

The protective efficacy and safety of bandage contact lenses in children aged 5 to 11 after frontalis muscle flap suspension for congenital blepharoptosis

A single-center randomized controlled trial

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Abstract

Background: Postoperative complications, lagophthalmos and exposure keratopathy sometimes occur after surgery for congenital blepharoptosis. Bandage contact lenses (BCL) can help prevent some ocular surface disorders. The study aims to evaluate the efficacy and safety of BCL for protection of the ocular surface in children aged 5 to 11 years after frontalis muscle flap suspension for congenital blepharoptosis.

Methods: We conducted a prospective randomized clinical study of 30 eyes of 30 patients with congenital blepharoptosis consecutively enrolled at the Ophthalmology Ward of the Children's Hospital of Chongqing Medical University, China from September 1, 2016, to February 30, 2017. After frontalis muscle flap suspension surgery, patients were randomly assigned to undergo BCL application (BCL group, 15 eyes) or no BCL application (control group, 15 eyes). All patients were treated with bramycin 0.3% and polyvinyl alcohol drops after surgery. The primary outcomes were dry eye assessed by tear film break time (TFBUT), fluoresce in corneal staining (FCS) on slit-lamp on days 1, 3, and 15 postoperatively, and lower tear meniscus height (LTMH) on optical coherence tomography on days 1 and 15 postoperatively. Secondary outcomes were pairwise correlation of TFBUT, FCS and LTMH.

Results: In the BCL group, abnormal TFBUT and FCS were only found in 2 patients (13.33%) on postoperative day 15. In the control group, the incidence of dry eye assessed by TFBUT was 67.00% (10/15 eyes) on day 1, 73.33% (11/15 eyes) on day 3, and 53.33% (8/15 eyes) on day 15 ($P < .001$). LTMH was significantly higher in the BCL group than the control group postoperatively ($P < .001$). Significant positive correlations were found between LTMH and TFBUT pre-operation and on days 1 and 15 post-operation. For LTMH and FCSS ($R = -0.815$, $P < .001$), and TFBUT and FCS ($R = -0.837$, $P < .001$), the Pearson coefficient was negative on postoperative day 1, but not correlated on day 15.

Conclusions: Silicone hydrogel BCL were safe and efficacious for protective use in children after frontalis muscle flap suspension for congenital blepharoptosis.

Abbreviations: AS-OCT = anterior segment optical coherence tomography, BCL = Bandage contact lenses, FCS = fluoresce in corneal staining, FCSS = fluorescein corneal staining scores, FDA = Food & Drug Administration, LTMH = lower tear meniscus height, OCT = optical coherence tomography, SD = standard deviation, TFBUT = tear film break time.

Keywords: bandage contact lens, blepharoptosis, frontalis muscle flap suspension, ophthalmologic surgical procedures, treatment outcome

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1. Introduction

Congenital blepharoptosis, also known as congenital ptosis, is as an eyelid disorder where there is an abnormal low-lying upper eyelid margin with the eye in primary gaze. The disorder is frequently associated with amblyopia, refractive error, anisometropia, and strabismus.^[1] A population-based study found an incidence of blepharoptosis of 7.9 per 100,000 children under the age of 19, in which 89.7% were congenital.^[2] Remarkably, as well as problems arising from obstructed vision, congenital blepharoptosis has negative effects on the psychological development of a child.^[3] Abnormal head posturing develops in bilateral cases, and it can cause deprivation amblyopia. Therefore, congenital blepharoptosis should be corrected in the early years of childhood, and then correction of any refractive error and treatment of amblyopia should begin as soon as possible after operation.^[4]

There are a number of different surgical options for correction of congenital blepharoptosis, and their selection depends mainly on the age and severity of the ptosis.^[5] Although its etiology is unknown, myogenic ptosis is the most common form of congenital blepharoptosis.^[3] In myogenic ptosis, if there is no levator function or the levator function is less than 4 mm, the most common surgical approach is the frontal suspension technique that creates a link between the frontalis muscle and the tarsus, so that the frontalis muscle is used to elevate the eyelid.^[6] Frontalis suspension is also the surgery of choice for ptosis with poor levator function in other forms of congenital blepharoptosis.^[6,7]

Direct advancement of the frontalis muscle to treat severe eyelid ptosis is effective and stable in the long term avoiding the use of a linking structure.^[8] But, earlier study showed that overcorrection may be associated with dry eye syndrome and keratopathy.^[9] Lagophthalmos is the most common postoperative complication. The incidence of postoperative lagophthalmos ranged from 40.4% to 6.25%,^[10–12] and exposure keratopathy was 11.1%^[13] in earlier studies. Lagophthalmos is also the most common late complication, and the use of appropriate local treatment in prevention of corneal drying is better tolerated by children than by adults with incomplete lids closure, which is reflected in an improvement of corneal adaptation.^[12] Dry eye and exposure keratitis can destroy the function of the ocular surface. Therefore, proper postoperative management is seriously important to avoid complications of ocular surface.^[14] The traditional postoperative nursing strategy of using eyedrops and gauzing does not prevent the occurrence of lagophthalmos after frontalis suspension surgery.^[10–12]

Bandage contact lenses (BCL) have been gaining popularity and widespread acceptance as an adjuvant therapy for ocular diseases over the past 40 years, especially as the materials that are used for their construction are developing rapidly.^[15–17] Conventional nonsilicone contact lenses were widely used as BCL, but their low oxygen permeability increases corneal swelling during extended wear.^[18] Improvements in BCL material and technology have enabled the use of high-water content BCL for extended wear. Silicone hydrogel contact lenses have a very high gas permeability, which reduces complications related to corneal hypoxia.^[19] BCL of this type have been used for various ocular surface disorders, such as dry eye, corneal persistent epithelial defects, lagophthalmos-induced keratitis, postoperative management of corneal transplantation, and photorefractive keratectomy.^[20–22] And they have even been found to reduce pain in patients with corneal erosion.^[23] The popularity of these lenses means that several silicone hydrogel contact lenses have been introduced in recent years. The Balafilcon A silicone hydrogel contact lenses used in this study have been approved by the Food & Drug Administration (FDA) in the USA for continuous wear 21 days after refractive surgery.^[24]

To our knowledge, no clinical trial has assessed whether application of BCL after frontal suspension could protect pediatric patients against complications of the ocular surface and cornea. Therefore, we conducted a prospective randomized study to evaluate the protective efficacy and safety of the Balafilcon A silicone hydrogel contact lenses for the ocular surface in children who had undergone frontalis muscle flap suspension for congenital blepharoptosis.

2. Methods

2.1. Study design and participants

This prospective randomized clinical trial study was carried out at Ophthalmology Ward in the Children's Hospital of Chongqing Medical University from September 1, 2016, to February 30,

2017. Thirty young patients (30 eyes) who underwent frontalis suspension for correction of congenital blepharoptosis were consecutively enrolled. The children included in study were between 5 and 11 years of age.

The criteria for inclusion in the study were the eye involved was considered a severe case, with poor levator function defined as the height of the palpebral fissures was less than or equal to 4 mm, and levator function was less than 4 mm; the patients had a normal TFBUT test (>10 seconds) and no lid abnormalities before operation; the patients were aged 5 to 11 years. The exclusion criteria were patients with previous ocular surgery, ocular trauma, ocular infection or other ocular pathology; patients who were unable to understand the study or communicate. Recruited patients were excluded from the final statistical analysis if they experienced significant trauma or infection to the eye, or displaced a contact lens. The study was approved by The Ethics Committee of the Children's Hospital of Chongqing Medical University, Chongqing, China. Written informed consent was obtained from the parents or guardians of the children. The study was conducted in accordance with the principles of the Declaration of Helsinki.

2.2. Surgical procedure and postoperative treatment

All the patients underwent frontalis muscle flap suspension under general anesthesia in the supine position. All of the surgeries were performed by a single experienced surgeon who was a deputy chief physician. At the end of the operation, the patients were randomly allocated into 1 of 2 groups by computed generated random number table so that there were 15 cases in each group. Patients in the BCL group were fitted with a Balafilcon A (Pure Vision™ Bausch & Lomb, Rochester, NY) contact lens and patients in the control group did not receive contact lens therapy. The State Food and Drug Administration (SFDA) of China approved this contact lens for continuous use for up to 21 days. In bilateral cases, where both eyes were treated, only 1 eye was included in the analysis, and in those cases, the right eye was selected to avoid unintentional bias in eye selection.

For all of the patients, erythromycin eye ointment was applied in the palpebral fissure to prevent infection, and a pressure dressing was placed on the frontal and eyebrow areas for 24 hours.

The postoperative medication regimen was the same for all eyes. Tobramycin 0.3% and polyvinyl alcohol drops, 4 times per day, were prescribed for 15 days and all patients showed good compliance with this regimen.

2.3. Clinical assessment

All patients were examined on postoperative days 1 to 3 by slit-lamp. They were examined every day using slit-lamp and fluorescein staining. On postoperative day 1, optical coherence tomography (OCT) imaging of lower tear meniscus height (LTMH) was done before tear film break up time test (TFBUT) and fluorescein corneal staining (FCS) to avoid their influences on imaging. The contact lenses were removed on postoperative day 15, and the patients were examined by OCT and slit-lamp at approximately 2 hours later when BCL were removed on that day.

Postoperative day 1 was the first day of postoperative examination; during this examination, the corneal condition was observed to guide the administration of postoperative medication. Postoperative day 3 was the day before discharge and was undertaken in order to guide the medication required

after discharge. Postoperative day 15 was the day of first visit after discharge to observe the postoperative corneal and ocular surface conditions. OCT was only performed on postoperative days 1 and 15, because the price of this examination was high. Although both TFBUT and FCS were also performed on postoperative days 1 to 3, and 15, as these were more routine eye examinations, the cost was very low and affordable for the patients.

The examination on postoperative day 15 was provided free of charge, so the children had good compliance, and there was no loss to follow-up.

2.4. Lower tear meniscus height (LTMH)

Anterior segment OCT (AS-OCT) measurement of the lower tear meniscus was performed as described by Koh et al.^[25] The AS-OCT measurements were performed by 2 experienced technicians who were blinded to the clinical ophthalmic examination results. All tests were performed in a dim lit room between 21°C and 25°C with regulated humidity to avoid reflex tearing. All patients were instructed not to use any topical eye drops at least 2 hours before testing to negate the effect of medication on tear film. Subjects were instructed to blink and OCT measurements were taken immediately after blinking to avoid the effects of delayed blinking. The subject was asked to fixate on a target, but was allowed to blink freely throughout the duration of the measurement, and an image of the vertical cross-section through the center of the lower tear meniscus was recorded. One or more images were taken until a good quality scan, showing the concave profile of the tear meniscus from the inferior lid margin to the corneo-conjunctival surface, was captured (Fig. 1). All measurements were taken from the inferior tear meniscus because there is less visualization and less retention of upper tear meniscus due to presence of eye lashes.

2.5. Tear film break up time test (TFBUT) and fluorescein corneal staining (FCS) on slit-lamp

The stability of the tear film over the conjunctiva and cornea was assessed using a Burton lamp with a cobalt blue filter and sodium fluorescein.^[26] A single drop of 2% sodium fluorescein was applied to the eye, and the children were asked to blink 5 times to allow a film to form over the cornea and bulbar conjunctiva. The children were then asked to refrain from blinking during which time black spots or lines, indicating dry spots, were seen. The children practiced this procedure before the test was performed. The interval between the last blink and the first randomly distributed dry spot was taken as the tear break-up time. An average of 3 measurements was recorded. Ten seconds for TFBUT was set as a reference value.

Fluorescein stain scoring on the corneal surface was performed after the TFBUT test. The corneal surface area was divided into upper, middle, and lower areas of equal size. In each area, a staining score of 0 to 3 was assigned, depending on the severity of damage.^[27] The total fluorescein staining score therefore ranged from 0 to 9 points. Fluorescein corneal staining scores (FCSS) above 3 points were regarded as abnormal. Each independent examination was performed by the same physician or technician.

2.6. Follow-up

The patients were followed-up until 15 days postoperatively. Any adverse events that occurred were noted. The primary outcome measures were dry eye as assessed by the TFBUT and FCSS on slit-lamp evaluated on days 1 to 3 and day 15 postoperatively, and LTMH on OCT at days 1 and 15 postoperatively. Secondary outcomes were pairwise correlation of TFBUT, FCS, and LTMH.

2.7. Statistical analysis

SPSS 16.0 (IBM Corp., Armonk, NY) was used for statistical analysis. The measurement or count data are presented as

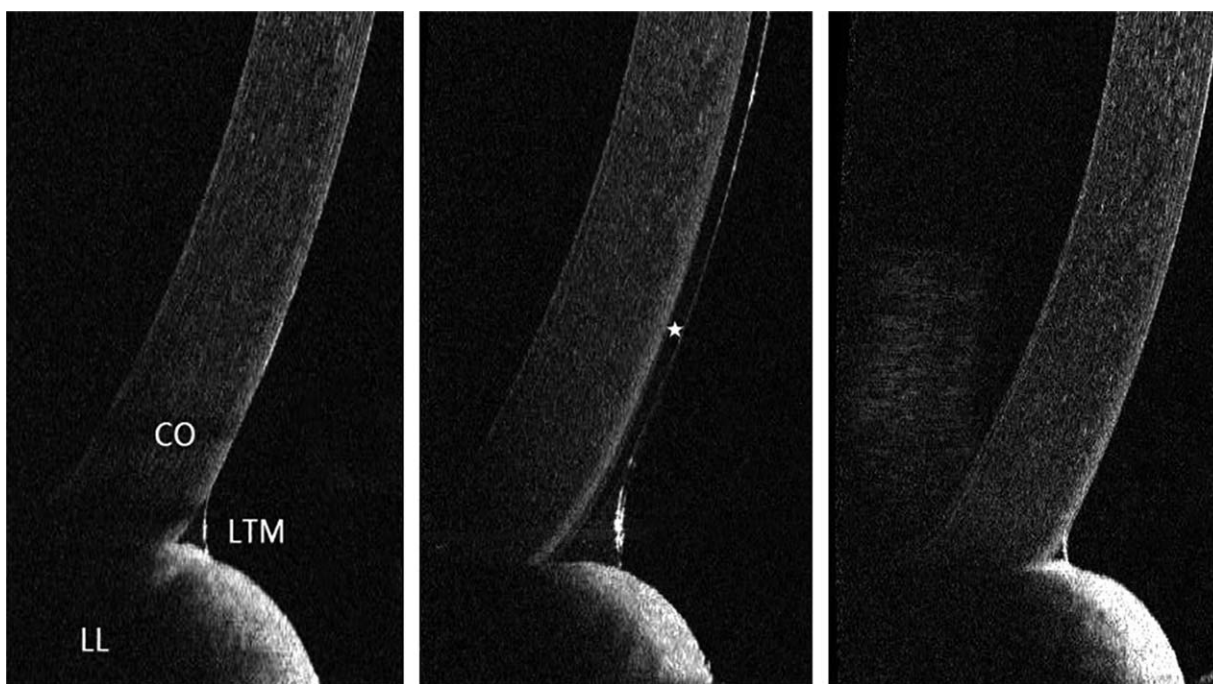


Figure 1. Lower tear menisci (LTM) imaged with anterior segment optical coherence tomography (AS-OCT). Analysis was done of the height of the triangular region at the junction of the cornea (CO) and lower lid (LL). The images obtained from a preoperative patient (left), a postoperative patient fitted with a silicone hydrogel contact lens (marked as star in middle image), and a postoperative patient in control group (right) after operation are shown.

Table 1

Demographic data and clinical measurements in the bandage contact lens (BCL) group and the control group.

	BCL group (n=15)	Control group (n=15)	P
Age, y	7.11 ± 1.92	7.12 ± 1.58	.89
Gender (Male:Female)	11:4	12:3	.61
Preoperative TFBUT, s/FCS score	13.09 ± 1.46/0	13.29 ± 1.30/0	.70
Postoperative TFBUT, s/FCS score			
Day 1	14.22 ± 1.04/ 0	8.73 ± 1.31/ 1.33 ± 0.82	<.001* / <.001*
Day 2	14.36 ± 1.26/ 0	8.49 ± 1.25/ 0.80 ± 1.08	<.001* / .013†
Day 3	14.25 ± 1.10/ 0	8.58 ± 3.01/ 0.67 ± 0.72	<.001* / .003*
Day 15	12.44 ± 1.47/ 0.13 ± 0.35	8.91 ± 2.36/ 0.40 ± 0.63	<.001 / .17
Preoperative LTMH, μm	251.47 ± 19.40	250.33 ± 14.33	.83
Postoperative LTMH, μm			
Day 1	368.06 ± 44.82	193.47 ± 28.06	<.001*
Day 15	236.13 ± 19.26	192.40 ± 20.16	<.001*

Data are expressed as mean ± standard deviation.

LTMH = lower tear meniscus height, TFBUT = tear film break time.

* $P < .01$.

† $P < .05$.

mean ± standard deviation (SD), frequency, percentile, and the range. For the normally distributed continuous variables, the independent-sample t test was used; for the non-normally distributed continuous variables, the rank sum test was used. Variables in the contingency table were analyzed by the χ^2 test (or the Fisher exact test). Pearson correlation coefficient (R) was calculated to assess the relationship between 2 parameters. P values less than .05 were considered statistically significant.

3. Results

Of the 30 patients (30 eyes) enrolled in this study, 15 (15 eyes) were assigned to the BCL group and 15 (15 eyes) were assigned to the control group. The male-to-female ratio was similar in the 2 groups ($P = .41$). There were 11 males and 4 females in the BCL group and 12 males and 3 females in the control group. The mean age of the patients was 7.11 ± 1.83 years (range 5–11 years) and there was no significant difference between the groups ($P = .89$). There were 5 bilateral cases and 10 unilateral cases in both the BCL group and the control group. In bilateral cases, the right eye was assessed and analyzed.

Preoperative TFBUT, FCSS, and LTMH details showed no difference statistically between the 2 groups (Table 1).

The primary endpoint of dry eye assessed by TFBUT and fluorescein corneal staining was not found on postoperative day 1 to 3 in the BCL group, and only in 2 patients (13.33%) on postoperative day 15. In the control group, the incidence of dry eye assessed by TFBUT was 67.00% (10/15 eyes), 73.33% (11/15 eyes), 73.33% (11/15 eyes), and 53.33% (8/15 eyes) on postoperative day 1 to 3, 15, respectively.

The TFBUT was significantly higher in the BCL group than in the control group on postoperative day 1 (14.22 ± 1.04 vs 8.73 ± 1.31), 2 (14.36 ± 1.26 vs 8.49 ± 1.25), 3 (14.25 ± 1.10 vs 8.58 ± 3.01), and 15 (12.44 ± 1.47 vs 8.91 ± 2.36) ($P < .001$).

FCSS showed a significant difference between the 2 groups on postoperative day 1 to 3 ($P < .001$), but no difference on day 15 ($P = 0.17$). The LTMH was significantly higher in the BCL group than in the control group on postoperative day 1 (368.06 ± 44.82 vs 193.47 ± 28.06) and day 15 (236.13 ± 19.26 vs 192.40 ± 20.16) ($P < .001$) (Table 1, Fig. 2).

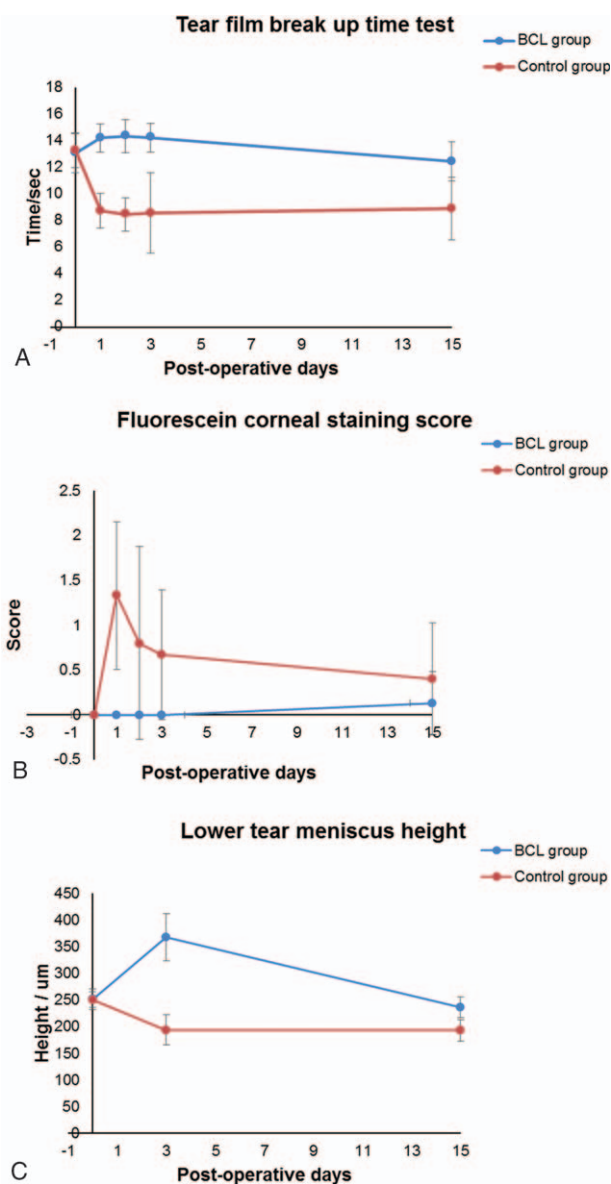


Figure 2. Graphs showing the dry eye tests in the 2 groups from preoperative assessment until 15 days after surgery. (A) The change in tear film break up time test (TFBUT). (B) The fluorescein corneal staining score (FCSS). (C) The lower tear meniscus height (LTMH).

3.1. Correlation data for the entire patient population, whether they used BCL or not

Significant positive correlations were found between LTMH and TFBUT before ($R = 0.740$, $P < .001$) and after operation ($R = 0.966$, $P < .001$ on day 1 and $R = 0.819$, $P < .001$ on day 15) (Table 2).

For correlation between LTMH and FCSS ($R = -0.815$, $P < .001$), between TFBUT and FCSS ($R = -0.837$, $P < .001$), Pearson coefficient was negative on postoperative day 1, but suggested no correlation on day 15.

During the 15-day follow-up, the BCL were well tolerated by all of the patients. No side effects were seen in patients in BCL group, such as infection, corneal vascularization, BCL damage, or loss. No patients showed any drug toxicity with concomitant

Table 2**The correlation of clinical findings of the patients before and after operation.**

R/P	Preoperation (n=30)	Postoperative day 1 (n=30)	Postoperative day 15 (n=30)
LTMH vs TFBUT	.740 [*] /.000	.966 [*] /.000	.819 [*] /.000
LTMH vs FCSS	†	-.815 [*] /.000	-.160/.398
TFBUT vs FCSS	†	-.837 [*] /.000	-.081/.671

FCSS = fluorescein corneal staining scores, LTMH = lower tear meniscus height, TFBUT = tear film break time.

^{*} $P < 0.01$. Pearson correlation coefficient (*R* value) was calculated for each comparison.

† Constant of FCSS of preoperation was 0, so the correlation cannot be calculated.

topical drug use for the duration of lens wear. No complications resulting from the surgical procedure were found in either group, including lid crease deformity, undercorrection, overcorrection, hematoma, conjunctival prolapse, or eyebrow asymmetry.

4. Discussion

The aim of this study was to investigate whether using BCL could protect the ocular surface in children undergoing frontalis muscle flap suspension for congenital blepharoptosis. The primary endpoint was assessment of dry eye and the results showed that when assessed by TFBUT, the patients in the BCL group showed significantly fewer cases of dry eye than the control group with only 2 cases at postoperative day 15 compared with 10/15 eyes on day 1, 11/15 eyes on day 3, and 8/15 eyes on day 15 in the control group. LTMH were significantly higher in the BCL group than in the control group postoperatively. Also, significant positive correlations were found between LTMH and TFBUT measurements preoperation and on days 1 and 15 postoperation and there were no significant adverse events, suggesting that BCL were safe and efficacious for children after frontalis muscle flap suspension for congenital blepharoptosis.

In the present study, the frequency of dry eye in the control group as assessed by TFBUT was 67%, 73%, 73%, and 53% on postoperative day 1 to 3, 15 respectively. Fluorescein corneal staining was not found on postoperative day 1 to 3 in the BCL group. These rates are obviously higher than the ones reported by Mokhtarzadeh et al and Hou et al,^[10–12] which may be due to the different methods of anesthesia. All our patients were under general anesthesia because of their young age, but other studies included adults under local anesthesia. During recovery from general anesthesia, eye lids are often open, leaving the cornea at the front, and thus making it more susceptible to trauma due to contact with eye patches.^[28]

Contact lenses as a therapeutic modality have been used in the treatment of various corneal and anterior segment disorders for pain relief, protection of the corneal epithelium, enhancement of corneal healing, and drug delivery for a long time. In a previous study with Pure Vision contact lens, good efficacy and safety were seen in a continuous wear therapy in children.^[21] With the advantage of increased oxygen transmissibility due to the silicon hydrogel, the lens provided a superior physiological environment compared with a traditional hydrogel material during continuous wear. In the present study, dry eye assessed by TFBUT and fluorescein corneal staining was not founded in BCL group on postoperative day 1 to 3, which was a significant difference between the 2 groups ($P < .001$). This may be due to BCL providing protection usually provided by the eyelids during recovery from general anesthesia and in the early postoperative stage. In the control group, the fluorescein corneal staining was mainly in the lower area of cornea because of Bell phenomenon.

So, the mean FCSS was not more than 3 points (mean value was 1.33 ± 0.44) after operation. In terms of the FCSS on postoperative day 15, the FCSS was higher in the control group than in the BCL group. However, there was not a statistically significant difference between 2 groups (0.13 ± 0.35 , 0.40 ± 0.63 , $P = 0.17$), and fluorescein corneal staining were found in 2 patients (13.33%) on postoperative day 15. We speculated this may be due to noncompliance when the BCL were removed and that some of the young patients had been rubbing their eyes, which caused mechanical friction between the cornea and contact lens.

A significant positive correlation was found between LTMH and TFBUT before and after operation, which is consistent with the findings by Wang et al^[29] and Tung et al.^[30] In the current study, we found that LTMH significantly decreased in the control group compared with the BCL group after operation. These results may be because greater evaporation and tear instability occurred in patients with different degree of lagophthalmos after operation, which resulted in a net reduction of tear volume in the control group (the cornea exposed) compared with those patients fitted with BCL. The lenses serve as a protective barrier between the eyelids and corneal surface, and disperse an unstable tear film over the surface of the cornea.^[21] The TFBUT reflects stability of the tear film, and the LTMH on OCT reflects the tear meniscus in its natural real time state. So, it is not surprising to find that the TFBUT and LTMH were significantly higher in the BCL group than the control group. The significant association between TFBUT and LTMH further confirmed that wearing BCL after the operation simultaneously protected the quality (stability) and volume of the tears, and reduced the exposure of the cornea, which are major factors in reducing dry eye incidence. In the current study, silicone hydrogel contact lenses performed well clinically and were well accepted by the young patients, and no side effects were seen in 15 days of continuous wear.

However, our study has several limitations. First, the processing of images could be biased depending on operator's judgment for detecting the junctions that can be reduced by introduction of automated image processing software in OCT. Second, the observation period is short, and longer observational times may be needed to evaluate later difference between the 2 groups. In addition, the sample size was quite small and was undertaken in a single center, more patients from more hospitals would increase the statistical validity of the results. The follow-up time was short and limited to the first 15-day outpatient checkup. A longer follow-up would ensure that no other complications arise at later time points and would be important for longer term outcomes. We did not evaluate the surgical efficacy of the frontalis muscle flap suspension because all operations were completed by the same experienced deputy chief physician.

In conclusion, silicone hydrogel BCL were found to be safe and efficacious for protective use for children with congenital blepharoptosis who had undergone frontalis muscle flap

suspension repair, especially in the early period postoperation. The stability of the tear film and tear volume were higher in patients fitted BCL than those without BCL. The cornea and tear film had fewer postoperative complications with BCL use. However, while BCL was safe and effective, it should be noted that pediatric patients still need rigorous and regular follow-up checks by ophthalmologists to ensure optimal outcomes.

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