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Comparison of corneal hysteresis and corneal resistance factor after small incision lenticule extraction and femtosecond laser-assisted LASIK: A prospective fellow eye study

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ABSTRACT

Purpose: To compare corneal hysteresis (CH) and corneal resistance factor (CRF) between eyes treated with small incision lenticule extraction (SMILE) and femtosecond laser-assisted laser in situ keratomileusis (femto-LASIK).
Setting: Beyoğlu Eye Training and Research Hospital.
Design: Prospective comparative case series.
Methods: Sixty eyes from 30 patients with bilateral myopia or myopic astigmatism were studied. Inclusion criteria were spherical equivalent of subjective manifest refraction (SE) <10 diopters (D) and a difference ≤0.50 D between the SEs of both eyes. One eye of each patient was treated with SMILE, and the fellow eye underwent femto-LASIK. Randomization was performed using a sealed envelope system. The main outcome measures were CH and CRF measured preoperatively and postoperatively (1 and 6 months).
Results: Preoperative SE was similar in both groups ($p = 0.852$). CH and CRF values were reduced postoperatively in both groups compared to their corresponding preoperative values ($p < 0.001$). At the 6-month follow-up visit, the mean CH values in the SMILE and femto-LASIK groups were 8.95 ± 1.47 and 9.02 ± 1.27, respectively ($p = 0.852$), and the mean CRF values were 7.77 ± 1.37 and 8.07 ± 1.26, respectively ($p = 0.380$).
Conclusion: CH and CRF decreased after SMILE. There were no differences between SMILE and femto-LASIK treatments in postoperative CH or CRF values.

1. Introduction

Femtosecond lenticule extraction is a new method for refractive correction of myopia and myopic astigmatism. The procedure involves the creation of an intrastromal lenticule between two photodisruption planes that is mechanically removed for refractive correction. If the procedure involves creating and lifting a hinged flap above the lenticule, it is called femtosecond lenticule extraction (FLEX) [1]. If a flap is not created, and the lenticule is extracted from a 3- to 4-mm arcuate side cut close to the edge of the lenticule, the procedure is referred to as small incision lenticule extraction (SMILE) [2]. These procedures can only be carried out with the Visumax femtosecond laser platform (Carl Zeiss Meditec AG, Jena, Germany). Lenticule extraction is an efficient and safe surgical procedure with refractive results comparable to those achieved with laser-assisted in situ keratomileusis (LASIK) [3].

LASIK alters corneal biomechanical properties that are thought to play an important role in the development of post-LASIK ectasia [4]. SMILE may have biomechanical benefits over LASIK because it does not involve the creation of a flap and leaves the stroma over the lenticule untouched. However, there are no published studies regarding the biomechanical effects of SMILE.

The ocular response analyzer (ORA; Reichert Inc., Buffalo, NY, USA) is designed to obtain in vivo measurements of corneal biomechanical properties [5]. Corneal hysteresis (CH) and corneal resistance factor (CRF) are two metrics used in this device to describe the biomechanical properties of the cornea. Previous studies reported that CH and CRF significantly decrease after LASIK surgery [6–8,5]. Here, we performed the first analysis of CH and CRF values after SMILE and compared them with the results of femtosecond LASIK (femto-LASIK) in fellow eyes.

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2. Patients and methods

This prospective pilot study was approved by the ethics committee of Beyoğlu Training and Research Hospital. All patients provided informed consent, and the study complied with the Declaration of Helsinki.

Patients with bilateral myopia or myopic astigmatism were included in the study if the spherical equivalent of subjective manifest refraction (SE) was <10 diopters (D) and if the difference in SEs between both eyes was ≤0.50 D. Other inclusion criteria were mesopic (4 lux) pupil size ≤6.5 mm and a calculated residual stromal bed thickness >300 μm. Patients who had an accompanying ocular disease, prior history of ocular surgery, or any contraindication to LASIK surgery were not included.

One eye of each patient was assigned to the SMILE group and the fellow eye was assigned to the femto-LASIK group using a random number table. The random numbers were placed in sealed envelopes to ensure allocation concealment. The envelopes were shuffled and sequentially numbered. The surgeon opened the next available envelope before the surgery. If the random number in the envelope was odd, then the right eye was allocated to the SMILE group, and if the number was even, the left eye was allocated to the SMILE group.

2.1. Sample size calculation

A sample estimate of the correlation between the two eyes of a person in the population was calculated to be $r = 0.75$ for CH and $r = 0.77$ for CRF based on a pilot study in our clinic (unpublished information). Because this was a pilot study, it was designed to reveal a medium-sized effect that was set at Cohen's $d = 0.5$ (representing half the standard deviation of the variable to be tested). Under these circumstances and with the two-sided alpha set at 0.05, a sample size of 30 subjects per group was calculated to yield statistical powers of 96% and 97% to detect differences in CH and CRF, respectively, between the groups. Power analysis was performed using G Power 2 version 3.1.5 (available at http://www.psycho.uni-duesseldorf.de/aap/projects/gpower/), and the study was designed to include 60 eyes from 30 patients.

2.2. Pre- and postoperative examinations

All patients underwent the clinic's standard detailed preoperative examination procedure to plan the surgical procedures. Uncorrected distance visual acuity (UDVA) and best-corrected visual acuity (CDVA) measurements were performed with an illuminated ETDRS chart (Ophtec 3500, Stereo Optical Co, Chicago, IL, USA). Corneal topography, dynamic infrared pupillography, and ocular and corneal wavefront analyses were performed with the Sirius corneal topography and aberrometry system (Costruzioni Strumenti, Oftalmici, Italy). Horizontal corneal diameter was measured with the IOL master (Carl Zeiss Meditec). Schirmer's test with topical anesthesia and intraocular pressure measurements (Goldmann applanation tonometer) were performed. Detailed anterior and posterior segment examinations were performed using a slit lamp. CH and CRF were preoperatively measured in all eyes using the ORA.

Preoperative SE, maximum calculated ablation depths, mean preoperative central corneal thickness (CCT), and mean simulated keratometry (simK) were determined. CH and CRF measurements performed 1 and 6 months after the procedure were compared between the groups. CH and CRF were also compared to their corresponding preoperative values in both the SMILE and femto-LASIK groups.

2.3. Statistical analysis

The average CH and CRF values calculated from four ORA measurements were used in the statistical analysis. Mean, standard deviation, frequency, and percentage were used for descriptive statistics. Variable distributions were checked with the Kolmogorov–Smirnov test. Student's *t*-tests were used to compare quantitative data. Repeated measures analysis of variance (rANOVA) and paired sample *t*-tests with Bonferroni corrections were used for the repeated measurement analysis. Chi-squared tests were used to compare qualitative data. SPSS 20.0 (IBM Corp, Armonk, NY, USA) was used for all statistical analyses.

2.4. Surgical technique

The same surgeons (A.D. and O.F.Y.) performed all surgeries in the study. The eyes in the SMILE and femto-LASIK groups were treated with SMILE and femto-LASIK, respectively. Both eyes underwent surgery on the same day and by the same surgeon. After adding one drop of topical anesthetic to both eyes and application of sterile draping, an eyelid speculum was inserted. The eye in the SMILE group was treated first. The flap of the other eye was created before transporting the patient to an excimer laser. An antibiotic drop was added at the end of the operation.

2.5. SMILE

Visumax (Carl Zeiss Meditec) femtosecond laser platform was used for the surgeries. The surgeries were performed as described by Shah and Shah [3]. The same parameters were used in all cases. The spot distance was 3 μm for lamellar cuts and 2 μm for side cuts. The spot energy was set to 140 nJ. The minimum lenticule side cut thickness was set to 15 μm. The lenticule side cut angle was 120°, and the optical zone was 6.5 mm. The optical zone diameter was equal to the lenticule diameter in patients with purely spherical refractive error. However, if the patient had astigmatism, the software added a transition zone to convert the oval lenticule into a circle. As a result, the lenticule diameter was 6.5–6.6 mm, depending on the presence or absence of astigmatism. The cap diameter was 7.5 mm with a 50° superior side cut and a side cut angle of 90°. A small-sized (Size S) patient interface was used in all patients.

2.6. Femto-LASIK

Flaps were created using the Visumax femtosecond laser platform (Carl Zeiss Meditec). The spot energy was set to 140 nJ. The spot distance was 3 μm for the lamellar flap cut and 2 μm for the flap side cut, which was 90°, and the flap diameter was set at 8.5 mm in all patients. A medium-sized (Size M) patient interface was used in all patients. After the flap was created, the patient was transported to the Schwind Amaris 750S (Schwind eye-tech-solutions, Kleinostheim, Germany) excimer laser platform. The flap was lifted with a blunt spatula (Katena Products, Inc., Denville, NJ, USA), and excimer laser photoablation was performed. The residual stromal bed was washed with a balanced salt solution, and the flap was repositioned.

3. Results

Preoperative patient characteristics are shown in Table 1. Preoperative SE of manifest refraction and maximum thickness of the removed tissue were not statistically different between the SMILE and LASIK groups ($p > 0.05$).

There were no statistically significant differences in CH and CRF values between the SMILE and LASIK groups in any pre- or postoperative measurements (Tables 2 and 3).