Small incision lenticule extraction (SMILE) procedure for the correction of myopia and myopic astigmatism

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PURPOSE: This retrospective study evaluated the feasibility of performing femtosecond lenticule extraction (FLEx) for the correction of myopia using the small incision lenticule extraction (SMILE) technique.

SETTING: Instituto de Microcirugia Ocular (IMO), Barcelona, Spain.

METHODS: Retrospective case series. A refractive lenticule of intrastromal corneal tissue was cut using the VisuMax® femtosecond laser system (Carl Zeiss Meditec AG). A small ‘pocket’ incision measuring 4 mm in arc length was immediately created by the laser system. Then, the lenticule was manually dissected using a spatula and removed through the incision using modified McPherson forceps. Main outcome measures; Uncorrected visual acuity (UCVA) and best spectacle corrected visual acuity (BSCVA) after a mean follow-up period of 3 months, objective and manifest refraction, optical quality analysis system (OQAS) as well as slit-lamp examination and side effects.

RESULTS: This study included 19 patients (38 eyes) affected by myopia with and without astigmatism, who completed the final mean 3 month follow-up period. Mean subject age was 32.78 years. The preoperative mean spherical equivalent (SE) was −4.97 D. Postoperatively, the mean logMAR UCVA was 0.06. The mean postoperative SPH was −0.09, mean postoperative CYL was −0.29 with a mean axis at 120.67° and the mean Objective Scatter Index (OSI) with OQAS was 1.4 in the right eyes and 2.03 in the left eyes at the end of the follow-up.

CONCLUSION: SMILE is a promising, minimally invasive, effective, predictable and safe new flapless refractive procedure for the correction of myopia and astigmatism.

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In the original keratomileusis procedure for myopia, an approximately 300 mm thick disc was dissected from the anterior cornea in a freehand fashion and reshaped using a cryolathe. In the late 1980s Ruiz developed an automated microkeratome that controlled speed as it passed across the cornea, leading to more consistent results. This procedure has become known as automated lamellar keratoplasty (ALK). In the 1990s the combination of a microkeratome and an excimer laser (for the refractive cut) was developed by Pallikaris, Burato and others, further improving the predictability of the refractive procedure. This procedure, known as laser assisted in situ keratomileusis (LASIK) has gained wide acceptance worldwide1. The limitations of this procedure have been already proven in long term 6 and 10 year follow-up studies related to the induction of aberrations and regression2,3. Recently, femtosecond
Lasers have become available for the cutting of the intrastromal lenticule and subsequent lenticule extraction. In the femtosecond-only technique for correction of refractive errors (femtosecond lenticule extraction), the intrastromal lenticule is removed using flap-like access. In small-incision lenticule extraction (SMILE), the incision is minimized and the procedure does not use a flap. Both types of procedures seem safe and promising for corneal refractive correction of myopia, although small-incision lenticule extraction is not yet widely performed.

**Patients and Methods**

**Subjects**

This retrospective, non-randomized, non-comparative, case series study included the very first 38 eyes of 19 patients who consecutively underwent the SMILE technique in our Institution to correct their refractive defects. All patients were fully informed of the details and possible risks of the procedure. Written informed consent to perform the surgical procedure was obtained from all patients before surgery in accordance with the Declaration of Helsinki, and the study was approved by the ethics committee of our institution, the Instituto de Microcirugía Ocular, and the Universitat Autònoma de Barcelona. All the surgical procedures were performed by two surgeons (JLG and DE).

**Preoperative Examination and Follow-up**

All the patients underwent a complete preoperative ophthalmologic examination, including refraction, LogMAR uncorrected visual acuity (UCVA) and best-spectacle corrected visual acuity (BSCVA), slit-lamp examination, Goldmann applanation tonometry, Orbscan (Orbtek Inc.) corneal topography, Optical Quality Analysis System (OQAS) evolution and a fundus examination.

Inclusion criteria were: myopia < 8 diopters (D), astigmatism < 2 D and < 20/30 BSCVA with glasses or contact lenses; contact lens intolerance; regular cornea without ectasia as assessed by Orbscan corneal topography, IOP within normal limits (with or without hypotensive drops); absence of retinal disease; and a minimum follow-up period of three months.

Exclusion criteria were: corneal ectasia or keratoconus suspect, central corneal thickness < 500 µm, history of recurrent uveitis, pigmentary glaucoma, cataract, proliferative diabetic retinopathy, and macular pathology.

Postoperative follow-up visits were held 24 hours after surgery, then at 4 weeks, 3 months, 6 months, and thereafter at yearly intervals. At each follow-up visit, UCVA, BSCVA, sphere (SPH), cylinder (CYL), slit-lamp examination and applanation tonometry were performed. The corneal topography and Optical Quality Analysis System (OQAS) measurements were performed 3 months after the surgery and then at yearly intervals together with a fundus examination.

**Surgical Procedure**

Patients were administered a mild oral anxiolytic and sedative (diazepam, Valium® 5 mg; Roche Farma S.A. Barcelona, Spain) 30 minutes before surgery. Topical anaesthesia was given (oxibuprocaine hydrochloride 0.4%, Prescain®; Laboratorios Llorens S.A., Barcelona, Spain) and after a povidone–iodine (Betadine®) scrub of the skin and eyelids, the patients were draped with a sterile head towel, their eyelashes were taped with sterile tape and they were positioned on the ergonomic pivoting patient table of the laser unit.

The SMILE femtosecond procedure was initiated with the application of an eyelid speculum to keep the eye open; the patient’s eye was positioned under a curved contact glass interface. A completely clean and diffusely wet cornea was ensured using a wet microspore. This contact glass is similar to a gonioscopic lens in that it possesses a curved surface designed to couple with the cornea with only minimal application force. Before coupling, the VisuMax® femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) calibrates the contact glass. The eye’s keratometry data is entered into the VisuMax® to account for the difference between the relaxed cornea and the contact glass curvature.

The first femtosecond laser used was version 2.7.3 with maximum spot spacing of 3.0 µm.

A fully device-integrated suction system ensures that low suction is only applied to the cornea during the actual laser treatment. Centration is assisted using several features including an internal fixation target for the patient which is designed to attract their attention, self-adjustment of the eye during docking to the contact glass, an easy to find line of sight for treatment positioning, and automated adaptation to patient eye refraction. Flap parameters that can be adjusted include flap thickness, flap diameter, hinge width, side-cut angle and hinge location.

Using this procedure, once contact is made between cornea and the contact glass, the patient is able to see the flashing fixation target in clear focus. The patient’s cooperation is fundamental for properly aligned treatment. When full contact glass application is achieved, suction is applied, the eye immobilized, and the laser activated by the surgeon by pressing on a foot pedal. A very accurately focused laser beam is guided through to the cornea, whereby the laser beam moves across and
through the cornea in a spiral manner, creating a layer of very tiny bubbles under its path. These bubbles quickly disappear, and the tissue above the bubbles becomes a corneal lenticule that can be easily lifted by the surgeon.

In the SMILE procedure, instead of making a complete flap side cut, only a small incision is created, and the flap is never lifted. Instead, the lenticule is extracted from within the cornea through a small incision.

In these cases, the duration of the entire procedure was relatively consistent, from 50 to 55 seconds, regardless of the refractive error to be corrected. This is an advantage in terms of postoperative assessment of results among different correction groups. The shape of the lenticule generated was designed to correct for refractive errors. In all cases in this particular preliminary study group, the anterior surface of the lenticule was 100 µm deep and the maximum diameter of the first cleavage plane, 6.0 mm. For technical reasons, astigmatism corrections result in an oval posterior surface of the lenticule.

For all myopic corrections, the optical zone size was 6.0 mm. The spot-and-track spacing for the cleavage plane, which defines the posterior surface of the lenticule, was slightly higher than the spot-and-track spacing for the cleavage plane, which defines the anterior surface of the lenticule (i.e. the cap). The posterior part of the lenticule was created by laser scanning in spirals from the centre of the pupil to the periphery of the optical zone. The anterior part of the lenticule was created by laser scanning in spirals from the periphery to the centre of the pupil. All passes and spot-and-track distance changes were automatically performed by the laser software and hardware with no user intervention (Figure 1).

Our standard postoperative treatment consisted of antibiotic and steroid drops (Tobradex®; Alcon Cusi, El Masnou, Spain) twice a day during one week which was then slowly tapered over a four week period, with preservative-free artificial tears five times a day for almost a month.

Statistical analysis

Microsoft Excel (Microsoft; Redmond, Washington, USA) was used for data collection and for performing descriptive statistics. Continuous variables were described with mean and standard deviation (SD).

The results were analyzed using SPSS software version 17.0 (SPSS Inc., Chicago, Illinois, USA). Comparison between preoperative and postoperative data were performed using Wilcoxon-Signed-Rank tests for non-parametric data (UCVA, BSCVA, CYL, SPH). The tests were performed before surgery, at 4 weeks and 3 months after the surgery. A p-value lower than 0.05 was considered to be statistically significant. The mean of eyes with UCVA and BSCVA > 20/20 and > 20/40, and the mean of eyes within ±1 D and ±0.5 D of emmetropia at each milestone of follow-up were also recorded.

RESULTS

Baseline characteristics and follow-up

Thirty-eight myopic eyes of 19 patients were treated. Mean age was 32.78 years (range 22 to 46 years); 17 were male and 21 female. Minimum follow-up time was 3 months. No history of previous ophthalmic surgical history was reported.

The mean K1 with Orbscan corneal topography was 42.56 (SD 1.28), the mean K2 was 43.52 (SD 1.29). The mean preoperative pachymetry was 575.84 µm (SD 36.07, range 503-655).

Visual acuity

Mean preoperative logMAR UCVA was < 1.30. Mean postoperative logMAR UCVA was: 0.17 (SD 0.23) at 24 hours, 0.09 (SD 0.28) at 1 month and 0.06 (SD 0.22) at 3 months. Mean logMAR UCVA improved progressively in a statistically significant manner throughout the follow-up period (p < 0.05; Figure 2).

Figure 1. Steps of the SMILE procedure.

Figure 2. Evolution of pre and post SMILE UCVA (Snellen).
Mean preoperative logMAR BSCVA was 0.01 (SD 0.04). Mean postoperative logMAR BSCVA was: 0.06 (SD 0.47) at 1 month and 0.025 (SD 0.31) at 3 months.Mean logMAR BSCVA improved significantly after surgery and remained stable throughout the follow-up period (p < 0.05).

Preoperatively, 38 eyes (100%) presented with BSCVA ≥ 20/40, 34 eyes (91.89%) with BSCVA ≥20/20 and none of the eyes presented with UCVA ≥ 20/40. Three months postoperatively, 38 eyes (100%) presented with BSCVA ≥ 20/40, 38 eyes (100%) presented with UCVA ≥ 20/40 and 33 eyes (86.84%) with UCVA ≥ 20/20.

Refractive Outcome

Mean preoperative sphere (SPH) was: −4.97D (SD 1.45). Mean postoperative SPH was −0.13 (SD 0.48) at 1 month and −0.09 (SD 0.46) at 3 months (Figure 3). Mean preoperative cylinder (CYL) was −0.70 (SD 0.59) and the mean axis was 88.89° (SD 21.21). Mean postoperative CYL was −0.39 (SD 0.47) at 1 month with a mean axis 94.38° (SD 63.27) and −0.29 (SD 0.36) with a mean axis at 120.67° (SD 64.77) at 3 months (Figure 4).

The refractive defects (SPH and CYL) significantly and progressively decreased after the surgery and remained stable throughout the follow-up period (p < 0.05).

Figure 3. Evolution of pre and post SMILE sphere.

Three months postoperatively, 37 eyes (97.36%) were within ±0.5 D of emmetropia. The mean OSI with QOAS preoperatively was 1.2 in the right eye and 1.75 in the left eye group. Postoperatively, this was 1.4 in the right eye and 2.03 in the left eye group, 3 months after the surgery (Figure 5). We did not observe differences in the results in relation to the age of patients.

Complications

No complications were observed during the surgery and the immediate postoperative period. In all cases the intraocular pressure was within normal limits without drops after the surgery.

DISCUSSION

During the past 20 years, studies have documented that the efficiency of excimer laser ablation is affected by several factors such as the ablation parallax whereby effective treatment depends on the curvature of the cornea and corneal hydration. Nomogram adjustments based on empirical data analysis are often implemented and additional adjustments based on wavefront refractions have also been shown to be useful.

SMILE is a fairly new procedure of corneal refractive surgery. Recent publications, including up to 150 patients, suggest that this femtosecond laser flap-free refractive procedure demonstrates predictability, safety, and efficacy similar to that of femtosecond laser–assisted LASIK. Another study involved treatment of moderate and high myopia in 670 eyes confirmed that SMILE is predictable, effective, and safe.

SMILE provides good outcomes in terms of refraction as well as additional benefits, such as a reduction in scatter that leads to better vision quality.

Despite the proven efficacy of LASIK, it still requires the use of two machines: one for the flap creation and another for Excimer ablation. This increases costs as well as the surgical time for the procedure. SMILE uses only one laser machine, thus potentially reducing surgical time and cost. Moreover, SMILE does not involve any flap creation, which potentially reduces risk of side effects such as dry eyes and other flap related complications (Figure 6).

In our study, the mean postoperative SPH was −0.09 and mean postoperative CYL was −0.29 with a mean axis at 120.67 at the end of the follow up period. Refractive errors significantly and progressively decreased after the surgery and remained stable throughout the follow-up period.

In a recent study, there was a high correlation between attempted and achieved correction, and the error in spherical equivalent correction did not depend on the degree of myopic correction nor the presence of
simultaneous astigmatic correction. The mean difference between achieved and attempted spherical equivalent correction was 0.25 D (undercorrection). Patient age and corneal curvature significantly influenced the error in spherical equivalent correction. The effect of patient age amounted to approximately 0.10 D of undercorrection per decade of increasing age, which contrasts with excimer laser-based procedures where overcorrection may be seen with increasing age\textsuperscript{10}.

We did not observe such a difference in our study group although the number of cases may be insufficient.

SMILE is a new form of refractive surgery, which may potentially supersede LASIK and change clinical practice. This procedure may have a positive impact on healthcare as surgical time and costs could be reduced with this new, “all-in-one” laser procedure. SMILE procedures eliminates flap displacement, and there is no risk of the flap dislocating with trauma to the eye at a later point. Additional benefits may include postoperative reduction or elimination of dry eye problems and improvements in corneal biomechanical stability.

In the near future, we foresee that SMILE may develop into a reversible surgical procedure. Unlike LASIK which uses an excimer laser to ablate corneal tissue, SMILE cuts and removes a piece of corneal...

**Figure 5.** Orbscan (Orbtek Inc.) corneal topography and OQAS pre and post SMILE.

**Figure 6.** Post SMILE anterior segment photo and OCT.
lenticule, which may be stored and replaced into the cornea later on. This is important as we can potentially reverse the refractive procedure many years later when the patient’s myopia decreases. The ability to re-implant the cornea lenticule allows for treatment of corneal ectasia, reversal or monovision, or even the possibility of use as a presbyopic implant.

REFERENCES