BLEPHAROSCOPE™*: A NEW HANDHELD INSTRUMENT FOR USE BY THE NON-OPHTHALMOLOGIST IN SCREENING BLEPHAROPLASTY CANDIDATES

DEPARTMENTS OF OTOLARYNGOLOGY, HEAD AND NECK SURGERY,
FACIAL PLASTIC AND OCCULOPLASTIC SURGERY
MANHATTAN EYE, EAR AND THROAT HOSPITAL AND LENOX HILL HOSPITAL

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MICHELLE R. YAGODA, M.D
THOMAS ROMO, III, M.D.
ARTHUR MILLMAN, M.D.

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ABSTRACT

Blepharoplasty can be performed by ophthalmologists, otolaryngologists, and plastic surgeons alike. Yet, pre- and post-operative evaluation of candidates often require the aid of an ophthalmologist for slit-lamp examination of the cornea. A new handheld instrument, the **Blepharoscope™** has been developed in order to provide the non-ophthalmologist with the ability to perform screening evaluation of the cornea. In this portion of the study, results on initial **Blepharoscope™** examination are compared with secondary "gold-standard" slit-lamp evaluation in order to determine clinical usefulness, accuracy and reliability. Patients undergoing blepharoplasty surgery are evaluated at three time intervals: 1) pre-operatively; 2) one week post-operatively; and, 3) one month post-operatively. Results demonstrate the **Blepharoscope™** to be a clinically useful, accurate and reliable new tool.

Introduction

"He speaketh not, and yet there lies a converstion in his eyes."
Henry Wadsworth Longfellow
The Hanging of the Crane, III

Eyes are probably the most expressive feature of the human face. For this reason, errors in the technique of eyelid surgery are immediately manifest. Fortunately, serious complications of blepharoplasty are uncommon. Yet, the bothersome dry-eye syndrome is the most common functional problem following blepharoplasty.[1] [2] Avoidance of eyelid surgery in those patients with decreased lacrimal function is extremely important since the most minimal interference with lid closure can produce any degree of symptoms associated with keratoconjunctivitis sicca. Understanding the anatomy and physiology of the eyelids is important. This knowledge combined with a thorough history and physical examination may aid the surgeon in reducing the incidence of post-operative complications.

Background

Anatomically, the eyelids are composed of two lamella. The outer is comprised of skin and orbicularis muscle and the inner includes the tarsus and conjunctiva. Physiologically, as the orbicularis oculi muscle contracts with each blink, the lacrimal pump mechanism begins. During the contractile portion of the blink, the canaliculi shorten. As the blink is released, the canaliculi return to their original length and create a siphoning effect whereby tears are drawn in to the lacrimal sac. Additional muscular attachments in the medial canthal region contract and compress the lacrimal sac forcing the tears down the nasolacrimal duct into the nose. The eyelids must be closely apposed to the globe to allow the tear film to be applied to the cornea with each blink and to prevent pooling of tears in the inferior cul-de-sac. [3],[4]

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[1] Mc Carthy, J. Plastic Surgery,1990, Philadelphia, W.B.Saunders - Harcourt, Brace and Jovanovich, Inc.; ch. 34 and 43, pp. 1671-1684 and 2320-2363.
[2] Wolfley, D.E.; "Blepharoplasty: The Ophthalmologist's View" *Symposium on the Aging Face*,Otolaryngology Clinics of North America,Vol.13, No.2, May 1980, pp237-263.
[3] Holt, J.E. and Holt, G.R.;Blepharoplasty: Indications and Preoperative Assessment, *Arch Otol*; June 1985; III:394-397.
[4] Hugo,N.E. and Stone,E.; Anatomy for a Blepharoplasty; *Plastic and Reconstructive Surgery*,1974, 53:381.

A history of high myopia, systemic illness, previous eyelid surgery, foreign body sensation, burning or mucoid secretion should alert the surgeon to a potential problem.[5,6] The lacrimal system should be evaluated by Schirmer's I test or the basic tear secretion test. Several additional tests have been recommended for inclusion in the pre-operative screening of candidates seeking blepharoplasty surgery in attempt to prevent such post-operative complications as dry eye, foreign body sensation, and corneal abrasion. Preoperative evaluation of each patient should include documentation of visual acuity, pupillary function, intraoccular pressure, and extraoccular muscle balance. Lid and punctum position should be noted. Observation for lagophthalmos and Bell's phenomenon should occur. Ophthalmoscopic examinaton should enable quantification of tear lake in the inferior cul-de-sac and determination of the overall health of the corneal epithelium, stroma and endothelium.[7] Finally, photodocumentation should be obtained.

A comprehensive preoperative exam of the cornea requires the ophthalmologist's use of a slit-lamp. Yet some basic screening may be able to be performed by the non-ophthalmologist blepharoplasty surgeon. Undoubtedly, unfortunate patients who develop post-operative complaints of dry eye, tearing, and foreign body sensation will likely be referred back to the ophthalmologist for slit lamp examination and treatment. However, a preliminary diagnosis made on screening examination by the non-ophthalmologist blepharoplasty surgeon can put the minds of both the patient and surgeon at ease. Additionally, it might eliminate potentially embarassing questions posed by the patient such as "Since you performed my eye surgery why can't *you* evaluate my eye?" or perhaps unasked questions such as "Shouldn't I have gone to the Ophthalmologist for this surgery in the first place?" This scenario may be more easily understandable if translated into that of the general surgeon whose patient after thyroidectomy complains of breathy voice and inability to drink liquids without coughing. Since the general surgeon is unable to examine the vocal cords, this patient must be referred to an Otolaryngologist. Examples such as these

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[5] Beekhuis, G.J., "Blepharoplasty" *Symposium on the Aging Face*, Otolaryngology Clinics of North America, Vol. 13, No. 2, May 1980, pp 225-235.

[6] Wolfley, D.E.; "Blepharoplasty: The Ophthalmologist's View" *Symposium on the Aging Face*, Otolaryngology Clinics of North America, Vol.13, No.2, May 1980, pp237-263.

[7] Wolfley, D.E.; "Blepharoplasty: The Ophthalmologist's View" *Symposium on the Aging Face*, Otolaryngology Clinics of North America, Vol.13, No.2, May 1980, pp237-263.

underline the need for surgeons to have the ability to adequately screen the sites upon which they operate in order to facilitate a cost-effective multidisciplinary team approach to patient care. Based on this concept and the recognition that there was a need for the development of a handheld instrument to be used for screening examination of the cornea, the **Blepharoscope™** was developed.

Development of Instrument

Once the idea was conceived, the next goal became to create a working model device. A hand-held lighted magnifier with the capacity for a cobalt blue filter was conceptualized. A modification of a promotional gift came to mind as a prototype. Once localized, the instrument underwent modification. It was a hand-held instrument which was operated by two triple A batteries. It had a 2X magnifying surface which was nine square centimeters with an inset circle of 0.5 centimeter radius which provided 3X magnification. There was a 0.5 watt/2.2 volt/0.25 amp bulb which allowed illuminated magnification.

Initially, in the first model, a filter of cobalt blue plastic was applied to the surface of the magnifing lens closest to the light source. It soon became apparent that fashioning the filter in such a manner would only filter the reflected light which was inadequate. Thus, the filter required repositioning with placement between the light source and the subject. This allowed filtration of the emitted light.

In the second model, cobalt blue stained glass paint was applied to the bulb. This did not provide durability as the heat of the light bulb caused the paint to crack and peel. In the third prototype, permanent cobalt blue ink was applied to the bulb. This provided appropriate filtration, ample intensity and durability; howerver, it was soon obvious that the magnification was too low to appreciate ophthalmic pathology other than gross corneal abrasions. At this point, a search was made for a new, higher powered lighted magnifier. One was found with more intense magnification, superior illumination and larger surface area. This hand-held, battery-operated unit was powered by two double A batteries. It contained a circular surface area of approximately twenty square centimeters with a 2.25 centimeter radius. It had 6X magnification with a 0.75 watt/2.5 volt/0.3 amp bulb. This prototype was completed and therefore its use in the initial study commenced.

Trademark and Patent Information

Once the prototype instrument was in its working form, the name **Blepharoscope™** was conceptualized and a logo was created. "A trademark is either a word, phrase, symbol or design or combination of words, phrases, symbols or designs, which identifies and distinguishes the source of the goods or services of one party from those of others."[8] The next undertaking was that of a trademark search in a Patent and Trademark Depository LIbrary and the filing of papers and drawings with the Patent and Trademark Office for state and federally registered rights to use the mark in commerce regulated by the United States Congress. Unlike trademarks which last indefinately and can be renewed every ten years, patents are limited to seventeen years. "A patent is a grant of a property right by the Government to the inventor 'to exclude others from making, using or selling the invention'."[9] Finally, a patent search was initiated and papers and drawings were filed to obtain patent pending status.[10]

Study Design

The aim of the initial study was to prove that the **Blepharoscope™** is a clinically useful, accurate and reliable new instrument for corneal screening. The first ten patients requesting blepharoplasty from the senior author were selected in succession. There were six females and four males. Ages ranged from 39 to 67 years old with a mean age of 59. One patient had Sjogren's syndrome; one had facial paralysis. No other predisposing medical conditions were detected. All ten were deemed acceptable candidates for surgery and therefore none were excluded. One patient underwent bilateral punctal plugging and two patients each underwent unilateral punctal obliteration prior to blepharoplasty in order to increase the tear lake in the inferior cul-de-sac in attempt to prevent the progression of corneal exposure post-operatively. Twenty eyes were examined by each method at three distinct time intervals: 1) pre-operatively, 2) one week post-operatively; and, 3) one month post-operatively. A

[8] "Basic Facts about Registering a Trademark," US Department of Commerce - Patent and Trademark Office; Washington, D.C. Government Printing Office, October 1994.
[9] "Basic Facts about Patents," US Department of Commerce - Patent and Trademark Office; Washington, D.C. Government Printing Office, October 1994.
[10] "A Guide to Filing a Patent Application" US Department of Commerce - Patent and Trademark Office, Washington, D.C.,May 1993.

total of sixty comparative exams were performed and hence sixty data points were obtained.

Methods

All patients were examined by the senior author to prevent interobserver variability. All **Blepharoscope™** examinations were performed prior to the "gold-standard" slit-lamp examination in order to eliminate the possibility of slit-lamp examination findings biasing the findings on **Blepharoscope™** evaluation. Interval examinations were performed blinded to the previous findings. All data was complied onto the data entry forms from the charts at the completion of the study. Prior to examination of the cornea, one drop of 2% fluorescein sodium ophthalmic solution (Johnson & Johnson; Claremont California) was instilled into each eye.

Corneal surface epithelium was evaluated and classified as normal or abnormal. Normal corneas were graded as "0". Trace corneal abnormalities were labelled as "+". More extensive abnormal keratopathy was further graded on a scale from 1-4+. Corneal abrasion was noted as "CA" and mid-corneal band was noted as "CB".

Data

As the "gold-standard" examination, the findings on slit-lamp evaluation are considered as true positive findings. Table I summarizes the actual data obtained in evaluation of corneal epithelium by **Blepharoscope™** as compared to slit-lamp in the preoperative period.

Table I

Patient #	Pre-Op OD Slit lamp	Pre-Op OD **Blepharoscope™**	Pre-Op OS Slit Lamp	Pre-Op **Blepharoscope™**
1	+	0	+	0
2	0	0	0	0
3	1+	+	0	0
4	0	0	0	0
5	CB	CB	0	0
6	4+	4+	4+	4+
7	2+	1+	0	0
8	1+	+	0	0
9	0	0	0	0
10	1+	+	3+	2+

Table II summarizes the actual data obtained in evaluation of corneal epithelium by **Blepharoscope™** as compared to slit-lamp in the one week post-op period.

Table II

Patient #	1 Week Post-Op OD Slit lamp	1 Week Post-Op OD **Blepharoscope™**	1 Week Post-Op OS Slit Lamp	1 Week Post-Op OS **Blepharoscope™**
1	1+	+	1+	+
2	0	0	0	0
3	1+	+	0	0
4	0	0	0	0
5	CB	CB	0	0
6	4+	4+	4+	4+
7	2+	1+	0	0
8	0	0	0	0
9	CA	CA	0	0
10	1+	+	3+	2+

Table III summarizes the actual data obtained in evaluation of corneal epithelium by **Blepharoscope™** as compared to slit-lamp in the one month post-op period.

Table III

Patient #	1 Month Post-Op OD Slit lamp	1 Month Post-Op OD **Blepharoscope™**	1 Month Post-Op OS Slit Lamp	1 Month Post-Op OS **Blepharoscope™**
1	+	0	+	0
2	0	0	0	0
3	1+	+	0	0
4	0	0	0	0
5	CB	CB	0	0
6	4+	4+	4+	4+
7	2+	1+	0	0
8	0	0	0	0
9	0	0	0	0
10	1+	+	3+	2+

Therefore, findings on **Blepharoscope™** examination are summarized in Table IV below.

Table IV

True+ (Abnormal)	True+ (Biased*)	True- (Normal)	False+	False-
10	15	31	0	4

* detection of abnormal cornea by **Blepharoscope™** occured but to a degree that was uniformly down-graded on the scale in comparison to slit-lamp exam

Sensitivity = [True Positives]/[True Positives + False Negatives] = [25]/[25+4] = [25]/[29] = **86%**
Specificity = [True Negatives]/[True Negatives + False Positives] = [31]/31+0] = [31]/[31] = **100%**
Reliability = [True Positives + True Negatives]/[Total Trials} = [56]/[60] = **93%**
Accuracy = [True Positives (unbiased only) + True Negatives]/[Total Trials] = [10 + 31]/[60] = [41]/[60] = **68%**

Interpretation of Results

The data obtained demonstrate that the **Blepharoscope™** detects the same findings as those on "slit-lamp" examination in 93% of cases. In four examinations, abnormal corneas were not detected with the **Blepharoscope™.** Clinically, this bears little significance since only trace keratopathy was missed and this is often a variation of "normal" in older patients and does not contribute signifcantly to post-operative complications of dry-eye and foreign body sensation. One-hundred percent of normal corneas are detected as such; while, eighty-six percent of abnormal corneas are detected with the **Blepharoscope™.** Of the abnormal corneas detected, there is a bias in that 32% are likely to be underevaluated by a unit of one on the detection scale. This is believed to be due to the limitation of magnification of the instrument. Again, the clinical significance of this is questionable since screening for abnormalities is the goal and this is 93% reliable.

Finally, of note, there was no worsening of keratopathy after blepharoplasty with the exception of one patient who had a corneal abrasion. This resolved with conservative treatment. None of the patients with preoperative corneal epithelial abnormalities had progression of their symptoms or findings after blepharoplasty. This may demonstrate the benefits of preoperative punctal obliteration for preservation of corneal lubrication.

Conclusion and Future Directions

The **Blepharoscope™** is a clinically useful, accurate, reliable, sensitive and specific new handheld instrument for screening evaluation of the cornea. The newest generation prototype (currently being developed) will have a 10X magnifying lens in attempt to reduce the bias seen in quantifying fine keratopathy. Once completed, the initial study will be repeated to determine improved accuracy and sensitivity. Then the next stage of the study will begin.

In this part, the non-ophthalmologist will evaluate ten patients by **Blepharoscope™** examination and compare these results to those found by the ophthalmologist. Finally, the license to produce the instrument for distribution will be made available in order to begin production and distribution of the device.

References

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