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Comparison of visual acuity and higher-order aberrations after femtosecond lenticule extraction and small-incision lenticule extraction

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ABSTRACT

Purpose: To compare postoperative visual acuity and higher-order aberrations (HOAs) after femtosecond lenticule extraction (FLEX) and after small-incision lenticule extraction (SMILE).
Methods: Medical records of refractive lenticule extraction patients were retrospectively reviewed. Twenty patients were treated with FLEX. A comparable group of 20 SMILE patients were retrospectively identified. Only one eye of each patient was randomly chosen for the study. Visual acuity, subjective manifest refraction and corneal topography before and 6 months after the surgery were analyzed for both groups. Total HOAs, spherical aberrations, coma and trefoil were calculated from topography data over the 4- and 6-mm-diameter central corneal zone.
Results: The mean preoperative SE was -4.03 ± 1.61 in the SMILE group and -4.46 ± 1.61 in the FLEX group. One year after surgery, the mean SE was -0.33 ± 0.25 in the SMILE group and -0.31 ± 0.41 in the FLEX group ($p = 0.86$). In the SMILE group a greater number of eyes were within ± 0.50 D of the target refraction (95% versus 75%); however, the difference was not statistically significant ($p = 0.18$). Furthermore, 80% of FLEX eyes and 95% of SMILE eyes had an uncorrected distance visual acuity of 20/25 or better ($p = 0.34$). Total HOAs, spherical aberration, coma and trefoil increased postoperatively in both groups. However, there was no statistically significant difference between the groups preoperatively and postoperatively.
Conclusion: FLEX and SMILE result in comparable refractive results. In addition, corneal aberrations induced by different techniques of lenticule extraction seemed similar to each other.

1. Introduction

Refractive lenticule extraction is a relatively new method for the correction of myopia and myopic astigmatism [1–7]. VisuMax femtosecond laser platform (Carl Zeiss Meditec AG, Jena, Germany) is the only commercially available femtosecond laser platform enabling refractive lenticule extraction (RELEX). RELEX can be performed in two ways: (1) femtosecond lenticule extraction (FLEX), which involves creating and lifting a hinged femtosecond flap above the lenticule, and (2) small-incision lenticule extraction (SMILE), whereby no flap is created and the lenticule is extracted from a 3 to 4 mm side cut [1–7]. There are a limited number of studies comparing the efficacy, safety and corneal higher-order aberrations after RELEX with femtosecond laser-assisted in situ keratomileusis (FS-LASIK), and in all these studies both types of RELEX surgery (FLEX and SMILE) seem to be comparable to FS-LASIK, although visual recovery is relatively slower [8–10]. However there have been no studies comparing FLEX with SMILE.

The purpose of this article is to compare the efficacy and safety of the FLEX procedure with SMILE.

2. Patients and methods

This retrospective study was approved by the ethics committee of the Beyoglu Training and Research Hospital. The medical records

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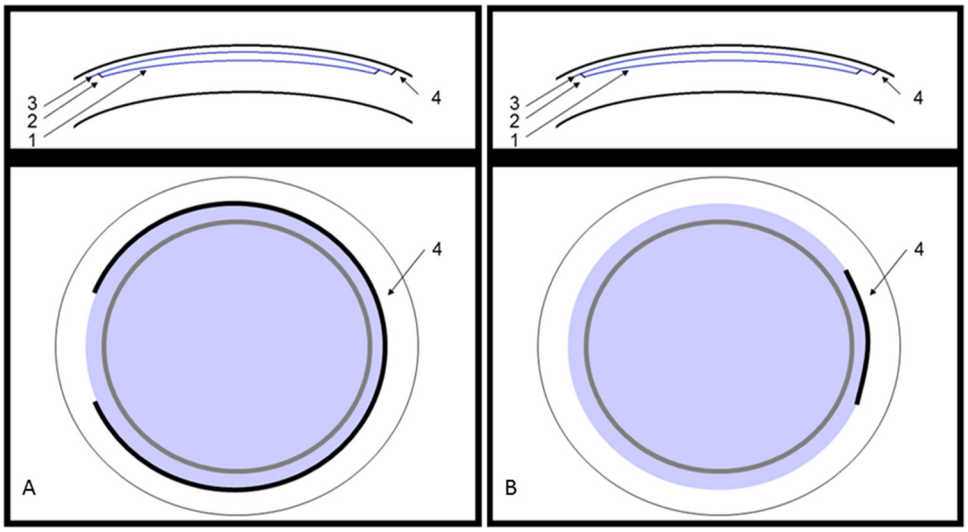

Fig. 1. The four photodisruption planes in FLEX (A) and SMILE (B). Only the last step is different in SMILE (number 4 in the diagram).

of all the RELEX procedures performed in our hospital were retrospectively reviewed. Twenty patients were treated with FLEX. A comparable group of 20 SMILE patients were retrospectively identified. All patients were older than 18 years old with myopia or myopic astigmatism with spherical equivalent (SE) <10 D, mesopic (4 lx) 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. None of the patients had ocular disease other than the refractive error. Only those patients with a distance-corrected visual acuity of at least 20/25 in both eyes and a 1-year follow up were included in the study.

2.1. Preoperative and postoperative examinations

All patients received the standard preoperative refractive surgical procedure of the clinic. All visual acuity measurements were completed using an illuminated ETDRS chart (Optec 3500 Vision Tester, Stereo Optical Co., Chicago, IL). Corneal topography, dynamic infrared pupillography, ocular wavefront analysis and corneal wavefront analysis were performed using a Sirius corneal topography and abberometry system (Costruzione Strumenti Oftalmici, Firenze, Italy). All patients had a detailed anterior and posterior segment examination via a slit lamp.

Preoperative and postoperative complications, subjective manifest refraction (MR), uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) and Sirius corneal topography data were recorded at the preoperative and 1-year visit for statistical analysis. Total higher-order abberations (HOAs), spherical aberration, coma and trefoil were calculated from topography data over a 4- and 6-mm-diameter central corneal zone. Visual acuities were converted to LogMAR prior to statistical analysis.

2.2. Surgical technique

The same surgeons (A.D. and O.F.Y.) performed all surgeries in the study. After topical anesthesia and sterile draping of the eye, a speculum was inserted. The patient was asked to look at the internal fixation light and the surgeon adjusted the position of the eye in relation to the patient interface. Once the patient interface was centered on the pupil and a sufficient amount of contact was achieved, the surgeon activated the suction mechanism incorporated in the patient interface. If the pupil was appropriately centered and the suction was sufficient, the surgeon activated the laser by pressing the foot pedal. The femtosecond dissection planes were created for either FLEX or SMILE as described in detail in the literature. Fig. 1 shows photodisruption planes in SMILE and FLEX. The spot energy was set to 140 nJ and the optical zone was set to 6.5 mm in both surgeries. The flap thickness for FLEX and cap thickness for SMILE were set to 120 μm for all the eyes. The patient bed was then repositioned under the operating microscope of the Visumax platform for the remainder of the surgery. For FLEX surgery, a blunt spatula (Katena, Denville, NJ) was used to separate the anterior surface of the lenticule from the overlying stroma and to lift the flap. The lenticule was separated from the underlying stroma with the same spatula and it was removed manually with flap forceps. The stromal bed was washed with a balanced salt solution and the flap was repositioned. For SMILE surgery a blunt spatula was used to separate the lenticule from the overlying and underlying stroma, as described previously. The lenticule was then removed from the side cut and positioned at 90° using flap forceps. After the surgery, patients received a topical antibiotic for 5 days and a topical steroid for 2 weeks. Artificial tears were prescribed for at least 1 month.

2.3. Statistical analysis

Main outcome measurements were: visual acuity at 1 year, total HOAs, coma, spherical aberration and trefoil at 4- and 6-mm pupil sizes. All visual acuities were recorded as the total number of identified letters and the corresponding Snellen acuities. Mean visual acuities were determined by calculating the geometric mean with the standard deviation stated in logMAR format, as defined by Holladay and Prager [11]. The Kolmogorov–Smirnov test and SigmaPlot software (Systat, Chicago, IL) was used to test for normality. The Mann–Whitney (Wilcoxon) rank sum test was used to compare the mean outcomes for non-normally distributed data. If data were normally distributed, a two-tailed Student's t-test was used. As the two eyes of any one subject are not independent, only one eye of each subject was chosen for analysis. Eyes were randomly chosen using a random number generator in Excel 2007 (Microsoft, Redmond, WA). All analyses were completed using PASW statistics 18 (SPSS Inc., Chicago, IL) and the graphics were reconstructed with Excel 2007. Results were considered statistically significant at $p < 0.05$.

3. Results

Optical zone was 6.5 mm in both groups. Cap thickness was 120 μm in all SMILE patients, while flap thickness was 120 μm