·Clinical Research·

Clinic study on silicone hydrogel contact lenses used as bandage contact lenses after LASEK surgery

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Abstract

• AIM: To compare the clinical performance of two types of silicon hydrogel contact lenses used as bandage lenses after LASEK surgery.

• METHODS: A prospective, double-masked study was conducted on 42 eyes of 21 patients who received binocular LASEK surgeries. The interocular difference in spherical equivalent power was less than -1.50D. Patients were randomly assigned to wear Galyfilcon A (Lens A) bandage contact lens in one eye and Balafilcon A (Lens B) in the fellow eye after the surgery. The responses to a subjective questionnaire on comfort of wearing, corneal epithelial status, conjunctival hyperemia, limbal neovascularization, lens fitting and contact lens debris were assessed 1 and 5 days postoperatively. Corneal endothelium was assessed before and 5 days after the surgery upon bandage lens removal.

• RESULTS: There was no difference between the two groups in terms of conjunctival hyperemia, limbal neovascularization, contact lens fitting, corneal epithelial status, corneal endothelium cell density (CD) and endothelium cell size (CS) at any postoperative visit. Complaints of discomfort, including foreign body sensation, pain and intolerance were statistically more among Lens B wearers at any postoperative visit (P <0.05). Lens B appeared to attract much more debris than Lens A at the 5-day post-operative follow-up visit (P<0.01).

• CONCLUSION: The two types of silicon hydrogel lenses investigated in this study demonstrated similar clinical performance in terms of corneal responses and lens fitting. However, Lens A showed a better performance in terms of comfort of wearing and deposit resistance.

• KEYWORDS: therapeutic contact lens; bandage contact lens; silicone hydrogel contact lens; LASEK

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INTRODUCTION

Laser subepithelial keratomileusis (LASEK) is widely used for vision correction in recent years because of good post-operative vision quality and fewer corneal flap-related complications comparing to laser *in situ* keratomileusis (LASIK)[1,2]. Bandage lenses are usually used after LASEK surgery to relieve the pain and promote corneal epithelial wound healing [3] .Bandage lenses can keep the epithelial flap in its proper position after LASEK. In this way it can keep the epithelial cell more active and alleviate the reaction and irritation due to the surgery[4,5].

Moderate to high water content hydrogel soft lenses have been commonly used earlier as bandage lenses after LASEK because of the comfort, easy handling and short adaptation of patients. Continuous lens wearing for 3-5 days or longer is often necessary to ensure a complete recovery of corneal epithelia. However, these traditional hydrogel soft lenses can not meet the recommended Dk (oxygen permeability) thresholds to avoid corneal swelling during extended lens wearing[6].

Silicon hydrogel lenses have been commercially available for more than 10 years. The history of these lenses in Chinese market, however, is not that long. They have been widely reported to offer improved ocular health and are 5-6 times more oxygen-permeable than traditional hydrogel soft lenses [7]. Therefore the silicon hydrogel lenses can be considered for extended wearing for some special clinical indications. Silicon hydrogel contact lenses have been used as bandage lenses for LASEK surgery for many years. Clinic studies indicated that silicon hydrogel lenses could promote corneal epithelial recovery and alleviate the pain of LASEK better than traditional soft lenses [8]. Commercially-available silicon hydrogel contact lenses are quite different in their features and specifications. Thus the benefits these lenses offer to LASEK patients as post-operative bandage lenses can be different as well. To better understand the performance of silicon lenses as bandage lenses after LASEK, a study was conducted to compare the performance

of two silicon hydrogel lenses by assessing subjective symptoms and slit lamp findings.

MATERIALS AND METHODS

Subjects The study was a prospective, double -masked study which included 21 consecutive patients (42 eyes) who had received binocular LASEK refractive surgeries. All patients were 18 years or older and myopic with stable refractions, and were eligible for LASEK. The interocular difference in spherical equivalent was less than 1.50D among all the patients. No patient reported contact lens wearing during the 2 weeks right before surgeries. No patient has other ocular diseases or contraindications to wear contact lens before the surgeries. Informed consents were obtained from all the patients prior to the surgeries.

Preoperative examinations included corrected visual acuity, refraction, slit-lamp examination, intraocular pressure (NIDEK NT-2000), corneal topography (Zeiss ATLAS), pachymetry (Oculus pentacam Type 70700), contrast sensitivity (CCT-1000), wavefront aberration (WASCA Analyzer 1369-202), axial length (IOL-Master Zeiss), corneal endothelium specular microscopy (SP 2000P) and fundus examination after pupil dilation.

Methods All surgeries were performed by one surgeon (JHD). Laser ablation was performed with Zeiss Mel-80 excimer laser. After laser ablation, the cornea was irrigated with balanced salt solution and the epithelial flap was repositioned onto the ablated stromal bed. A silicon hydrogen soft contact lens was applied to the corneal immediately after the LASEK surgery. Patients were randomly selected to be fitted with Galyfilcon A (Lens A) bandage contact lens in one eye and Balafilcon A (Lens B) in the fellow eye. Specifications of the lenses were listed in Table 1. Postoperative medication included a combination of topical antibiotic eye drops (0.3% ofloxacin for 2 weeks) and topical steroids eye drops (0.1% fluorometholone for 12 weeks).

All patients were asked to return to the clinics for follow-up visit 1 day and 5 days after surgery. During each visit, objective and subjective assessments were performed. Patients were asked about the severity of the following symptoms: foreign body sensation (FB), photophobia (PP), lacrimation (LM), pain, fluctuating vision (FV), and intolerance (IT). The results were recorded on a 1-5 scale (1=no, 2=very slightly, 3=slightly, 4=severe, 5=very severe). Lens fitting assessment included lens centration, coverage and movement. Each index was recorded on a 1-3 scale (1 = optimal, 2= acceptable, 3= unacceptable). Contact lens debris was assessed at each visit. The score of debris was determined by estimating the percent area of the lens that was covered by the deposits (0=No, 1=yes, extent:1-100%)[9].

Table 1 Parameter of both lenses

Parameter	Lens A	Lens B
Material	Galyfilcon A	Balafilcon A
Water content (%)	47	36
Surface treatment	No treatment	Plasma oxidation
Oxygen permeability(Dk) $(cm^2/s)(mlO_2/ml\times kPa)\times 10^{-11}$	60	99
Tensile modulus (psi)	65	148
BOZR (mm)	8.7	8.6
Central thickness (μm)	70	90
TD (mm)	14.0	14.0

BOZR: Back optic zone radius; TD: Total diameter

Table 2 Contact lens debris and corneal epithelial status

Score	Contact lens debris	Corneal epithelial edema area	Corneal epithelial edema severity
1	≤10%	≤10%	Very clear
2	10-20%	10-30%	Clear to see iris
3	20-30%	30-50%	Slightly blurred to see iris
4	30-50%	50-70%	Iris details still visible
5	>50%	≥70%	Iris details obscured

Conjunctival hyperaemia (0=None, 1=slight injection of conjunctival vessels, 2=mild injection, 3=moderate injection, 4=severe injection), limbal neovascularization (0=None, 1=0.5, 2=0.50-1.00, 3=1.00-2.00, 4=>2.00) [9] and corneal epithelial status were assessed at the baseline and during each follow-up visit. The epithelial edema and transparency were recorded on a 1-5 scale (Table 2). Corneal endothelia were assessed at the baseline and 5-day postoperative visit upon lens removal.

Statistical Analysis Statistical analysis was performed by using SPSS-11.0 software. The comparison of two Lens groups and the evaluation of post-operative corneal endothelial changes were conducted by using wilcoxon (nonparametric) and t-test. One -way ANOVA test was done to compare the overall symptoms in two groups. $P<0.05$ was considered statistically significant.

RESULTS

Twenty-one subjects (9 females, 12 males) were enrolled in this study. The mean age was 24±5.2 years old. Clinical characteristics of eyes wearing Lenses A and B were listed in Table 3. Spherical equivalent refraction, BSCVA, keratometry, corneal pachymetry, corneal endothelial cell density and endothelial cell size, corneal ablation depth and total ablation spherical equivalent power, conjunctival hyperemia and limbal neovascular were analyzed. There were no significant differences between the two groups at the baseline ($P>0.05$).

Subjective Symptoms During the post-operative follow-up visit on day 1, significantly fewer subjects in Lens A group reported symptoms of foreign body sensation and pain compared to those in Lens B group ($P<0.05$). Other responses including photophobia, lacrimation, fluctuating

Table 3 Preoperative data of the two groups of the study

Preoperative data	Lens A group	Lens B group	*P*
Spherical equivalent refraction (D)	-5.02±-2.73	-5.07±-2.62	0.757
BSCVA	1.07±0.13	1.04±0.14	0.055
Keratometry H (mm)	7.78±0.19	7.74±0.22	0.055
Keratometry V (mm)	7.62±0.21	7.60±0.22	0.258
Pachymetry(mm)	0.52±0.04	0.53±0.03	0.105
CD(cells/mm^2)	3404.48±321.52	3288.24±393.26	0.141
CS (μm^2)	309.10±22.64	319.40±21.60	0. 224
CV (%)	13.24±5.64	14.76±9.19	0.531
Spherical equivalent ablation (D)	5.65±2.76	5.68±2.76	0.837
Ablation depth (μm)	93.81±24.67	94.95±26.25	0.594

Table 4 Subjuective symptoms, contact debris and corneal edema statistical result

Subjuective symptoms	1d		5d	
	Z	*P*	*Z*	*P*
Foreign body sensation	-2.381	0.017	-3.358	0.001
Photophobia	-0.577	0.564	-1.732	0.083
Lacrimation	-1.508	0.564	-1.342	0.180
Pain	-2.121	0.034	-2.236	0.025
Fluctuating vision	-0.632	0.527	-2.952	0.003
Intolerance	-1.602	0.109	-3.153	0.002
Contact lens debris	0.00	1.00	-3.272	0.001
Corneal epithelial edema area	-0.447	-0.625	-1.134	0.257
Corneal epithelial edema severity	-1.342	0.180	-1.613	0.107

Table 5 Corneal endothelium specula-microscopy

	CD (cells/mm^2)		CS (μm^2)		CV (%)	
	Lens A	Lens B	Lens A	Lens B	Lens A	Lens B
Pre	3,404.48±321.52	3,288.24±393.26[a]	309.10±22.64	319.40±21.60[a]	13.24±5.64	14.76±9.19[a]
5d	3,363.11±401.48[b]	3,280.83±338.89[b]	307.94±33.17[b]	305.25±30.10[b]	14.78±10.71[b]	14.17±5.61[b]

[a]$P>0.05$ *vs* Lens A , [b]$P>0.05$ *vs* Pre

vision and intolerance of the lens were similar in both groups ($P>0.05$, Table 4). Considering the interference factor of LASEK surgery, using corneal ablation depth as association variables, the general symptom was similar in both groups ($F=2.600$, $P>0.05$). On the post-operative 5th day, significantly fewer subjects in Lens A group reported symptoms of foreign body sensation, pain, fluctuating vision and intolerance ($P<0.05$). No significant differences in other responses, including photophobia and lacrimation were found between two groups ($P>0.05$, Table 4). But the general symptom was significantly more in Lens B group than in Lens A group ($F=7.714$, $P<0.05$).We also observed an obvious decrease of discomfort symptoms with time in both lens groups (except vision fluctuation in Lens B group).

Lens Fitting Performance The overall lens fitting for both groups were acceptable or optimal. Lenses were centered well, with good corneal coverage and proper movement. There was no difference between the two groups at any follow-up visit ($P>0.05$) although we found both lenses tended to move less with time.

Lens deposits accumulated with time. There was no significant difference between the two groups at the 1-day visit, but at the 5-day visit, deposits on Lens B were significantly more than that on Lens A ($P<0.01$, Table 4).

Slit –lamp and Corneal Endothelium Specular Microscopy Findings Conjunctival hyperemia gradings were higher after the LASEK surgery, but similar between two lenses groups ($P>0.05$). Also, there was no change of limbal neovascularization from baseline to any follow-up visit in either group ($P>0.05$). The scores of the corneal epithelial edema area and severity decreased with time after surgery. There was no significant difference between two groups at any visit point ($P>0.05$, Table 4). Corneal endothelium specular microscopy was done before and 5 days after LASEK surgery upon lens removal. Cell density (CD) and morphometric characteristics of corneal endothelia of both groups were assessed, which included CD, mean endothelial cell size (CS) and coefficient of variation of cell size (CV). No significant difference was found between two groups at the baseline or post-operative examinations ($P>0.05$). The baseline data of corneal endothelium was not statistically different from the post-operative data in each group, either ($P>0.05$, Table 5).

Visual Acuity There was higher rate of blur vision reported by patients with time in Lens B group than in Lens A group. But there were no difference in visual acuity at the 5-day follow-up visit upon lens removal between two groups (Lens A=0.76±0.27, Lens B=0.70±0.32, $P > 0.05$).

DISCUSSION

Using hydrogel lenses for bandage purpose after corneal refractive procedures was applied first in PRK. Its mechanism is to protect the cornea during healing and provide pain relief[3, 10]. However, it has not been widely used until the application of LASEK. During LASEK or Epi-LASEK procedure, corneal epithelial flap is created and flipped away before the excimer-laser ablation and flipped back afterwards. Bandage lens is applied immediately to keep the epithelial flap in its proper position and physiological conditions. The high DK lens is required because of the need of continuous lens wearing (3-5 days) and the changes in corneal physiological characteristics after surgery. The high oxygen permeability is expected to facilitate wound healing and epithelial regeneration.

Since the introduction of silicon hydrodel soft lens in 1998, it has become the top choice for extended wear in contact lens practice. The new high Dk silicon hydrogen soft lenses offer up to 5-6 times greater oxygen supply than conventional HEMA lenses do [7]. Many studies have shown that using silicon hydrogel as bandage after LASEK surgery is safe, effective with good tolerance [8,11,12]. Silicon hydrogel lenses as bandage lenses significantly reduced subjective responses and helped to achieve a faster corneal healing in comparison to conventional soft lenses [8,12] . Studies have shown a lower rate of haze in patients wearing silicon hydrogel lenses during the early stage after surgery when compared to conventional low Dk lenses, but there is no difference in terms of visual acuity, contrast sensitivity and haze at the long term.

In order to further understand the clinical performance of silicon hydrogel lenses as bandage lenses after LASEK surgery, we compared two commonly used silicon hydrogel lenses by measuring ocular responses and grading subjective feelings of patients upon wearing of the lenses. The overall performance was acceptable. No inflammatory reaction, infectious responses, or hypoxia-related complications occurred. Neither type of silicon hydrogel lens induced limbal neovascularization. Morphologic analysis of the corneal endothelial cells showed no change in mean cell density or cell size after 5 days of wearing post-operatively. Several studies show that contact lens wearing affects corneal endothelium [13,14]. Also, people are interested in whether corneal refractive surgeries can affect the endothelium as well [15]. Our study shows that short term extended wearing of silicon hydrogel lens does not cause any damage to the endothelium, which is consistent with previous results of other investigators. It is necessary to note, however, that this study was a short term study and further study is needed to better understand the long term impact. Nevertheless, for bandage lens usage after surgery whereby lenses stay in the eyes for only a few days, one can assume that these lenses will cause no or very limited damage to the endothelium.

The analysis of the patients' subjective responses indicated that scores were lower in Galyfilcon A lens group in terms of foreign body sensation, pain and intolerance. This may be due to the mechanical characteristics, especially stiffness of lens materials [16].Tensile modulus of Balafilcon A lens is significantly greater than that of Galyfilcon A. Balafilcon A lenses are also thicker. Both these characteristics may serve as reasons why the subjective sensation in Balafilcon A lens group was more obvious than that in the other group. However, we also found all subjective responses decreased with time. More people complained about blurred vision in Balafilcon A lens group, but visual acuity was quite similar in two groups upon lens removal. The possible reason could be the accumulation of deposits on the lens with time.

Although there were no differences in lens fitting characteristics between the two groups, we found the lens movement reduced with time. Unlike high water content thin lenses, stiffer high Dk silicon hydrogel lenses do not tighten over time. Extended wearing may be the reason for the loss in lens mobility.

In contrast to the silicon rubber lenses used earlier, the surface of new high Dk silicon lens offers better wettability and deposit resistance. Most of lenses do not have severe deposits even after 5 days of extended wear. But in this study, it is very interesting to find that lens deposits were greater on Balafilcon A lens 5 days after LASEK, which may be due to the classical plasma oxidation treatment of lens surface that lower the resistance to deposit formation[16]. Tear film and eye drops can be the source of the deposits. In this study, topical antibiotic (0.3% ofloxacin) and steroids eyedrops (0.1% fluorometholone) weres used afer LASEK surgery. Currently we know little about the effects of these drugs on silicon hydrogel lenses. Fluorometholone is widely used after LASEK surgery to reduce inflammatory reaction. The compatibility of the silicon hydrogel lenses and eye drops remains to be clarified. Maybe suspension eye drops like fluorometholone are more prone to deposit on certain types of lenses with surface treatment.

This study demonstrates that both silicon hydrogel lenses (Galyfilcon A and Balafilcon A) performed well as bandage lenses after LASEK surgery. Short term extended wear of

both silicon hydrogel lenses did not cause any hypoxia-related complications or damage to corneal endothelia. Subjective responses differed between two lens types because of the difference in stiffness of lens materials. Deposit formation on the lenses is still an issue, which can make patients uncomfortable and blur their visions. Further studies on compatibility between eye drops and silicon hydrogel lenses are warranted for proper selection of eye drops for patients who wear certain types of silicon hydrogel bandage lenses, or vice versa. When choosing a contact lens as bandage lens, many factors, especially high oxygen transmission, comfort and deposit resistance, should be considered.

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