Risk factors for loss of epithelial flap integrity in laser-assisted subepithelial keratectomy surgery

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PURPOSE: To evaluate risk factors leading to loss of epithelial flap integrity in laser-assisted subepithelial keratectomy (LASEK).

SETTING: Boston Eye Group, Brookline, Massachusetts, USA.

DESIGN: Retrospective case study.

METHODS: This retrospective chart review was performed for LASEK surgeries that occurred between January 2009 and October 2013. Logistic regression was performed to determine whether epithelium preservation was correlated with age, sex, sphere, cylinder, spherical equivalent (SE), keratometry, and central corneal thickness (CCT).

RESULTS: The study reviewed 1009 eyes of 509 patients with a mean age of 29.1 years ± 12.2 (SD). The mean preoperative spherical refraction was −4.7 ± 2.5 diopters (D), and the mean preoperative cylinder was −1.1 ± 0.8 D. The mean preoperative decimal corrected distance visual acuity was 1.01 ± 0.07. Single-sheet mobilization of the loosened epithelium flap was found in 72.3% of cases. Fragmented preservation events occurred in 17.6% of cases; the flap was discarded in 10.0% of cases. Epithelium preservation was significantly correlated with age ($P = .048$) but not with other parameters ($P > .05$ for sex, sphere, cylinder, SE, keratometry, CCT, and surgeon experience). Epithelial flap dissection was less likely to lead to a single epithelial sheet in patients older than 50 years than in younger patients (56.3% versus 74.9%). The mean postoperative decimal uncorrected distance visual acuity (UDVA) at 3 months was 0.98 ± 0.08. There was no statistical difference in postoperative UDVA between the undiscarded flap group and discarded flap group ($P = .128$).

CONCLUSION: Successful dissection of single-sheet epithelial flap diminished with age.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2016; 42:591–595 © 2016 ASCRS and ESCRS

Laser-assisted subepithelial keratectomy (LASEK) was first conceptualized by Azar et al.[1] in 1996 (reported in 2001) and later popularized by Camellin in 1998[2] and 2000.[A] This technique was developed to improve corneal healing and consequently accelerate visual recovery time while reducing postoperative discomfort and haze formation associated with photorefractive keratectomy (PRK).[2,A] Although some studies have not shown the expected benefits of LASEK over PRK,[3–5] a metaanalysis comparing LASEK and PRK reported that a major advantage of LASEK is less corneal haze 1 month and 3 months after surgery.[6]

Preserving epithelium integrity is key to a successful a LASEK procedure.[6,7] Several techniques have been proposed to attain this. The classic Azar et al.[1] and Camellin[2,A] techniques as well as the Vinciguerra et al.[8] butterfly approach all have similar reported success rates in their ability to preserve epithelial flap integrity, with no significant differences in visual outcomes.

Despite several studies describing LASEK techniques and their effectiveness, none has comprehensively evaluated the possible risk factors in flap preservation. In the present report, we analyzed

whether factors such as age, sex, sphere, cylinder, spherical equivalent (SE) refraction, keratometry, and central corneal thickness (CCT) correlate with successful epithelial flap creation.

PATIENTS AND METHODS

A retrospective chart review was performed for LASEK surgeries that occurred between January 2009 and October 2013. All the surgeries procedures included in this study were performed at the Boston Eye Group, Brookline, Massachusetts, USA. Images and patient data were recorded by the investigators in such a manner that patients could not be identified directly or through identifiers linked to the patients. The study was hence exempt from human subject regulations and did not require review by an institutional review board as per Guidance 45 CFR 46.101(b) (5) from the U.S. Office for Human Research Protections.

Exclusion from Study

No enhancements (second treatments) were considered. Any patient who did not have a failure (partial or complete flap removal) or success (complete flap preservation) event recorded on the intraoperative page in his or her electronic chart was also excluded from this study.

Preoperative Evaluation

The preoperative examinations included a full eye examination with decimal uncorrected (UDVA) and corrected (CDVA) distance visual acuities, manifest and cycloplegic refractions, slitlamp evaluation, pachymetry, applanation tonometry, Scheimpflug analysis videokeratometry readings (Galilei, Ziemer Ophthalmic Systems AG), and a fundus evaluation.

Surgical Technique

Figure 1 shows a breakdown of the LASEK technique. Epithelial sheets were created using a 9.0 mm LASEK barrel well (model OK 048, Titan Surgical) filled with 20% alcohol dispensed from a 33 mm cannula (Titan Surgical) for 40 seconds. A dry cellulose sponge was used to remove the alcohol. This area was subsequently rinsed with a balanced salt solution before the well was lifted off the cornea. A 120 mm round spatula with a 30-degree angle (model OT 001, Titan Surgical) was used to mobilize the loosened epithelial sheet to expose the stromal bed, leaving an intact hinge at the 6 o'clock position. If the epithelial sheet was successfully mobilized and repositioned after laser ablation (flap = 360 degrees), the intraoperative event was noted as "single sheet." If the flap was split in 2 portions (flap = 180 degrees), it was designated as "2 sheets." If the flap was split in more than 2 portions (flap <180 degrees), it was designated as "more than 2 sheets." A flap was discarded if the epithelial removal resulted in significant disruption of the epithelium, loss of more than 30% of the flap, or more and this was designated as "flap removed."

Statistical Analysis

The consultation parameters and intraoperative notes were obtained through generated reports using the practice's Nextgen electronic record registrar (Nextgen Healthcare Information Systems, LLC). Statistics were calculated using SPSS software (version 13.0, SPSS, Inc.). Significance was determined if the P values were less than $\alpha = 0.05$.

RESULTS

The study evaluated 1009 eyes (508 right eyes, 501 left eyes) of 509 patients (278 men, 231 women). The mean age was 29.1 years ± 12.2 (SD) (range 20 to 89 years). The mean preoperative spherical refraction was −4.7 ± 2.5 diopters (D) (range −11.50 to +3.00 D), and the mean preoperative cylinder was 1.1 ± 0.8 D (range −0.25 to −5.75 D). The mean preoperative CDVA was 1.01 ± 0.07 (range 0.25 to 1.33).

Surgical Outcomes and Risk Factors

Single-sheet mobilization of the loosened epithelium flap was found in 907 (89.9%) of the LASEK cases performed in the 3.5-year study period. Fragmented preservation events combined (2 sheets and >2 sheets) occurred in 178 cases (17.6%); the flap was discarded in 101 cases (10.0%).

Table 1 shows the correlation between epithelial removal success and the clinical parameters. Epithelium preservation was significantly correlated with age ($P = .048$) but not with the other parameters. Surgeon experience was not shown to be associated with surgery outcomes. Patient age was comparable between patients operated on by a senior surgeon and those operated on by a junior surgeon (29.2 ± 10.1 years versus 27.8 ± 9.8 years old) ($P = .217$).

Age-Group Comparison

Table 2 shows the outcomes within each category organized by age group Figure 2 shows the frequency of epithelial flap preservation by percentage according to age. Flap preservation for patients 50 years and older was statistically different from their younger

Submitted: June 9, 2015.
Final revision submitted: January 5, 2016.
Accepted: January 8, 2016.

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