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Efficacy of two silicone-hydrogel contact lenses for bandage use after photorefractive keratectomy

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ABSTRACT

Purpose: To evaluate the efficacy of two silicone hydrogel (SiH) contact lenses, approved for continuous wear for one week, following photorefractive keratectomy (PRK).
Methods: Forty seven myopic patients (94 eyes) undergone bilateral PRK were enrolled in this prospective, double-masked, comparative study. One eye of each patient was fitted with a Lotrafilcon B lens (Ciba Vision, Duluth, US; 30-day recommended replacement) whereas the fellow eye was fitted with an Asmofilcon A lens (Menicon, Nagoya, Japan; 14-day recommended replacement). Epithelial defect size was assessed using slit lamp biomicroscopy on the day of surgery and at days 1–4 post-operatively. Uncorrected and best-corrected visual acuity and retinal straylight (C-Quant, Oculus Optigerate, Germany) were evaluated pre-operatively and one month post-operatively.
Results: Average epithelial defect size for Asmofilcon A and Lotrafilcon B was $25.5 \pm 11.0\,mm^2$ vs. $27.1 \pm 9.9\,mm^2$ at day 1 ($p = 0.007$) and $6.3 \pm 7.0\,mm^2$ vs. $9.2 \pm 9.5\,mm^2$ at day 2 ($p = 0.012$) post-operatively. Re-epithelialization at day 3 was completed in 87.2% of the eyes fitted with Asmofilcon A lenses, compared to 74.5% with Lotrafilcon B lenses ($p = 0.012$). At the 3rd post-operative day 29.8% of re-epithelialized eyes showed irregular suture with Lotrafilcon B, compared to 12.8% eyes with Asmofilcon A lenses ($p < 0.001$). Finally, no statistically significant differences were found post-operatively between the two lenses retinal straylight ($p = 0.98$) and best-corrected visual acuity ($p = 0.68$).
Conclusions: SiH lenses can be used as an effective bandage after PRK due to the limited time requested for achieving complete corneal re-epithelialization. Faster and smoother epithelial healing is provided with Asmofilcon A over Lotrafilcon B lenses.

1. Introduction

Photorefractive keratectomy (PRK) and laser-assisted sub-epithelial keratomileusis (LASEK) are well-established, flapless refractive procedures that are still performed today in about 20% of refractive surgery patients [1]. Prolonged visual recovery remains today the undesirable side effect of PRK, when compared to LASIK [1,2] and this possibly due to the process of epithelial wound healing and remodeling and defective pre-corneal tear film. To improve the rate and the quality of epithelial healing following refractive surface procedures, bandage contact lenses (BCLs) are commonly used [3–14], although other approaches, such as occlusive pressure patching [15], have been suggested. This procedure was initially adopted to reduce postoperative pain and decrease dependence on pain medications, as a consequence of the mechanical irritation caused by the eyelids on the abraded cornea [3,4,14,16]. Other studies have demonstrated that a BCL diminishes corneal haze following PRK [17], while it protects the epithelial flap and reduces any risk of flap repositioning in LASEK [8,9,11,13,18].

Different soft contact lens materials (hydrogels vs. silicone-hydrogels) have been suggested for bandage use after corneal refractive surgery. It is plausible that, in order to achieve optimal biocompatibility for overnight wear, BCLs should allow sufficient oxygen flow in order to maintain corneal aerobic metabolism. Conventional or daily-disposable hydrogel contact lenses, which still form a common type of bandage contact lens after corneal refractive surgery, are associated with reduced oxygen availability, which does not fulfill the criteria for overnight wear. The introduction of silicone-hydrogel (SIH) lenses, just over 10 years ago, offered the choice of a material with high oxygen permeability (Dk) for therapeutic applications, which was also approved from the U.S. Food and Drug Administration (FDA) for extended/overnight wear [19,20]. It was not surprising, then, that the first clinical

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studies [6,13] showed that a SIH lens with an FDA approval up to 30 day continuous wear provided fast corneal re-epithelialization and reduced patient discomfort after PRK or LASEK.

In the last 10 years, other contact lenses made from new-generation silicone hydrogel materials were introduced to the market. Although most of these materials are FDA approved for a week, rather than 30 days, of continuous wear, this period satisfies the criteria for epithelial healing, which is usually completed in less than a week in uncomplicated cases [6,9,10,13]. The aim of this study was to evaluate post-PRK visual performance and corneal epithelial healing with two types of SIH contact lenses approved by FDA for six nights (one week) of continuous wear.

2. Patients and methods

2.1. Patient population

Forty seven patients (22 men and 25 women) with an average age of 29 ± 10 years (range: 20–45 years) were enrolled in this prospective, double-masked, comparative, clinical study. All patients underwent bilateral PRK for the correction of myopia (94 eyes), at the Institute of Vision and Optics (IVO), University of Crete. Recruitment was performed in a prospective consecutive non-randomized fashion. Exclusion criteria included previous refractive surgery, myopic refractive error >8.00 D, anisometropia >2.00 D, and ocular or systemic disease that could affect epithelial healing. All patients were asked to cease contact lens wear at least three weeks before the preoperative examination. Written consent was obtained from all participants prior to their enrollment in the study. The research conformed to the tenets of the Declaration of Helsinki and followed a protocol approved by the University of Crete Research Board.

Using a sample size of 40 the study was designed to detect a difference in "epithelial defect size" of 2.3 with 80% power, at a significance level of 5%. This was based on previously published studies [6,10], in which the standard deviation of the differences in "epithelial defect size" was at maximum 5.0.

2.2. Surgical technique

The surgical procedure was conducted by the same surgeon (GDK) under sterile conditions and topical anesthesia with proxymetacaine hydrochloride 0.5% eyedrops (Alcaine, Alcon Laboratories, Inc.). The epithelium was removed using a rotating soft brush. Stromal ablation was performed with the 400 Hz Allegretto laser platform (WaveLight Laser Technologies AG). After completion of the ablation, mitomycin-C (with a concentration of 0.02%) was applied for up to 15 s.

At the end of the procedure, one eye of each patient was fitted with a Lotrafilcon B contact lens (Ciba Vision, Duluth, GA, US; 30-day recommended replacement) whereas the fellow eye was fitted with an Asmofilcon A lens (Menicon, Nagoya, Japan; 14-day recommended replacement). The specifications of the lenses fitted are summarized in Table 1. The lens type fitted in each eye was counterbalanced, i.e. the right eyes of the patients were fitted with 24 Lotrafilcon B and 23 Asmofilcon lenses. Contact lens fitting was evaluated in all cases by the same clinician using a slit lamp biomicroscope and was found to be satisfactory in both eyes of all subjects. Both the clinician and the patient were unaware of the contact lens type fitted in each eye.

The post-operative medication regimen was the same for both eyes of all subjects and included nepafenac sodium 0.1% (Nevanac, Alcon Lab Inc.) for 2 days, ofloxacin 0.3%, w/v (Exocin, Allergan) as well as antibiotic/corticosteroid (chloramphainicol/dexamethasone) drops (Dispersadron C, Novartis) until the removal of the bandage contact lens. No topical anesthetics for pain control were given. Patients were encouraged to use artificial tears every 20 min, until the day of complete re-epithelialization. For pain control, if necessary, 1 or 2 tablets of oral nimesulid 100 mg (Mesulid; Boehringer Ingelheim GmbH, Ingelheim, Germany) were prescribed.

Table 1
Contact lens details.

Product	premiO	Air Optix Aqua
Manufacturer	Menicon	Ciba Vision
Material name	Asmofilcon A	Lotrafilcon B
Material type	Silicone hydrogel	Silicone hydrogel
Dk and Dk/t @ −3.00 D (barriers)	129 and 161	110 and 138
Water content (%)	40	33
Replacement	15-day	Monthly
Diameter (mm)	14.0	14.2
Back vertex power (D)	−0.25 D	Plano
Back optic zone radius (mm)	8.60	8.60

2.3. Post-operative follow-up

Epithelial defect size was assessed using slit lamp biomicroscopy on the day of surgery and at days 1–4 post-operatively. Post-operative examination also included assessment of uncorrected and best-corrected visual acuity and retinal straylight at one month post-operatively.

Visual acuity was measured with the European-wide logMAR charts (Precision Vision, LaSalle, USA) [21] at 4.0 m distance. Two versions of charts were used for recording the VA in the right and the left eye of each patient, respectively. Retinal straylight was evaluated with a commercial computerized straylight meter (C-Quant, Oculus Optigerate, Germany), based on a compensation comparison principle, described elsewhere [22]. Slit lamp biomicroscopy was performed by an ophthalmologist who examined the integrity of the corneal media as well as the amount and the quality of remaining epithelial defect. Epithelial defect size was calculated from the area (A) of the epithelial defect using the following equation:

$$A = \pi \left[\frac{a+b}{4}\right]^2$$

where a and b were the longest and shortest dimensions of the defect, respectively. This equation has also been employed in previous studies [6,10]. When re-epithelialization was complete the ophthalmologist graded the suture as smooth or irregular (see Fig. 1). An irregular suture had sharper and thicker edges and covered a larger area. Each contact lens was removed upon full re-epithelialization of the eye. After the removal of the lens, fluorescein was instilled in order to confirm the absence of an epithelial defect.

To compare objective and psychophysical outcomes paired Student's t-test and chi-square tests were used when appropriate. To compare the paired proportions, tests based on the exact binomial probabilities were used, as the number of discordant pairs in each case was small (<10). Statistical analysis was performed using MedCalc (version 11.6.1.0, MedCalc software bvba, Mariakerke, Belgium).

3. Results

The mean attempted spherical equivalent did not differ between the two groups (−3.97 ± 1.87 for Asmofilcon A vs. −3.92 ± 1.89 for Lotrafilcon B, $p = 0.79$). Since the same soft rotating brush was used for epithelium removal the mean epithelial defect size just after surgery (day 0) was almost the same for both groups

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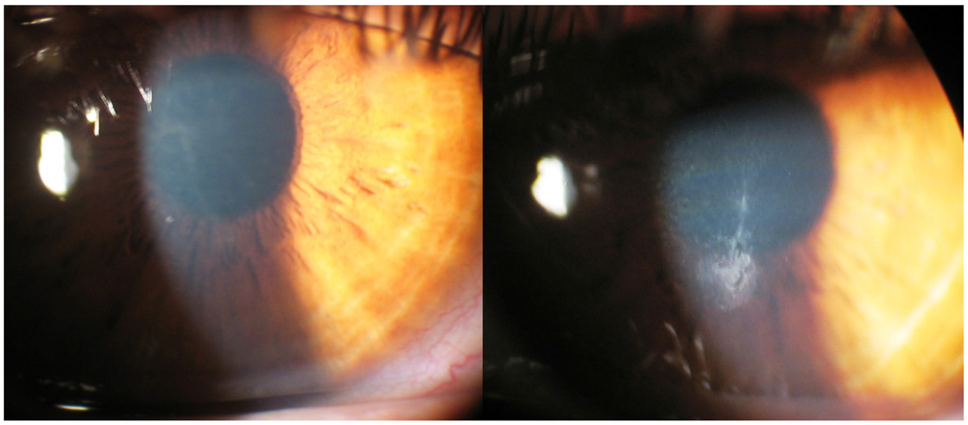

Fig. 1. Slit lamp biomicroscopic images of an eye with smooth (epithelialized) suture (left) and an irregular suture (right).

($56.9 \pm 1.7\,mm^2$ for Asmofilcon vs. $57.0 \pm 2.6\,mm^2$ for Lotrafilcon B, $p = 0.73$).

On average larger areas of epithelial defect were observed with the Lotrafilcon B lenses compared to the Asmofilcon A lenses. Statistically significant differences were observed for epithelial defect size, between the two types of lenses at day 1 (Lotrafilcon B vs. Asmofilcon A: $27.1 \pm 9.9\,mm^2$ vs. $25.5 \pm 11.00\,mm^2$, $p = 0.007$) and day 2 (Lotrafilcon B vs. Asmofilcon A: $9.2 \pm 9.5\,mm^2$ vs. $6.3 \pm 7.0\,mm^2$, $p = 0.012$) post-operatively (Fig. 2).

At day 2 post-operatively, 8.5% (4/47) eyes fitted with the Asmofilcon A lens were fully re-epithelialized, compared to 6.4% (3/47) of the eyes fitted with the Lotrafilcon B lens ($x^2 = 0.76$, $p > 0.10$). At the 3rd post-operative day, re-epithelialization was completed in 87.2% (41/47) of the eyes fitted with the Asmofilcon A lens, compared to 74.5% (35/47) of the eyes with the Lotrafilcon B lens ($x^2 = 8.57$, $p = 0.012$), whereas at day 4 re-epithelialization was achieved in 97.9% (46/47) vs. 93.6% (44/47) of the eyes fitted with the Asmofilcon A and the Lotrafilcon B lenses, respectively ($x^2 = 3.03$, $p = 0.08$).

An important observation concerned the quality of the suture (see Fig. 3). At the 3rd post-operative day the 14/35 (29.8%) of re-epithelialized eyes showed irregular suture with Lotrafilcon B, compared to 6/41 (12.8%) eyes with Asmofilcon A lenses ($x^2 = 16.9$, $p < 0.001$).

Finally, low amounts of post-operative retinal straylight were observed at one month following PRK for both types of lenses (Asmofilcon A: 1.00 ± 0.21, Lotrafilcon B: 0.98 ± 0.17, $p = 0.98$). Moreover, no statistically significant difference was found in best-corrected decimal visual acuity (Asmofilcon A: 1.03 ± 0.13, Lotrafilcon B: 1.03 ± 0.12 $p = 0.68$).

4. Discussion

In this study PRK recovery was evaluated with two types of SIH contact lenses (Asmofilcon A vs. Lotrafilcon B), approved for continuous wear for one week. Effective bandage was exhibited with both lenses: complete corneal re-epithelialization was achieved in more than 3/4 of eyes by the 3rd post-operative day (87.2% with the Asmofilcon A vs. 74.5% with the Lotrafilcon B lens), and in almost all eyes (97.9% with the Asmofilcon A vs. 93.6% with the Lotrafilcon B lens) by the 4th post-operative day. Statistically significant differences were observed for epithelial defect size between the two types of BCLs at the first and second postoperative day. The study design controlled factors that could influence the epithelial healing process, such as environment and physiologic healing response, where both patients and examiners were masked to the type of the BCL fitted in each eye. Also, low amounts of post-operative retinal straylight were observed for both types of lenses while no statistically significant difference was found in visual performance assessed with best-corrected visual acuity.

In surface refractive procedures, the removal of the epithelium leaves an open wound that takes about one week to heal. A BCL protects the cornea from exposure or from the irritation caused by rubbing the eye as the corneal epithelium is healing [23]. However, contact lenses interact mechanically with the cornea and

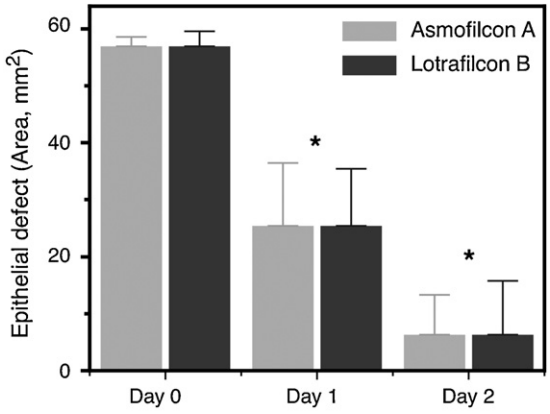

Fig. 2. Plot of the average area of epithelial defect size for the two silicone hydrogel lenses at all post-operative days. Error bars represent ±1 SD. * significantly different.

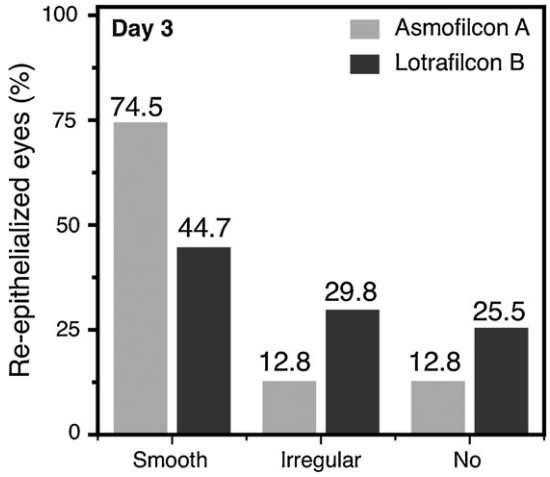

Fig. 3. Plots of the proportion of eyes achieved complete re-epithelialization for the two silicone hydrogel lenses, at days 3 and 5, post-operatively.

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modify the physiological processes of the corneal tissue. Since frequent complications of contact lens wear occur as a direct result of impaired oxygen supply to the cornea, new materials that can satisfy the corneal oxygen requirements have been developed, which significantly diminish any hypoxic effects, previously associated with extended wear of hydrogel lenses [24,25]. SIH materials with high oxygen transmissibility, specifically designed for continuous wear, should secure enhanced wound healing and epithelial cell reproduction, following refractive surgical procedures. Thus, is not surprising that improved and faster corneal healing after PRK and LASEK and reduced patient discomfort has been reported with SIH lenses compared to conventional lenses [6–13].

The question to be asked is whether all SIH lenses of different materials, that have received U.S. FDA approval for at least one week, could perform with the same efficacy. Recent literature is rather contradictory with studies showing difference between SiH lenses, when used as bandage following PRK or LASEK, in pain reduction/patient discomfort [9,11,12] and debris deposition [11]. In contrast, similar healing effects have been reported between different types SIH lenses, with complete re-epithelialization achieved on days 4 or 5 post-operatively [9–12]. The use of mitomycin-C may also influence epithelial healing. However, the effect of mitomycin-C in wound healing following PRK is not predictable [26,27].

Previous clinical trials simply quantified epithelial defect. In this study the quality of healing was also subjectively graded as smooth or irregular. An irregular suture had sharper and thicker edges and covered a larger area compared to a smooth suture. At the 3rd post-operative day irregular re-epithelialization was observed in more eyes fitted with Lotrafilcon B (29.8%) than with Asmofilcon A lenses (12.8%) and the difference reached statistical significance. These differences may be attributed to the design and the material of the Asmofilcon A lens. This polymer incorporates a plasma surface treatment (Nanogloss) that preserves the original surface quality of the polymer aimed at reducing dryness symptoms and lipid deposition during CL wear [28]. Additionally, the lower modulus of rigidity of Asmofilcon compared to Lotrafilcon B material, is likely to alleviate some mechanically related complications [29]. Finally, the high oxygen transmissibility of the Asmofilcon A lens possibly enhances a smoother wound healing as well as epithelial cell reproduction.

Concluding, this study shows that SiH contact lenses can be used as an effective bandage after PRK due to the limited time requested for achieving complete corneal re-epithelialization. Asmofilcon A lenses provide faster and smoother epithelial healing in comparison to Lotrafilcon B lenses.

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