

# Comparison of effectiveness of silicone hydrogel contact lens and hydrogel contact lens in patients after LASEK

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## Abstract

• **AIM:** To conduct a comparative study of effectiveness of silicone hydrogel contact lens and hydrogel contact lens, which are used in patients after laser-assisted subepithelial keratomileusis (LASEK).

• **METHODS:** Sixty-three patients (121 eyes) with a spherical equivalent  $\leq -5.0$  D were chosen after undergoing LASEK in 2012 at Guangdong General Hospital. They were randomly divided into 2 groups. The silicone hydrogel group included 32 cases (61 eyes) that wore silicone hydrogel contact lenses for 4-6d after the operation, while the hydrogel group included 31 cases (60 eyes) who wore hydrogel contact lenses for 4-6d after the operation. Patients' self-reported postoperative symptoms (including pain, photophobia, tears, and foreign body sensation) were evaluated. The healing time of the corneal epithelium, the visual acuity of patients without contact lens after epithelial healing, and the incidence of delayed corneal epithelial shedding were also assessed. The follow-up time was 1mo.

• **RESULTS:** Postoperative symptoms were milder in the silicone hydrogel group than in the hydrogel group. There were significant differences in pain, foreign body sensation, and photophobia between the 2 groups ( $P < 0.05$ ), although there was no significant difference in postoperative tearing ( $P > 0.05$ ). The healing time of the corneal epithelium in the silicone hydrogel lens group was markedly shorter than that in the hydrogel group ( $4.07 \pm 0.25$  vs  $4.33 \pm 0.82$ d,  $t = 2.43$ ,  $P = 0.02$ ). Visual acuity without contact lenses after healing of the corneal epithelium was better in the silicone hydrogel group compared with the hydrogel group ( $\chi^2 = 7.76$ ,  $P = 0.02$ ). There was no significant difference in the occurrence of

delayed corneal epithelial shedding between the 2 groups ( $P > 0.05$ ).

• **CONCLUSION:** Patients with LASEK using silicon hydrogel contact lenses had less discomfort and shorter corneal epithelial healing time compared with those using hydrogel contact lenses, suggesting that silicon hydrogel contact lenses may be considered to be a better choice of bandage contact lens after LASEK.

• **KEYWORDS:** laser-assisted subepithelial keratomileusis; silicone hydrogel contact lens; hydrogel contact lens; epithelial healing

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## INTRODUCTION

In recent years, bandage contact lenses have been widely used after corneal refractive surgery, because they protect the corneal wound, prompting the healing of the corneal epithelium and relieving patients' discomfort after laser-assisted subepithelial keratomileusis (LASEK)<sup>[1,2]</sup>. The hydrogel bandage contact lenses are conventionally used to accelerate corneal epithelial healing, however, continuous wear of hydrogel contact lenses may easily cause corneal edema and delay the corneal healing because of their low oxygen transmissibility. A new kind of bandage contact lenses consisting of silicone-hydrogel is highly noted by researchers because these lenses have oxygen transmissibility 5 to 10 fold higher than the conventional hydrogel ones<sup>[3]</sup>. It has been found that, the oxygen permeability and the material of the therapeutic contact lens affect the repair of the corneal epithelium and the degree of postoperative pain<sup>[4-6]</sup>. Therefore, we conducted a comparative study of the commonly used hydrogel contact lens and silicone hydrogel contact lens to investigate the effectiveness of these 2 kinds of bandage corneal contact lenses, made of different materials, in repairing the ocular surface and relieving discomfort after LASEK.

## SUBJECTS AND METHODS

**Subjects** Sixty-three patients (121 eyes) who had undergone LASEK in our hospital from Jan. to Dec. 2012 were enrolled

**Table 1 Comparison baseline parameters of the eyes between the silicone hydrogel and the hydrogel group**  $\bar{x} \pm s$

Parameters	Silicone hydrogel group	Hydrogel group	<i>t</i>	<i>P</i>
Mean spherical equivalents ( $\phi/D$ )	-3.24±0.957	-3.27±0.99	-0.16	0.87
Intraocular pressure (mm Hg <sup>a</sup> )	15.61±2.67	15.35±2.74	-0.53	0.60
Central corneal thickness ( $\mu\text{m}$ )	548.93±39.23	546.70±35.29	-0.33	0.74
Corneal ablation depth ( $\mu\text{m}$ )	50.75±14.83	50.75±15.39	-0.72	0.94

<sup>a</sup>1 kPa=7.5 mm Hg.

in this study. Patients between 18 and 45 years of age who had undergone LASEK and had a spherical equivalent  $\leq -5.0$  D were included. Exclusion criteria were: 1) previous history of discomfort after using of corneal contact lens; 2) serious heart, liver, lung, or autoimmune disease, diabetes, or renal insufficiency. The patients were randomly divided into silicon hydrogel group and hydrogel group. There were 23 men (46 eyes) and 9 women (15 eyes), 18 to 45 years old, with an average age of 24 (24.41±6.50)y in the silicon hydrogel group, and there were 21 men (41 eyes) and 10 women (19 eyes), 17 to 37 years old, with an average age of 24 (23.90±5.00)y in the hydrogel group. No significant differences in baseline parameters of the eyes were found between the 2 groups ( $P > 0.05$ ; Table 1). The research followed guidelines of the Declaration of Helsinki for humans, and was approved by the Ethical committee of the Guangdong General Hospital and Guangdong Eye Institute. Written informed consent was obtained from all participants.

**Methods**

**Parameters of corneal contact lens used postoperatively**

1) Patients in the silicone hydrogel group wore silicone hydrogel contact lens (Pure Vision; Bausch & Lomb, USA) with Balafilcon material (silicone hydrogel complex): diameter, 14 mm; base curve, 8.6 mm; water content, 39%; Dk/L value,  $99 \times 10^{-9}$  barrer/mm. 2) In the hydrogel group, patients wore hydrogel contact lens (Shu Che; Johnson & Johnson, USA) with Etafilcon material (hydrophilic polymer hydrogel material): diameter, 14 mm; base curve, 8.6 mm; water content, 59%; Dk/L value,  $26.7 \times 10^{-9}$  barrer/mm.

**Excimer laser surgery** All operations were performed by the same experienced surgeon. After the operative eye was washed, sterilized, and draped, surface anesthesia with Alcaine<sup>®</sup> was applied 3 times, and a corneal epithelium ring with a diameter of 8 mm was used. An epithelial flap was made using 20% ethanol for 15s. A Technolas<sup>®</sup> 217z Excimer Laser (Bausch & Lomb, USA) was used for laser ablation. The corneal epithelial flap was discarded after the completion of laser ablation, and a corneal contact lens was placed, after blotting up the conjunctival sac. Finally, the positioning and fit of the lens was examined under a slit lamp.

**Postoperative medication regimen** Tobradex<sup>®</sup> eye drops were used every 5min within 20min after the operation, for a total of 3 times. Postoperative medication: Tobradex eye

drops, ofloxacin eye drops, pranopulin eye drops, and Recombinant Bovine Basic Fibroblast Growth Factor eye drops were used separately 4 times each day during the first week postoperatively, and the contact lens was removed after the epithelium had healed completely, as indicated by the slit lamp examination. Fluorine eye drops (0.1%) were then used 4 times a day initially, reducing the dosage gradually to once every 2wk.

**Postoperative follow-up** Postoperative follow-up included the quantitative evaluation of subjective symptoms by patients, such as pain, photophobia, foreign body sensation, and tears, after surgery. The scoring criteria of the subjective symptoms were based on the study of Autrata and Rehurek<sup>[7]</sup>, and were adapted with slight modifications to this research. Scoring criteria were as follows: no discomfort: 0; mild symptoms, which do not affect everyday life: 1 point (mild); moderate symptoms, which have a mild influence on everyday life: 2 points (moderate); severe symptoms that affect the everyday life of the patient or must be controlled by medication: 3 points (severe). The healing of the corneal epithelium was observed under a slit lamp 4, 5, and 6d after surgery, and the corneal contact lens was removed when the epithelium had healed completely. Finally, visual acuity was examined, and the patient was followed for 1mo.

**Statistical Analysis** SPSS 17.0 statistical software was used for data collection and analysis. Numerical data were displayed as percentage, Chi-square test and Fisher's exact probability method was used for the comparison of classification data, and the rank-sum test was used for ranked data. Measurement data were displayed as mean ±standard deviation (SD) or median (interquartile spacing), and their statistical analysis was performed using the *t*-test or the Wilcoxon rank-sum test.

**RESULTS**

**Scoring of Postoperative Subjective Symptoms** 1) Of all included subjects, 56 (91.80%) eyes in the silicone hydrogel group and 34 (56.67%) eyes in the hydrogel group scored 1 point or below for pain ( $Z = -5.16$ ,  $P < 0.01$ ). 2) Fifty-nine (96.72%) eyes in the silicone hydrogel group and 50 (83.33%) eyes in the hydrogel group scored 1 to 2 points for photophobia ( $Z = -2.27$ ,  $P = 0.02$ ). 3) Similarly, 60 (98.36%) eyes in the silicone hydrogel group and 48 (80.00%) eyes the hydrogel group scored 1 point or below for foreign body sensation ( $Z = -2.97$ ,  $P < 0.01$ ). 4) Fifty-two (85.25%) eyes in

**Table 2 Comparison of self-symptoms between the silicone hydrogel and the hydrogel group**

Score			Z	P
	Silicone hydrogel group, eyes	Hydrogel group, eyes		
<b>Pain score</b>				
0	21 (34.43)	3 (5.00)	-5.16	<0.01
1	35 (57.38)	31 (51.67)		
2	3 (4.92)	22 (36.67)		
3	2 (3.28)	4 (6.67)		
<b>Photophobia score</b>				
0	0 (0.00)	0 (0.00)	-2.27	0.02
1	32 (52.46)	22 (36.66)		
2	27 (44.26)	28 (46.67)		
3	2 (3.28)	10 (16.67)		
<b>Foreign body sensation score</b>				
0	30 (49.18)	18 (30.00)	-2.97	< 0.01
1	30 (49.18)	30 (50.00)		
2	1 (1.64)	10 (16.67)		
3	0 (0.00)	2 (3.33)		
<b>Tears score</b>				
0	29 (47.54)	20 (33.33)	-1.71	0.09
1	23 (37.70)	27 (45.00)		
2	9 (14.75)	9 (15.00)		
3	0 (0.00)	4 (6.67)		

**Table 3 Comparison of healing time of corneal epithelium between the silicone hydrogel group and the hydrogel group**

Groups	Healing time of corneal epithelium, eyes				$\bar{x} \pm s$ (d)	t	P
	4d	5d	6d	7d			
Silicone hydrogel group	57 (93.44)	4 (6.66)	0 (0.00)	0 (0.00)	4.07±0.25	2.43	0.02
Hydrogel group	49 (81.66)	6 (10.00)	1 (1.67)	4 (6.67)	4.33±0.82		

the silicone hydrogel group and 47 (78.33%) eyes in the hydrogel group scored 1 point or below for tears ( $Z=-1.71$ ,  $P=0.09$ ) (Table 2).

**Epithelial Healing Time** The average corneal epithelial healing time was  $4.07 \pm 0.25$ d in the silicon hydrogel group, and it was  $4.33 \pm 0.82$ d in the hydrogel group ( $t=2.43$ ,  $P=0.02$ ) (Table 3).

**Postoperative Unaided Eye Vision After Epithelial Healing** Unaided eye vision of 8 eyes (13.11%) in the silicon hydrogel group and 10 eyes (16.67%) in the hydrogel group was below 0.6; unaided eye vision of 36 eyes (59.02%) in the silicon hydrogel group and 45 eyes (75.00%) in the hydrogel group was between 0.6 to 0.8; unaided eye vision of 17 eyes (27.87%) in the silicon hydrogel group and 5 eyes (8.33%) in the hydrogel group was greater than or equal to 0.8. There was significant difference between the 2 groups ( $\chi^2=7.76$ ,  $P=0.02$ ).

**Late-onset Shedding of the Corneal Epithelium** No late-onset shedding of the corneal epithelium occurred in the silicone hydrogel group. In the hydrogel group, late-onset shedding of the corneal epithelium occurred in 3 eyes (5%) within 24h after removing the contact lens for subjects who removed contact lens on day 4. These subjects wore the contact lens again and removed it after another 48h. There

was no significant difference between the 2 groups ( $\chi^2=3.13$ ,  $P=0.12$ ).

**Others** No serious complications or loss of contact lens occurred in any of the operated eyes.

## DISCUSSION

LASEK has often been used as the first choice for safe and effective corneal surface refractive surgery in short-sighted patients with thin corneas, athletes, and those with special professions. But the occurrence of mild to moderate irritation and corneal haze after LASEK often makes surgeons and patients hesitate to choose this type of surgery<sup>[8-11]</sup>. Therefore, attempts to reduce irritation and achieve faster corneal epithelial healing have become the focus of specialists in corneal refractive surgery. Patients have often been required to wear a bandage corneal contact lens for a few days after LASEK to cover the bare cornea and prevent mechanical friction between the cornea and the eyelid, thereby reducing pain, protecting the corneal epithelium, promoting the healing of the epithelium, and reducing the breakup of the epithelial and substrate layers<sup>[12,13]</sup>.

Clinically, the bandage cornea contact lens commonly used overnight has been made with hydrogel, with relatively low oxygen permeability and a Dk/L typically around  $30 \times 10^{-9}$  barrer/mm. When patients wear hydrogel bandage corneal

contact lens after LASEK, the lack of oxygen could easily lead to a decrease of energy metabolism of the cornea, delay corneal epithelial cell differentiation, decrease in the number of cells, thin epithelial layer, increase in the rate of cell aging, and disorder the cellular structure hierarchy, thereby impeding corneal epithelium healing [6,14-16]. For traditional hydrogel lenses, the Dk increases as the percentage of water increases, while for silicone hydrogel lenses, the inverse is true. This trend is driven by the fact that silicone hydrogel is more permeable to oxygen than water, which in turn is more permeable than traditional hydrogel material [17]. Holden and Mertz [18] suggested that the contact lens should have good oxygen permeability when used overnight, with a Dk/L of at least  $87 \times 10^{-9}$  barrer/mm. In this study, the oxygen permeability of the silicon hydrogel contact lens reached  $99 \times 10^{-9}$  barrer/mm for Dk/L. A prospective, observer-masked study show the silicone hydrogel lens was associated with better corneal epithelium healing 5d after LASEK [6]. Another study reported the investigators found significantly faster corneal reepithelialization and reduced patient discomfort during the first 48h after PRK in the eyes fitted with a silicone hydrogel contact lens [19,20]. In this study, the corneal epithelium healing time was significantly shorter in the silicon hydrogel group than that in the hydrogel group, with 100% of eyes in the silicon hydrogel group and only 91.7% of eyes in the hydrogel group removing the contact lens at 5d postoperatively. We hypothesized that a silicone hydrogel contact lens with high Dk/L value could reduce the incidence of corneal edema and hypoxia during the process of corneal repair, so corneal epithelial healing would be faster in patients in the silicon hydrogel group, which is consistent with the results of study by Gil-Cazorla *et al* [6]. We found that patients in the silicon hydrogel group had faster vision recovery, which may have been due to the better oxygen permeability of the lens in the silicon hydrogel group, which made epithelial cells less affected by a lack of oxygen and allowed faster healing. For subjects who removed the contact lens on day 4 after the operation in the hydrogel group, late-onset shedding of the corneal epithelium occurred in 3 eyes within 24h after removing the contact lens. This may have been related to a lack of oxygen during the process of corneal epithelial repair, which caused a decline of energy metabolism of the cornea and incomplete repair of the epithelial and substrate layer connection.

The scoring of subjective postoperative symptoms by patients also indicated significant differences in pain, foreign body sensation, and photophobia between the 2 groups, although postoperative ocular symptoms of most patients in both groups were mild. All patients had mild to moderate photophobia postoperatively. We speculate that because the corneal epithelial layer is the main barrier between the ocular surface and air and the trigeminal nerve endings are exposed

postoperatively at the corneal epithelium defect area, photophobia becomes the initial symptom after corneal epithelial injury. Thus, the incidence of mild photophobia in patients after LASEK could be considered as a normal phenomenon. In our study, 52.46% of eyes in the silicone hydrogel group and 36.66% of eyes in the hydrogel group scored below 1 for photophobia, with the silicon hydrogel group slightly better than the hydrogel group. Pain and foreign body sensation scoring showed significant differences between the 2 groups ( $P < 0.01$ ), which could be attributed to the following reasons. First of all, water content of the contact lens in the silicon hydrogel group was 39%, and it was 59% in the hydrogel group. Previous research had found that corneal contact lenses with higher water content were more likely to cause corneal discomfort during the process of long-term wear [21]. In contrast to hydrogel contact lenses, silicone hydrogel contact lenses are made using a special material with high oxygen permeability. Since their oxygen permeability is not restricted by water content, high oxygen permeability can be reached, even in case of low water content. Consequently, silicon hydrogel corneal contact lenses can result in quicker corneal healing and a higher comfort level for patients wearing the lenses overnight. In addition, the surface of the silicon hydrogel lenses are treated with Performa™ lens surface coating technology. This technology can improve the wettability of the material and reduce the formation of material sediments such as proteins. As a result, pain, foreign body sensation, and photophobia were lighter in patients in the silicon hydrogel group than those in the hydrogel group. We also found that 47.54% of patients in the silicone hydrogel group and 33.33% of patients in the hydrogel group scored 0 for tear symptoms. Although there was a difference of about 14%, this was not statistically significant ( $P = 0.09$ ). Further studies are needed to determine whether this was due to inadequate sample size. However, there were several limitations in the current study. Based on one month observation period, it was hard to determine the differences of long-term indicators including the vision improvement and safety between these two kinds of lenses. The use of visual analog scales for postoperative symptom evaluation might have impact on the results for the reason of the different tolerance for pain and discomfort among the subjects. Future a long-term study with a more reasonable method for symptom assessment is warranted to confirm the different characteristics of these two kinds of bandage contact lenses.

In conclusion, compared to patients who used hydrogel contact lenses after LASEK surgery, patients using silicon hydrogel contact lenses had less discomfort and shorter corneal epithelial healing time. Thus, silicon hydrogel contact lenses may be considered to be a better choice of bandage contact lens after LASEK.

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