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EDITOR'S CHOICE

Predictability of SMILE over four years in high myopes

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SMILE;
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Predictability

Summary
Objective. — To determine whether the visual outcomes of the refractive surgery technique small incision lenticule extraction (SMILE), are stable, effective, and predictable for high myopia over a four-year period.
Research design. — This is a retrospective study. The data were collected between March 2012 and July 2016.
Participants. — Two hundred and forty-eight patients participated in the study; that is, 496 eyes: 140 eyes of 70 patients (52 women/18 men) were classified into the highly myopic group (refraction measured in spherical equivalent (RMSE) > —6 D), and 356 eyes of 178 patients (98 women/80 men) into the control group (RMSE < —6 D). Follow-up tests were conducted immediately following the procedure (D + 1), after three months, after one year, and after four years. Refraction, uncorrected visual acuity (UCVA), and best visual corrected acuity (BCVA) were measured. The highly myopic group (HMG) contained more women, and astigmatism was higher for this group than for the control group (CG).
Primary and secondary study criteria. — These were BCVA, refractive stability, the index of safety (SI: BCVA preoperatively D + 1/BCVA postoperatively), and predictability (the percentage of eyes within ± 0.5 D of the target).
Results. — In both groups, UCVA was better after the fourth year than it was immediately after the procedure (HMG: $P = 0.001$; CG: $P = 0.001$). Although it differed at one year ($P = 0.01$), the groups' refractive stability tended to converge over four years ($P = 0.138$). The groups' SI was found to be identical in the four follow-up tests ($P = 0.734$ at D + 1; $P = 0.07$ at M + 1; $P = 0.160$ at M3 and Y1; and $P = 0.274$ at Y4). For the HMG, SI stability was attained after three months

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(1.00 ± 0.1); whereas it was attained after one month (0.91 ± 0.11) for the CG. Four years after the surgery, we observed that 87% of the operated-upon eyes in the HMG were within 0.5 D of the target.

Conclusion. — SMILE is a good refractive surgery technique for treating high myopia. It yields stable, safe, effective, and predictable results over four years.

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Introduction

The refractive surgery technique SMILE (SMall Incision Lenticule Extraction), for the correction of myopia and astigmatism, is a recent technique [1—3], performed with a single laser: the Visumax© femtosecond laser (Carl Zeiss Meditec, Jena, Germany). Short-term studies in moderate and high myopes have confirmed the safety of refractive surgery using SMILE [4—8]. The long-term results of the procedure appear equally encouraging [9—11]. To find out whether this procedure is a long-lasting solution, as well as to respond to the growing demands of patients, is a significant objective in the management of high myopia.

The goal of this study is thus to determine, as with similar studies performed to date, if the visual outcomes over four years of the refractive surgery technique SMILE are stable, safe, effective, and predictable in a group of high myopes as compared to a group of low and moderate myopes.

Materials and methods

Patient population

This was a retrospective study of a cohort of patients who underwent refractive surgery at the Saint-Martin Clinic in Caen between March 2012 and July 2016. The inclusion criteria were absence of contraindications to refractive surgery or the SMILE procedure, based on the Randelman criteria [12], i.e. signs of forme fruste keratoconus on topography; a residual bed less than 250 microns in thickness; age less than 20 years; corneal thickness less than 500 microns; as well as severe dry eye syndrome, atopy, and best corrected visual acuity less than 8/10. The patient was seen for postoperative follow-up the first day, at one month, at three months, at one year, and at four years. At these visits, refraction, uncorrected visual acuity (UCVA), and best corrected visual acuity (BCVA) were measured.

The study included 496 eyes of 248 myopic and astigmatic patients separated into two groups (Table 1) depending on their preoperative spherical equivalent refraction (MRSE): 70 patients or 140 eyes were classified into the high myope group (MRSE > −6 D); and 356 eyes of 178 patients into the control group (MRSE < −6 D).

The control group (CG) consisted of 55% women and 45% men, with a mean age of 29 years (± 5.17); the youngest patient was 20 years and the oldest 55 years. The mean MRSE was −3.77 ± 1.15 D, the mean sphere was −3.52 ± 1.13 D, and the mean cylinder was −0.51 ± 0.41 D.

The high myope group (HMG) consisted of 74% women and 26% men, with a mean age of 30 years (± 5.95); the youngest patient was 20 years, and the oldest 49 years. The mean MRSE was −7.59 ± 1.12 D, the mean sphere was −7.23 ± 1.14 D, and the mean cylinder was −0.71 ± 0.57 D.

The two groups thus presented differences preoperatively in terms of MRSE ($P < 0.001$), sphere ($P < 0.01$), gender distribution ($P < 0.053$; more women in the HMG), and cylinder ($P = 0.001$; higher astigmatism in the HMG). However, there was no notable difference in mean age.

Surgical technique

An experienced surgeon (DN) performed all the SMILE procedures. The Visumax© (Carl Zeiss Meditec, Jena, Germany) 500 kHz femtosecond laser was used for this procedure. The energy delivered per spot was 140 nJ, and the spacing between spots was 4 to 4.5 microns. The cap thickness was 130 microns, and the optical zone diameter was 6.5 mm for all patients. The side cuts were at a 90° angle. The chosen target refraction was emmetropia for patients up to 35 years; and a monovision strategy for those over 35 years with an amplitude of 1 dioptre maximum as a function of the initial refraction. A correction factor of the order of 8% was programmed for high ametropia to prevent an under-correction of the myopia. The surgical procedure was performed under topical anaesthesia only, with 1% tetracaine drops (Laboratoire Théa) — 2 to 3 drops per eye — prior to the procedure, and was supplemented by a 10 mg tablet of Vératran (Laboratoire Amdipharm Limited) taken one hour beforehand.

A standard lid speculum was used to keep the eyes open. The suction ring kept the pupil centered. To start, the posterior lenticule cut was performed in a centripetal direction, and the anterior cap cut in a centrifugal direction. Then, the 2.2 mm primary incision was placed at 12:00 in all patients.

After the laser treatment, the Reinstein manipulator (Malosa Laboratory, Yorkshire, England) was used to detach stromal adhesions, and the lenticule extracted mechanically through the primary incision. No secondary incision was necessary. Medications at the conclusion of the procedure were systematically alike for all patients: Tobradex four times per day (Alcon Laboratory) for one week, and Vismed four times per day (HORUS pharma laboratory) for one month.

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