Study to the Effect of Involutional Blepharoptosis Surgery Using Objective and Subjective Parameters

Shinichi Asamura, MD, PhD
Yoshitaka Wada, MD, PhD
Saiichi Tanaka, MD, PhD
Shizuya Saika, MD, PhD

1 Department of Plastic and Reconstructive Surgery, Wakayama Medical University, Wakayama City, Wakayama, Japan
2 Department of Ophthalmology, Wakayama Medical University, Wakayama City, Wakayama, Japan

Address for correspondence Shinichi Asamura, MD, PhD, Department of Plastic and Reconstructive Surgery, Wakayama Medical University, 811-1 Kimiidera, Wakayama City 641-0012, Wakayama, Japan (e-mail: asamura@wakayama-med.ac.jp).

Abstract

Background We investigate the effect of involutional blepharoptosis (IB) surgery based on dry eye symptoms by analysis using objective and subjective measures.

Methods We recorded various parameters from patients that underwent levator advancement surgery for IB, totaling 125 eyes (total 65 patients, 5 unilateral, 60 bilateral). Subjective assessment comprised a questionnaire on dry eye-related quality of life score (DEQS), a summary score calculated from DEQS, and six-grade evaluation, the patient’s own measure of eye comfort. Objective assessment comprised marginal-reflex distance-1 (MRD-1), measurement of tear film breakup time, and superficial keratopathy (SPK) existence by slit lamp microscope.

Results Subjective assessments showed that IB patients had improvement of dry eye symptoms and eye comfort when surgery increased MRD-1. On the other hand, objective assessments showed that the presence of SPK is suspected when the postoperative MRD-1 level is 3 mm or higher.

Conclusion IB surgery must not only increase MRD-1 value, but also to perform maintenance of the appropriate ocular surface condition. From our parameters, we suggest postoperative MRD-1 value should be maintained at < 3 mm to safe and effective of IB surgery.

Introduction

Surgery for involutional blepharoptosis (IB) is among the most frequently performed oculoplastic procedures worldwide. Majority of Japanese plastic surgeons that use it tend to be most interested in eyelid fold contour, pretarsal show, and eyebrow height. IB treatment therefore tends to be categorized as "cosmetic" rather than "functional." IB may be associated with an increase in dry eye symptoms, so we suggest that as well as the clinical signs, an IB patient’s reported symptoms should also be considered. There is debate about IB surgery; some surgeons believe it aggravates such dry eye symptoms, others have noted no effect on the ocular surface condition in relation to dry eye symptoms. The effect of IB surgery is unclear because pre- and postoperative evaluation of the ocular surface of the
patients who underwent IB has not been commonly performed.\textsuperscript{11,12}

IB surgery aims not only to improve the marginal-reflex distance-1 (MRD-1) value, but also must care maintenance of the appropriate ocular surface condition. In this study, we investigate the safe and effective IB surgery by a combination of subjective and objective measures.

**Methods**

**Patient Information**

Approval was obtained from our hospital Institutional Review Board prior to initiation of this study (authorization number: 1718, IRB number: 11000505, Registration number: 5NuhaMi2Pm). The research was conducted in accordance with the Declaration of Helsinki, and prior written informed consent was obtained from all patients after receiving a detailed explanation of the study protocols and the possible consequences associated with participation.

Between February 2016 and November 2018, 125 eyes (65 patients, 5 unilateral, 60 bilateral) underwent levator advancement surgery for blepharoptosis at our institution. In total, 17 males and 48 females were recruited to the study, with a mean age of 74 years (range: 56–95). All patients had bilateral blepharoptosis, but five had surgery on just one of their eyes. Surgery for blepharoptosis comprised transcutaneous levator advancement with resection of skin, subcutaneous tissue, and orbicularis oculi muscle.

We excluded patients with eyelid malposition (eyelid retraction, ectropion, entropion) and patients with congenital, myogenic, neurogenic, traumatic, and contact lens-related ptosis, and those who had previously undergone eyelid surgery. Patients using any kind of drops (antiglaucoma drops, antibiotic drops, and topical steroids) and those younger than 55 years were also excluded.

**Subjective Measurements**

The following parameters were recorded before and 6 months after surgery: subjective evaluation comprising a questionnaire by dry eye-related quality of life score (DEQS),\textsuperscript{13} a summary score as calculated from DEQS, and a six-grade evaluation, which is a patient’s own measure of eye comfort.

**DEQS Questionnaire**

All participants completed the DEQS questionnaire, which assesses the frequency and degree of symptoms and disability. DEQS consists of 15 items and 2 subscales: (two-step scales) bothersome ocular symptoms and impact on daily life (\textsuperscript{13,14} Table 1).\textsuperscript{13,14} Bothersome ocular symptoms comprised foreign body sensation, dry sensation in the eyes, painful

| Item                                     | Frequency | Degree |
|------------------------------------------|-----------|--------|
| Bothersome ocular symptoms               |           |        |
| Foreign body sensation                   | 1.0       | 0.9    | 1.2   | 1.0 |
| Dry sensation in eyes                    | 1.0       | 1.1    | 1.1   | 1.1 |
| Painful or sore eyes                     | 0.5       | 0.3    | 0.5   | 0.4 |
| Ocular fatigue                          | 1.8       | 1.1\textsuperscript{a} | 1.8   | 1.0\textsuperscript{a} |
| Heavy sensation in eyelids               | 2.7       | 0.6\textsuperscript{a}    | 2.6   | 0.7\textsuperscript{a} |
| Redness in eyes                          | 0.5       | 0.3    | 0.4   | 0.2 |
| Impact on daily life                     |           |        |
| Difficulty opening eyes                  | 1.4       | 0.4\textsuperscript{a}    | 1.4   | 0.5\textsuperscript{a} |
| Blurred vision when watching something   | 1.6       | 0.8\textsuperscript{a}    | 1.9   | 0.8\textsuperscript{a} |
| Sensitivity to bright light              | 1.9       | 1.0\textsuperscript{b}    | 1.8   | 1.0\textsuperscript{a} |
| Problems with eyes when reading          | 1.5       | 0.9\textsuperscript{b}    | 1.5   | 0.9\textsuperscript{b} |
| Problems with eyes when watching television or looking at a computer or cell phone | 1.3   | 0.7\textsuperscript{a}    | 1.4   | 0.8\textsuperscript{a} |
| Feeling distracted because of eye symptoms | 1.3     | 0.6\textsuperscript{a}    | 1.5   | 0.6\textsuperscript{a} |
| Eye symptoms affect work                 | 1.0       | 0.3\textsuperscript{a}    | 1.1   | 0.3\textsuperscript{a} |
| Not feeling like going out because of eye symptoms | 0.8      | 0.3\textsuperscript{a}    | 0.8   | 0.4\textsuperscript{a} |
| Feeling depressed because of eye symptoms | 1.9      | 0.5\textsuperscript{a}    | 1.9   | 0.6\textsuperscript{a} |

Abbreviations: DEQS, dry eye-related quality of life score; Pre, preoperative; Post, postoperative at 6 months.

Note: Ocular symptoms of “ocular fatigue” and “heavy sensation in eyelids” and all items of impact on daily life were significantly different between the pre- and postoperative periods. There was no significant preoperative increase in superficial keratopathy (SPK).

\textsuperscript{a}p < 0.0001.

\textsuperscript{b}p < 0.005.

\textsuperscript{c}p < 0.05.
or sore eyes, ocular fatigue, heavy sensation in the eyelids, and redness in eyelids. Impact on daily life comprised difficulty opening eyes, blurred vision when watching something, sensitivity to bright light, problems with eyes when reading, problems with eyes when watching television or using a computer or cell phone, feeling distracted because of eye symptoms, eye symptoms that affect work, not feeling like going out because of eye symptoms, and feeling depressed because of eye symptoms.

**Summary Scores and Six-Grade Grade Evaluation**

Frequency of symptoms was scored on a five-point Likert scale ranging from 0 to 4, where “0” indicated that the respondent had no symptoms and “4” indicated the highest frequency. The degree or severity of symptoms was scored on a four-point Likert scale ranging from “1” to “4,” with larger numbers indicating a greater burden. When the score of the frequency scale was “0,” the score of the degree scale was also “0.” We used the degree score because we believe it represents the patient’s burden and evaluates the effect of IB surgery on daily life. The summary score was calculated with the following formula:

\[
\text{Summary score} = \frac{\text{sum of the degree scores for all questions answered} 	imes 25}{\text{total number of questions answered}}
\]

The summary score ranges from 0 to 100, with a higher score representing greater disability. Six-grade evaluation, a patient’s own measure of eye comfort, was documented with the patient using the following six ratings: very good, good, satisfactory, unsatisfactory, bad, and very bad. The six-grade evaluation was scored on a six-point Likert scale ranging from 1 to 6, with a larger score indicating a greater level of eye discomfort.

**Objective Measurements**

Objective evaluation which comprised MRD-1, measurement of tear film breakup time (BUT), and superficial keratopathy (SPK) existence with slit lamp microscope were measured preoperatively and then 6 months postoperatively.

**MRD-1 and BUT Values and SPK Existence**

The upper eyelid height before and after surgery was assessed in primary position using MRD-1 value, defined as the distance from the central pupil reflex to the upper eyelid margin. The presence of any corneal staining was documented as follows: after administrating fluorescein in the inferior fornix using a paper fluorescein strip (FLUORES Ocular Examination Test Paper 0.7 mg; Ayumi Pharmaceutical, Tokyo, Japan), the corneal epithelium and BUT was examined by slit lamp (RO-5000; Rodenstock, Munich, Germany). Subjects were subsequently asked to blink several times. The time in seconds between the last complete blink and the appearance of the first corneal black spot was measured three times, and the mean value was recorded. SPK was documented as either present or absent. There were no cases with eyelid malposition after surgery.

**Statistical Analyses**

All parameters were analyzed by the paired Student’s t-test and by Spearman rank correlation coefficient. A p-value of < 0.05 was considered statistically significant. Statistical analyses were performed using JMP version 11.0 software (SAS Institute Inc., Cary, NC). Receiver operating characteristic (ROC) curve analysis was also performed. The missing data rate for each item was less than 10%.

**Results**

**Descriptive Statistics**

According to DEQS, regarding the frequency of bothersome ocular symptoms, only two items (ocular fatigue and heavy eyelid sensation) had improved at 6 months postoperatively. The frequency of impact on daily life, meanwhile, was significantly improved in all items (Table 1). The preoperative summary score was 37.3 ± 1.9, significantly decreased postoperatively to 19.6 ± 2.1. The preoperative six-grade grade evaluation was 4.5, significantly decreased postoperatively to 3.0 (p < 0.01) (Table 2).

**MRD-1 and BUT Values**

The mean MRD-1 was 0.0 ± 0.1 mm (range: –3 to 2 mm) preoperatively and 2.6 ± 0.1 mm (range: 1 to 5 mm) at 6 months postoperatively. This represented a significant postoperative improvement (p < 0.001, paired t-test). BUT was 3.3 ± 0.2 seconds preoperatively and 3.9 ± 0.2 seconds at six months postoperatively. Normal is 10 seconds or more and abnormal is 5 seconds or less. BUT results increased slightly postoperatively, but the difference was not statistically significant (Table 3).

**Table 2 Summary score and six-grade comfortable score pre-/postoperatively**

| Parameter                  | Group, mean (SD) |
|----------------------------|------------------|
|                            | Pre              | Post             |
| Summary score              | 37.3 ± 1.9       | 19.6 ± 2.1       |
| Six-grade comfortable score| 4.5 ± 0.1        | 3.0 ± 0.1        |

Abbreviations: Pre, preoperative; Post, postoperative at 6 months; SD, standard deviation.

Note: The summary score and the six-point scale showed a significant pre- and postoperative difference. \( p < 0.0001 \).

**Table 3 MRD-1 and BUT values pre- and postoperatively**

| Parameter                | Group, mean (SD) |
|--------------------------|------------------|
|                          | Pre              | Post             |
| MRD-1 (mm)               | 0.0 ± 0.1        | 2.6 ± 0.1        |
| BUT (s)                  | 3.3 ± 0.2        | 3.9 ± 0.2        |

Abbreviations: BUT, breakup time; MRD-1, marginal-reflex distance-1; Pre, preoperative; Post, postoperative at 6 months; SD, standard deviation.

Note: The mean value of MRD-1 was 2.6 mm 6 months postoperatively. There was no significant difference in either BUT before and after surgery. \( p < 0.001 \).
SPK Existence: Change of Postoperative MRD-1 for the Groups with and without Postoperative SPK

All cases were found in the subcorneal area. Preoperatively, SPK was present in 21 of 125 eyes, while it was found in 15 more eyes, 36 eyes in total postoperatively (Fig. 1). SPK and MRD-1 were analyzed for 88 eyes that were followed up to 6 months after surgery, excluding 21 eyes that had SPK before surgery. Pre-/postoperative changes of MRD-1 and SPK existence are shown in Fig. 2A, B. In the patients with SPK, there were significant differences in the increased MRD-1 value. In the ROC curve analysis, area under the curve of MRD-1 was 0.708 (95% confidence interval, 0.5953–0.8206). Accordingly, the presence of SPK is suspected when the postoperative MRD-1 level is 3 mm or higher.

Discussion

Assessment of the effect of IB surgery has been insufficient, and an acceptable surgical outcome for IB has not been defined. There are a small number of objective reports that include measurements such as Schirmer test and BUT, and few subjective reports. Considering the disparity in reported results, we designed a pre- and postoperative evaluation of objective and subjective changes in ocular surface condition.

A validated questionnaire that assesses the effect of IB surgery on impact on daily life and ocular symptoms has been warranted because many Japanese people report dry eye symptoms as they age. As a subjective evaluation, we implemented a DEQS questionnaire that originated in

Fig. 1 All cases with superficial keratopathy (SPK) were found in the subcorneal area. In the photo taken with a slit lamp microscope, the dotted circle indicates SPK. (A) After breakup time (BUT) and (B) before BUT.

Fig. 2 Changes of marginal-reflex distance-1 (MRD-1) and superficial keratopathy (SPK) existence show pre- and postoperatively. (A) Graphs show mean ± standard deviation, p < 0.05. (B) Receiver operating characteristic (ROC) curve for MRD-1 to distinguish without SPK group from with SPK group.
Japan and a six-grade evaluation that measures our own index, that is, eye comfort. DEQS was developed as a dry eye-specific questionnaire to respond to the increasing need for a reliable assessment of the symptoms for diagnosis and the therapeutic effect for dry eye disease in Japan.\(^{13}\) It consists of 15 items and 2 subscales and requires only a few minutes to complete.\(^{14}\) There was noted improvement in bothersome ocular symptoms, ocular fatigue, and heavy sensation in the eyelids, which are typical findings among patients with IB. The frequency of impact on daily life, meanwhile, was significantly improved across all assessment items. IB surgery was found to improve dry eye symptoms. Sakane et al reported that their dry eye disease group had a summary score of approximately 34 points, and the nondry eye disease patient group had a summary score of 6 points.\(^{13}\) Our summary score for IB patients was approximately 37 points, which was significantly reduced to approximately 20 points after surgery. Another subjective measurement, six-grade evaluation, also improved postoperatively (\(\approx\)Table 2). DEQS questionnaire was shown to not only be a useful tool for evaluation of the surgery effects on IB, to some extent it also proved improvement of dry eye symptoms and quality of life after IB surgery.

In accordance with Japanese surgery guidelines, our surgical indications were also MRD-1 \(\leq\) 2 mm. Universal indication of IB surgery based on MRD-1 has not been well determined. Murchison et al reported that the MRD-1 was 2.7 mm in the average 56-year-old Caucasian individual, and ranged from a mean of 3.8 mm in Asians to 5.1 mm in Caucasians.\(^{21}\) MRD-1 depends on age, sex, and race, and tends to show lower values in males and the elderly.\(^{22}\) After our surgery, MRD-1 was significantly increased, the mean value of MRD-1 was 2.6 mm, maintained for at least 6 months. Increased MRD-1 had proved the effect of improving daily life and eye comfort with summary score and six-grade evaluation.

The new definition of dry eye disease in Japan emphasized that a short BUT, an unstable tear film, and the presence of combination of symptoms was sufficient to make a definite diagnosis of dry eye disease.\(^{23}\) We adopted BUT and SPK as objective evaluations in our study. Normal BUT is 10 seconds or more and abnormal is 5 seconds or less, but it is said that most Japanese middle-aged and elderly people take 5 seconds or less. Before and after surgery, mean BUT showed a low value of 3 seconds. Twenty-one patients had SPK before surgery. SPK cases then further increased to 15 cases after surgery, all of which were found in the subcorneal area (\(\approx\)Fig. 2). Causes of SPK include blink abnormalities, conjunctival laxity, conjunctival stones, and eyelash infestation, among others.\(^{24-26}\) Majority of patients in the current study were very elderly, so we speculate that blink abnormalities and conjunctival laxity may have been the main cause of SPK before surgery.\(^{27-29}\)

BUT shortening, and SPK existence, the more likely it is that dry eye symptoms will occur. Over 70% of Japanese people were reported to have dry eye symptoms after age 60.\(^{30}\) Objective parameters revealed that SPK should appear when the postoperative MRD-1 is \(\geq\) 3 mm (\(\approx\)Fig. 1).

Factors that cause SPK require future detailed examination. There are reports that changes in corneal shape and ocular surface can occur due to changes in eyelid pressure and tear volume after IB surgery. Specifically, ocular surface diseases caused by IB surgery include lid wiper epitheliopathy, superior limbic keratoconjunctivitis, filamentoza, and conjunctivochalasis.\(^{3,11,31-33}\)

The ultimate purpose of the IB surgery is to not only improve superior visual fields due to increase in MRD-1 value, but also to allow maintenance of the ocular surface condition.\(^{3,11,12}\) Minimum practice for plastic surgeons should include perioperative observation of the ocular surface with a slit lamp.

Author Contributions
Design and conceptualization of the study: S.A. and S.S.
Study conduct: Y.W. and S.T. Data curation: S.A., Y.W., and S.T. Writing - original draft: S.A. Writing-review & editing: S.A. and S.S. All authors read and approved the final manuscript.

Ethical Approval
Approval was obtained from our hospital Institutional Review Board prior to initiation of this study (authorization number: 1718, IRB number: 11000505, Registration number: 5NuhaMi2Pm).

Patient Consent
The research was conducted in accordance with the Declaration of Helsinki, and prior written informed consent was obtained from all patients after receiving a detailed explanation of the study protocols and the possible consequences associated with participation.

Prior Presentation
This study was presented at the 62nd Annual Meeting of the Japan Society of Plastic and Reconstructive Surgery, May 15–17, 2019.

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Conflict of Interest
None declared.

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Involutional Blepharoptosis Surgery

Asamura et al.

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