



Duration of the Operation Has No Effect on Early Visual Acuity After Small Incision Lenticule Extraction Surgery

Alper Ağca, Yusuf Yildirim, Burcin Kepez Yildiz, Onur Olcucu, Dilek Yasa, Ali Demircan, Ahmet Demirok

Beyoglu Eye Training and Research Hospital, Istanbul, Turkey

Abstract

Objectives: The effect of the duration of small incision lenticule extraction (SMILE) operation on early postoperative visual acuity (VA) was evaluated.

Methods: Medical records of refractive lenticule extraction patients were retrospectively reviewed. Data on 38 eyes of 20 consecutive patients operated on by the same surgeon were included in the study. Primary outcome measures were corrected distance VA at postoperative first day and first week. Duration of the surgery was determined from video recordings of the operations.

Results: Mean patient age was 27.8 ± 4.8 years (range: 21–40 years). Mean preoperative spherical equivalent was -4.38 ± 1.4 . Postoperative distance corrected visual acuity was 0.7 ± 0.1 and 0.8 ± 0.2 at day 1 and week 1 visits, respectively. Mean duration of operation was 229.5 ± 106 seconds (range: 95–525 seconds). No perioperative complications were seen. There was no statistically significant relationship between surgery time and postoperative VA at day 1 and week 1 visits.

Conclusion: Total time of operation does not have a statistically significant effect on early VA in SMILE patients.

Keywords: Femtosecond laser, small incision lenticule extraction, SMILE, visual acuity, visual rehabilitation.

Introduction

Refractive lenticule extraction (ReLEx) is a relatively new surgical procedure for correction of myopia and myopic astigmatism (1). It can be performed only with the VisuMax (Carl Zeiss Meditec AG, Jena, Germany) femtosecond laser platform. This platform provides ability to perform 2 types of ReLEx surgeries: femtosecond lenticule extraction (FLEx) and small incision lenticule extraction (SMILE). In SMILE procedure, an intrastromal lenticule is created with the femtosecond laser. Spatula inserted through side incision approximately 3 mm in length sweeps lamellar planes to dissect the tissue bridges connecting the lenticule to remaining stroma. The lenticule is then extracted from the side cut.

Results of SMILE are similar to FemtoLasik in terms of effectiveness and safety, and the concept behind both surger-

ies is also quite similar (2). Intrastromal refractive lenticule is removed from the same depth of cornea in both. Visual recovery after SMILE is delayed, however, when compared with FemtoLasik (3–5). The reason for the delay is not well understood. The dissection of the lenticule is the most difficult and time-consuming part of the surgery. It could be argued that fewer surgical maneuvers, less trauma, or ease of removing the lenticule could create some difference in postoperative VA among SMILE patients. It can also be assumed that duration of the surgery is an indicator of the difficulty of lenticule dissection and thus, surgical trauma.

This study is an investigation of relationship between the duration of surgery performed by the same surgeon using the same dissection spatula (Chansue SMILE spatula G-33950, Geuder AG, Heidelberg, Germany) and early postoperative VA.

Address for correspondence: Alper Ağca, MD. Beyoglu Eye Training and Research Hospital, Bereketzade Cami Sok., 34421 Beyoglu, Istanbul, Turkey

Phone: +90 212 251 59 00, **E-mail:** agcaalper@yahoo.com

Submitted Date: October 19, 2016 **Accepted Date:** November 06, 2016 **Available Online Date:** November 15, 2016

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Methods

Medical records of refractive lenticule extraction patients were retrospectively reviewed. Data regarding 38 eyes of 20 patients were included in the study. All patients were over 18 years of age with myopia or myopic astigmatism with spherical equivalent (SE) <10 D, mesopic (4 lux) pupil size ≤ 6.5 mm and calculated residual stromal bed thickness >300 μm , normal topographic pattern, regular retinoscopic reflex, corneal pachymetry >500 μm at the thinnest point, and stable refraction for at least 2 years.

Only patients who were operated on by the same surgeon (AD), had a complete video record of the surgery, and complete 1 day and 1 week visit data including measurements of distance corrected visual acuity (DCVA) were included. Patients who had a pre-existing eye disease or preoperative DCVA of less than 20/20, and patients who had an intraoperative or postoperative complication were excluded from the present research. In addition, if surgical spatula other than Chansue SMILE spatula G-33950 (Geuder AG, Heidelberg, Germany) was used, patient data was excluded.

Surgical videos of every eye operation included in the study were reviewed by the same author. Duration of the surgery was recorded and its correlation with postoperative VA was calculated using Pearson correlation analysis.

Results

Of the total, 9 participants were male and 11 were female. Preoperative patient characteristics are provided in Table 1. Mean preoperative SE was -4.38 ± 1.4 and mean postoperative SE was -0.25 ± 0.43 (paired samples t-test; $p < 0.05$). The same optical zone and energy parameters were used for all eyes (Table 2). Postoperative DCVA was 0.7 ± 0.1 and 0.8 ± 0.2 at day 1 and week 1 visits, respectively (paired samples t-test; $p < 0.05$). Mean duration of operation was 229.5 ± 106 seconds (range: 95–525 seconds). There was no statistically significant relationship between length of the operation and postoperative VA at day 1 and week 1 visits (Table 2; Pearson's correlation analysis; $p > 0.05$).

Discussion

SMILE is a relatively new alternative to LASIK for the correction of myopia. The concept behind SMILE surgery is very similar to femtosecond laser-assisted LASIK because intrastromal lenticule is removed from the eye in both procedures. However, VA is delayed in SMILE patients compared to those who undergo LASIK procedure (3–5). In addition, some patients have an unpredictable loss of more than 2 DCVA lines in the first few weeks after SMILE. Shah et al. (6) reported that only 58% of patients had 1-week postoperative uncorrected distance visual acuity (UDVA) better than

Table 1. Preoperative characteristics

| | Mean \pm SD |
|------------------|-----------------|
| Age (years) | 27.8 \pm 4.8 |
| Keratometry | 44.7 \pm 2.4 |
| Pachymetry | 532 \pm 29 |
| Refractive error | -4.38 \pm 1.4 |

SD: Standard deviation.

Table 2. SMILE parameters

| | |
|------------------------------|----------|
| Optical zone (mm) | 6.5 |
| Side cut (mm) | 3 |
| Side cut location (quadrant) | Superior |
| Spot energy (nJ) | 140 |
| Spot separation (μ) | 3.5 |

SMILE: small incision lenticule extraction.

Table 3. Correlation between duration of the surgery and visual acuity

| | CDVA (Day 1) | CDVA (Week 1) |
|----------|-----------------------|----------------------|
| Duration | $r=0.34$ ($p>0.05$) | $r=0.2$ ($p>0.05$) |

CDVA: corrected distance visual acuity; r: Pearson's correlation coefficient.

or equal to preoperative CDVA, though this figure improved to 86% at 6 months. They concluded that visual recovery is delayed in lenticule extraction when compared with best results of modern refractive surgery. In the present study, mean postoperative CDVA was better at first week compared to day 1 ($p > 0.05$). However, CDVA was only 0.8 ± 0.2 at week 1 though all patients had CDVA of at least 1.0 preoperatively. Our results are consistent with other studies in the literature in finding that early VA was not as good in SMILE patients when compared to LASIK patients.

While some patients do not experience a loss of CDVA after undergoing SMILE, some patients lose more than 2 or 3 lines of VA. This phenomenon is more pronounced in the earliest days and vision gradually recovers in a few weeks or months. However, it is not possible to predict which eyes will have better early postoperative VA. It could be argued that although the lenticule extraction is the same, fewer surgical maneuvers, less traumatic surgery, or ease of removing the lenticule could create some difference in postoperative VA among SMILE patients. To test this hypothesis, it was assumed that the difficulty the surgeon encounters and an increase in the number of surgical maneuvers would have an effect on the duration of the surgeries performed by that single surgeon if all remaining parameters such as the surgical instrument used remained the same. Thus, we evaluated the

surgeries of only 1 experienced surgeon and recorded the exact duration of the procedures based on video records. After watching the videos, we believe that it is not wrong to assume that the duration of surgery reflects the number of surgical manipulations and the ease of dissection (for that single surgeon) in this patient group. However, although the duration of the surgeries (range: 95–525 seconds) and postoperative VA were distributed in a wide range, there was no statistically significant correlation between operation time and early VA at day 1 or week 1.

Although the same lamellar cuts are performed with the same femtosecond laser platform and similar lenticule is removed in both SMILE and FLEEx surgery, the FLEEx procedure requires fewer surgical maneuvers and therefore creates less trauma to the underlying stroma. Thus, comparing VA of SMILE and FLEEx patients is another way of evaluating the effects of surgical maneuvers or surgery time on VA. Agca et al. previously compared SMILE and FLEEx surgeries in a small but matched group of eyes (7). Their results indicated that FLEEx surgery does not offer better VA compared to SMILE, and this supports the findings of the present study.

This study has important limitations. One limitation is that there were too few patients to make strong assumptions. In addition, duration of the surgery may not reflect the number of surgical manipulations or stromal trauma that occurs during surgery. Thus, stromal trauma during dissection may be a factor in loss of CDVA in early postoperative period and this study may have lacked sufficient power or the correct design to reveal such a relationship. However, after observing that some fellow eyes with similar preoperative characteristics, similar surgical maneuvers performed by the same surgeon, similar duration of surgery, and no intraoperative complications had very different surgical outcomes in the early postoperative period (1 eye may lose 2–3 lines while fellow eye does not lose any lines), we believe that there are other factors leading to loss of CDVA in the early postoperative period. It can be argued that 1 such factor may be related to the quality and regularity of femtosecond laser cuts on anterior or posterior surfaces of the lenticule.

In conclusion, we did not find a significant correlation between duration of the surgery and VA achieved in the early

postoperative period. The results of this study indicate that surgery time is not a major risk factor for loss of CDVA in uncomplicated SMILE surgery.

Disclosures

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned. These data have not been previously published.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

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