

# Evaluation of the safety and efficacy of therapeutic bandage contact lenses on post-cataract surgery patients

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## Abstract

• **AIM:** To evaluate the safety of therapeutic bandage contact lens for post-cataract surgery patients and to illustrate its efficacy on post-operative comfort and tear-film stability.

• **METHODS:** A total of 40 participants were recruited and randomly divided into two groups. Group one was instructed to wear bandage contact lenses for a week and use antibiotic eye drops for a month since the first day after surgery. Group two received sub-conjunctival injection of tobramycin and was asked to wear eye pads on the first day after surgery and then were instructed to use antibiotic eye drops as the first group did. Ocular surface disease index (OSDI) questionnaire, slit-lamp microscope examination of tear break-up time (TBUT), corneal fluorescein score (CFS), tear meniscus height (TMH) together with anterior segment optical coherence tomography (AS-OCT) and corneal topography were evaluated preoperatively and postoperatively.

• **RESULTS:** The subjective feeling ( $P=0.004$ ), TBUT ( $P<0.001$ ) and TMH ( $P=0.02$ ) post-surgery had improved in patients who used bandage contact lenses compared with those who did not at 1wk post-surgery. Until three month postoperatively, the comfort degree ( $P=0.004$ ) and TMH ( $P=0.01$ ) of group two were still worse than group one. Moreover, TBUT ( $P<0.001$ ) and CFS ( $P=0.004$ ) of the group with eye pads got worse than the results before, whereas the group with bandage contact lenses recovered to normal. None of these patients had infections or other complications.

• **CONCLUSION:** Wearing therapeutic bandage contact lens after cataract surgery, compared with traditional eye-pads, is a safe method to improve tear-film stability and reduce post-operative discomfort without hindering corneal incision recovery.

• **KEYWORDS:** bandage contact lens; cataract surgery; tear-film stability; comfort

## INTRODUCTION

Currently it has been a routine practice for patients after cataract surgery to use eye-pads to protect the operated eyes from exposure to external environment until the following day for check-up. This usually leads to inconveniences due to monovision and stereopsis defection; besides, patients have to suffer from the subconjunctival injection of tobramycin, since antibacterial eyedrops could not be used because of the eye-pad. Moreover, the corneal incision related post-surgery discomfort is always complained by patients.

To wear therapeutic bandage contact lenses after surgery could solve the monovision problem caused by eye-pads and enable the patients to use antibacterial eye drops soon after the surgery is finished. They have now been widely used for non-infective ocular diseases<sup>[1-2]</sup>, such as corneal laceration, epithelial defect, bullous keratopathy and dry eye syndrome<sup>[3-6]</sup>. In most of these cases, they are used to promote corneal recovery and relieve pain during the healing process, since they can enhance epithelial healing and control surface generated pain<sup>[7]</sup>. Moreover, it can be used as a drug delivery system for its remarkable property in controlling and sustaining ocular drug delivery<sup>[8]</sup>. However, bandage contact lenses applied after cataract surgery has not been reported before.

However, therapeutic bandage contact lens may cause two problems. The first is that the loss of tear through evaporation while wearing contact lens may result in hyperosmolarity of the tear-film or reduce the protective ability of the mucin layer<sup>[9-12]</sup>. The other problem is corneal infection, especially bacterial keratitis due to extended and overnight wearing of bandage contact lens<sup>[13-14]</sup>.

The aim of our study is to evaluate the safety of therapeutic bandage contact lens for post cataract surgery patients and to illustrate its effects on subjective feeling and tear film stability.

## SUBJECTS AND METHODS

**Patients Data** A cohort of 40 patients aged between 53 and 89y who diagnosed and willing to take cataract surgery at the Department of Ophthalmology of Peking University

**Table 1 General patients information**

Group	Number of subjects ( <i>n</i> )	Age (mean±SD)	Gender (M/F)
Contact lenses	20	72.16±9.40	9/11
Eye pads	20	74.47±6.44	10/10

**Table 2 Grading of ocular inflammation**

Symptom	None (0 score)	Mild (1 score)	Moderate (2 score)	Severe (3 score)	Extreme severe (4 score)
Secretion	No	Little bit	Awake	Most time	All day
Bulbar conjunctiva hyperemia	No	Little bit	Scatter hyperemia	Most hyperemia	Cannot see sclera
Ciliary hyperemia	No	Width<2 mm	2 mm<Width<3 mm	Width>3 mm	Reach fornix
Corneal edema	No	Mild	Iris clear	Iris blur	Cannot see iris
Tyndall effect	No	Mild	Iris and lens clear	Iris and lens blur	Exudate
Keratic precipitates (KP)	No	<3	4-10	>10, countable	Uncountable

Third Hospital between July 2017 and September 2017 were recruited and randomly divided into two groups without gender and age bias (Trial Registration Number: ChiCTR-IOC-17012167). Patients with ocular inflammation or other ocular diseases, eye-drops using experiences that can affect ocular surface condition, and those with intraoperative or postoperative complications were excluded. General information of the two groups is delineated in Table 1. Ethics committee approval was obtained from Peking University Third Hospital (Ref. LM2017174), and an informed consent was obtained from all patients before their participation in the study.

**Surgical Procedure** Cataract surgeries were successfully carried out by the same surgeon who used identical methods for standard phacoemulsification. Under retrobulbar anesthesia, a 3 mm clear corneal incision was made. Anterior chamber was filled with a dispersive viscoelastic substance. After continuous curvilinear capsulorhexis, hydrodissection and hydrodelineation was performed, then a sideport entrance was made. The nucleus was removed by using the “divide and conquer” technique. The cortex was aspirated with coaxial irrigation/aspiration. The capsular bag was filled with a cohesive viscoelastic substance. A foldable monofocal posterior chamber IOL (Nex-Acri, NIDEK, Japan) was implanted in the capsular bag through an injector system. The viscoelastic material was aspirated completely. The entrances were closed with stromal hydration. At the end of the surgery, patients of group one were instructed to wear therapeutic silicone hydrogel bandage contact lenses (Bausch&Lomb Pure Vision, balafilcon A, NewYork, USA) for a week and use antibiotic eye drops for a month since the first day after surgery. The subjects of group two received sub-conjunctival injection of tobramycin and were asked to wear eye pads for the first day of surgery. Then levofloxacin (Santen, Osaka, Japan), prednisolone (Allergan, Irvine, CA, USA) and pranoprofen (Senju, Osaka, Japan) eye drops were used four

times per day for one week and were then gradually reduced in both groups.

**Examinations Procedure** Participants’ symptoms were evaluated with a validated Chinese translation of the ocular surface disease index (OSDI) questionnaire before, one week, one month, and three months after the cataract surgery to evaluate post-surgery subjective feelings. We divided the questionnaire into three parts, including ocular discomfort, visual function and environmental triggers and subscale scores were measured and computed in a similar manner<sup>[15]</sup>.

Slit-lamp microscope examination of post-surgery inflammation was carried out one day and one week after the surgery. Inflammation scores were calculated by adding up all inflammatory index in Table 2, in which higher scores represented greater degree of inflammation<sup>[16]</sup>. Tear meniscus height (TMH), corneal fluorescein score (CFS), and tear break-up time (TBUT) were employed at the same time as OSDI. With a paper ruler, TMH was measured at the sites where the slit-lamp beam projected on the cornea and the inferior palpebral margin. CFS was performed in a conventional manner and evaluated by van Bijsterveld score<sup>[17]</sup> and at the same time, the same observer recorded the results of TBUT for each patient. Finally, the anterior segment optical coherence tomography (AS-OCT) (Carl Zeiss Meditec, Inc., Germany) and Pentacam corneal topography (OCULUS, Holladay module, Germany) were conducted to evaluate the corneal excision recovery in terms of corneal thickness and astigmatism.

**Data Analysis** Statistical analysis was conducted with the Statistical Package for Social Sciences software (version 23.0, SPSS, Inc., USA). Data of the corneal examinations were analyzed with independent sample *t*-test for comparisons between the two groups and One-way analysis of variance (ANOVA) for comparisons between the data before and after surgery. Data of the OSDI questionnaire and slit-lamp microscope examinations were analyzed with nonparametric

test. All data are presented in a form of means±standard deviations (SD). Statistically significance was set at  $P<0.05$ .

**RESULTS**

**Questionnaires** As shown in Table 3, at one week after surgery, most patients in the second group experienced post-operative discomforts such as foreign-body sensation and ocular discomfort scores increased greatly than before ( $P=0.001$ ). However, patients who wore bandage contact lens did not demonstrate severe post-surgery ocular discomfort after surgery, with the total score of ocular discomfort significantly lower than the second group ( $P=0.004$ ). The visual function scores decreased and the environmental trigger scores increased in both groups after surgery, with no statistical significantly difference between the two groups.

At one month after surgery, the ocular discomfort scores in both groups increased compared with those before surgery, still with a significant difference between the two groups ( $P=0.01$ ). However, there is no significant difference between two groups in environmental trigger scores ( $P=0.12$ ).

At three month post-surgery, the ocular comfort in the first group was better than that before the surgery, still marking a significant difference with group two ( $P=0.004$ ). The environmental trigger scores in both group reduced to those before the surgery with not much difference ( $P=0.11$ ).

**Slit-lamp Microscope Examination** None of the patients experienced any severe side effects necessitating the cessation of the contact lens. Neither group showed any difference in inflammation scores at one day and one week after the cataract surgery ( $P>0.05$ ), as shown in Table 4.

As shown in Table 5, at one week after surgery, TBUT in patients with eye pads increased significantly while the other group slightly decreased compared with that before surgery, marking an obvious difference between the two groups ( $P<0.001$ ). At one month after surgery, TBUT in the group with eye pads got worse ( $P=0.04$ ) whereas not much change in the group with bandage contact lenses ( $P=0.58$ ), showing no significant differences between the two groups ( $P=0.61$ ). At three month after surgery, the TBUT in the second group did not recovered to normal level ( $P<0.001$ ), however, not much difference with the first group ( $P=0.43$ ).

The CFS score increased significantly in the group with eye pads one week post-surgery ( $P<0.001$ ). At one month post-surgery, the score of both groups increased to a peak value, which then decreased at three month after surgery. However, the corneal staining of the group with eye pads was still worse than that before surgery ( $P=0.004$ ). Both groups did not show much difference during the observation period ( $P>0.05$ ).

During the observational period, the trend of TMH shown in Table 6 was nearly the same as that of TBUT. At one week after cataract surgery, TMH in patients who wore bandage contact lens were higher than that before surgery but decreased

**Table 3 OSDI (Ocular discomfort) before and 1wk, 1 and 3mo after cataract surgery** mean±SD

Group	Before	1wk	1mo	3mo
Contact lenses	18.86±13.56	17.99±18.69	19.58±15.51	10.06±5.42
Eye pads	15.00±7.18	34.44±11.73	25.63±13.79	16.25±7.30
<i>P</i>	0.47	0.004	0.01	0.004

OSOI: Ocular surface disease index.

**Table 4 Inflammation scores at 1d and 1wk after surgery** mean±SD

Group	<i>n</i>	1d	1wk
Contact lenses	20	3.47±1.43	0.47±0.77
Eye pads	20	3.87±1.55	0.33±0.62
<i>P</i>		0.41	0.66

**Table 5 TBUT before and 1wk, 1 and 3mo after surgery** mean±SD

Group	<i>n</i>	Before	1wk	1mo	3mo
Contact lenses	20	2.75±1.10	5.37±1.98	2.47±1.39	2.63±0.87
Eye pads	20	3.27±1.09	2.73±1.39	2.20±1.32	2.93±0.82
<i>P</i>		0.03	<0.001	0.61	0.43

TBUT: Tear break-up time.

**Table 6 TMH before and 1wk, 1, and 3mo after surgery** mean±SD

Group	<i>n</i>	Before	1wk	1mo	3mo
Contact lenses	20	0.26±0.10	0.36±0.10	0.24±0.08	0.31±0.09
Eye pads	20	0.31±0.13	0.25±0.16	0.17±0.12	0.26±0.08
<i>P</i>		0.06	0.02	0.02	0.01

TMH: Tear meniscus height.

in patients who wore eye pads, which showed a significant difference between the two groups ( $P=0.02$ ). At one month after cataract surgery, TMH in patients who wore eye pads continued to decrease ( $P=0.05$ ), making a statistic difference with patients with bandage contact lenses ( $P<0.001$ ). At three month post-surgery, there was still an obvious distinction in TMH between the two groups ( $P=0.01$ ).

**Corneal Incision Recovery** The corneal thickness of both the central and the incision locations of the two groups increased at 1wk post-surgery ( $P<0.001$ ) then recovered to normal, which did not show any significant difference between each other ( $P>0.05$ ). And the astigmatism showed the same trend as the corneal thickness without evident difference in the two groups ( $P>0.05$ ) at 1wk and 1mo post-surgery.

**DISCUSSION**

In this study, we investigated the safety of the therapeutic bandage contact lens for post-cataract surgery patients by slit-lamp observation of anterior segment inflammation and lens-related complications. In previous studies, there have been reports showing that contact lens wearing might increase the infection risk on cornea<sup>[14]</sup>. Cataract surgery generated two incisions might even worsen the outcome. However, results in this research indicated that therapeutic bandage contact lens combined with antibacterial eye drops did not show much different inflammation or infection compared with the traditional post-operative antibacterial treatments. This may be

accounted by the hyper-oxygen transmissible materials, which ensures safer bandage contact lens wearing without bringing any bacterial adhesion or risk for infectious keratitis<sup>[18-19]</sup>. Besides, bandage contact lenses can be used as transport model to deliver eye drop with higher bioavailability and can control and sustain drug delivery, increasing effectiveness of the antibacterial eye drops<sup>[20-21]</sup>.

We used OSDI questionnaire and slit-lamp microscope examination to evaluate the ocular surface environment and tear-film stability before and after cataract surgery with both subjective and objective index. Patients usually undergo different extents of discomfort after cataract surgery due to corneal incision and post-operative dry eye, such as grittiness and foreign body sensation. The difference of ocular discomfort score in OSDI questionnaire between the two groups in the three-month observation period indicated that therapeutic bandage contact lenses could be used to cover the epithelial nerves to control post-operative pain and effectively reduce the dry eye symptom related discomfort until three month post-surgery<sup>[22]</sup>. Thus, an introduction of the bandage contact lens would be a feasible way to control the operation-related discomfort.

Previous studies have recognized that cataract surgery is closely related to dry eye syndrome<sup>[15]</sup>. There are many factors that might affect the ocular surface environment weakening eye protective function and tear-film stability, such as preservative in post-surgery eye drops, corneal nerve transection, elevation of inflammatory factors, goblet cell loss and meibomian gland dysfunction<sup>[23-25]</sup>. This could explain why both groups in our study have demonstrated a remarkable deterioration on the subjective feeling related to dry-eye at one month after cataract surgery, which was reflected in the OSDI score. Compared with the group with eye pads, both TBUT and TMH greatly improved in patients who wore bandage contact lens at one week, indicating a more stable tear-film function with the help of the hyper-oxygen transmissible lens. Another evidence is that TMH, TBUT, and CFS of the group with eye pads got worse at three month post-surgery than the results before, whereas the group with bandage contact lenses recovered to normal. This can be explained by relevant studies about the relationship between contact lens and tear-film, which proved that silicone hydrogel lenses expand the single spot tear-film laterally across the contact lens, thus stabilizing the tear-film<sup>[10-11,26]</sup>. And a number of laboratory studies have found significantly less protein deposition on silicone hydrogel lenses, a characteristic that may also increase wettability and decrease friction<sup>[27-28]</sup>.

The relationship between corneal incision recovery and therapeutic bandage contact lenses was examined in this study, and using therapeutic bandage contact lens post-operatively would protect the cornea from exposing to irritation caused by

the incision recovery process and external environment<sup>[29-30]</sup>. Because the material of silicone hydrogel contact lens has the property of high-oxygen transmissibility, it would promote the epithelial cell reproduction, which enhances corneal wound recovery<sup>[31]</sup>. AS-OCT was used to measure the thickness of the corneal incision location and incision related astigmatism could be measured by corneal topography<sup>[32]</sup>. However, neither of the groups showed any significant differences, indicating that contact lenses caused neither obvious improvement nor deterioration on corneal excision recovery. It could be that the improvement in the epithelial healing was so trivial that it could not be discovered by the examinations we chose, therefore more specialized examination for corneal recovery could be implemented in future studies, such as corneal confocal microscopy to evaluate the incision-related structural or morphological changes on different cross sections from a micro level<sup>[33]</sup>.

Our study could be further improved from several aspects. It has been reported that bandage contact lenses with high oxygen transmissibility materials can ensure wearing for up to 30d without causing any side effects<sup>[30,34]</sup>. Considering this feature, further studies could focus on extending wearing of the therapeutic bandage contact lenses post-surgery. With drug-delivery system implemented in different manners<sup>[8,21,35]</sup>, post-operative antibiotic eye drops could be delivered into the eyes with certain concentration and frequency. As a result, patients could be saved from using different post-operative eye drops themselves, which is usually a challenging job, especially for the elderly.

In conclusion, wearing therapeutic bandage contact lens reduces post-surgery discomfort and eye-pads related inconveniences, stabilizes the tear-film and ocular surface and exhibits no severe harmful consequences related to post-surgery inflammation, infection or postponement of the incision recovery.

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