia and astigmatism with a small-beam, tracker-directed excimer laser. *Ophthalmology* 1999;106:1481–8 (discussion by RD Stulting 1488–1489).
- [2] Hashemi H, Mohammadpour M. Retreatment by lifting the original laser in situ keratomileusis flap after eleven years. *Iran J Ophthalmol* 2011;23(2):60–6.
- [3] Engle AT, Laurent JM, Schallhorn SC, Toman SD, Newacheck JS, Tanzer DJ, et al. Masked comparison of silicone hydrogel lotrafilcon A and etafilcon A extended-wear bandage contact lenses after photorefractive keratectomy. *J Cataract Refract Surg* 2005;31:681–6.
- [4] El-Maghraby A, Salah T, Waring III GO, Klyce S, Ibrahim O. Randomized bilateral comparison of excimer laser in situ keratomileusis and photorefractive keratectomy for 2.50 to 8.00 diopters of myopia. *Ophthalmology* 1999;106:447–57.
- [5] Mohammadpour M, Jabbarvand M, Nikdel M, Adelpour M, Karimi N. Effect of preemptive topical diclofenac on postoperative pain relief after photorefractive keratectomy. *J Cataract Refract Surg* 2011;37:633–7.
- [6] Brilakis HS, Deutsch TA. Topical tetracaine with bandage soft contact lens pain control after photorefractive keratectomy. *J Refract Surg* 2000;16:444–7.
- [7] Cherry PM. The treatment of pain following excimer laser photorefractive keratectomy: additive effect of local anesthetic drops, topical diclofenac, and bandage soft contact. *Ophthalmic Surg Lasers* 1996;27:S477–80.
- [8] Razmjoo H, Abdi E, Atashkadi S, Reza AM, Reza PA, Akbari M. Comparative study of two silicone hydrogel contact lenses used as bandage contact lenses after photorefractive keratectomy. *Int J Prev Med* 2012;3:718–22.
- [9] Bergenske PD, Caroline PJ, Smythe JK. Contact lens as an adjunct in refractive surgery practice. *Contact Lens Spectrum* 2002;17:30–7.
- [10] Demers P, Thompson P, Bernier RG, Lemire J, Laflamme P. Effect of occlusive pressure patching on the rate of epithelial wound healing after photorefractive keratectomy. *J Cataract Refract Surg* 1996;22:59–62.
- [11] Mohammadpour M, Mohajerzadifard Z, Khodabande A, Vahedi P. Antibiotic susceptibility patterns of pseudomonas corneal ulcers in contact lens wearers. *Middle East Afr J Ophthalmol* 2011;18(3):228.
- [12] Holden BA, Mertz GW. Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses. *Invest Ophthalmol Vis Sci* 1984;25:1161–7.
- [13] Lim L, Tan DT, Chan WK. Therapeutic use of Bausch & Lomb pure vision contact lenses. *CLAO J* 2001;27:179–85.

- [14] Grentzelos MA, Plainis S, Astyrakakis NI, Diakonis VF, Kymionis GD, Kallinikos P, et al. Efficacy of 2 types of silicone hydrogel bandage contact lenses after photorefractive keratectomy. *J Cataract Refract Surg* 2009;35:2103–8.
- [15] Qu XM, Dai JH, Jiang ZY, Qian YF. Clinic study on silicone hydrogel contact lenses used as bandage contact lenses after LASEK surgery. *Int J Ophthalmol* 2011;4:314–8.
- [16] Sweeney DF. Clinical signs of hypoxia with high-Dk soft lens extended wear: is the cornea convinced? *Eye Contact Lens* 2003;29:S22–5.
- [17] Gil-Cazorla R, Teus MA, Arranz-Márquez E. Comparison of silicone and non-silicone hydrogel soft contact lenses used as a bandage after LASEK. *J Refract Surg* 2008;24:199–203.
- [18] Brennan NA, Coles ML, Comstock TL, Levy BA. 1-year prospective clinical trial of balafilcon A (PureVision) silicone-hydrogel contact lenses used on a 30-day continuous wear schedule. *Ophthalmology* 2002;109:1172–7.
- [19] Compan V, Andrio A, Lopez-Aleman A, Riande E, Refojo MF. Oxygen permeability of hydrogel contact lenses with organosilicon moieties. *Biomaterials* 2002;23:2767–72.
- [20] Edwards JD, Bower KS, Sediq DA, Burka JM, Stutzman RD, VanRoekel CR, et al. Effects of lotrafilcon A and omafilcon A bandage contact lenses on visual outcomes after photorefractive keratectomy. *J Cataract Refract Surg* 2008;34:1288–94.
- [21] Plaka A, Grentzelos MA, Astyrakakis NI, Kymionis GD, Pallikaris IG, Plainis S. Efficacy of two silicone-hydrogel contact lenses for bandage use after photorefractive keratectomy. *Contact Lens Anterior Eye* 2013;36:243–6.
- [22] Gil-Cazorla R, Teus MA, Hernández-Verdejo JL, De Benito-Llopis L, García-González M. Comparative study of two silicone hydrogel contact lenses used as bandage contact lenses after LASEK. *Optom Vis Sci* 2008;85:884–8.