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Reports

Topography-Guided LASIK versus Small Incision Lenticule Extraction: Long-term Refractive and Quality of Vision Outcomes

LASIK and femtosecond laser-assisted LASIK have been the standard of care for myopic laser vision correction for the last 2 decades, as evidenced by a multitude of reports and some of ours in regard to safety and efficacy.[1] Small incision lenticule extraction (SMILE) is a relatively new method of intrastromal keratomileusis without the use of an excimer laser and was clinically introduced in 2006.[2] Several previous reports compare LASIK with SMILE, and their data have been summarized by a meta-analysis.[3] This prospective, randomized study was designed to compare in a contralateral eye fashion the safety and efficacy of topography-guided LASIK with SMILE. We have previously presented and reported our interim 3-month data for this study.[4]

The 22 myopic patients evaluated in this study underwent a femtosecond laser-assisted procedure for the correction of myopia or astigmatism (Institutional Review Board/Ethics Committee approval was obtained). One eye of each patient was assigned in random (coin flip) to the topography-guided LASIK group, and the fellow eye was then assigned to the SMILE group. The Alcon/Wavelight refractive suite (Alcon Laboratories, Fort Worth, TX) was used for all femtosecond-assisted LASIK procedures. Planned flap thickness was 110 μm, and planned flap diameter was 8.5 mm for all cases. The myopic ablation was accomplished by the EX500 excimer laser (Alcon/WaveLight). The cylindrical refraction was adjusted by the surgeon to match the amount and axis of the topographically measured cylinder, and appropriate sphere adjustments were made to keep the same spherical equivalent (topography-modified refraction).[5] All SMILE procedures were performed before the topography-guided LASIK procedures on a same-day basis using the Visumax femtosecond laser (Carl Zeiss Meditec, Jena, Germany). The intended thickness of the cap tissue was 130 μm, and planned lenticule diameter was 6.5 mm for all cases. Patients' subjective postoperative visual acuity was evaluated (Table S1, available at www.aaojournal.org).

There were no significant differences in any preoperative data between the 2 groups. The average uncorrected visual acuity for both groups was 0.02±0.07 decimal (range, 0.01−0.25 decimal). The average preoperative spherical equivalent was −5.56±2.32 (range, −2.12 to −10) diopters and cylinder −1.02±0.97 (range, 0 to −4.25) diopters.

In our study, both procedures appeared to be effective and safe in refractive error correction, with comparable results throughout 1 year.

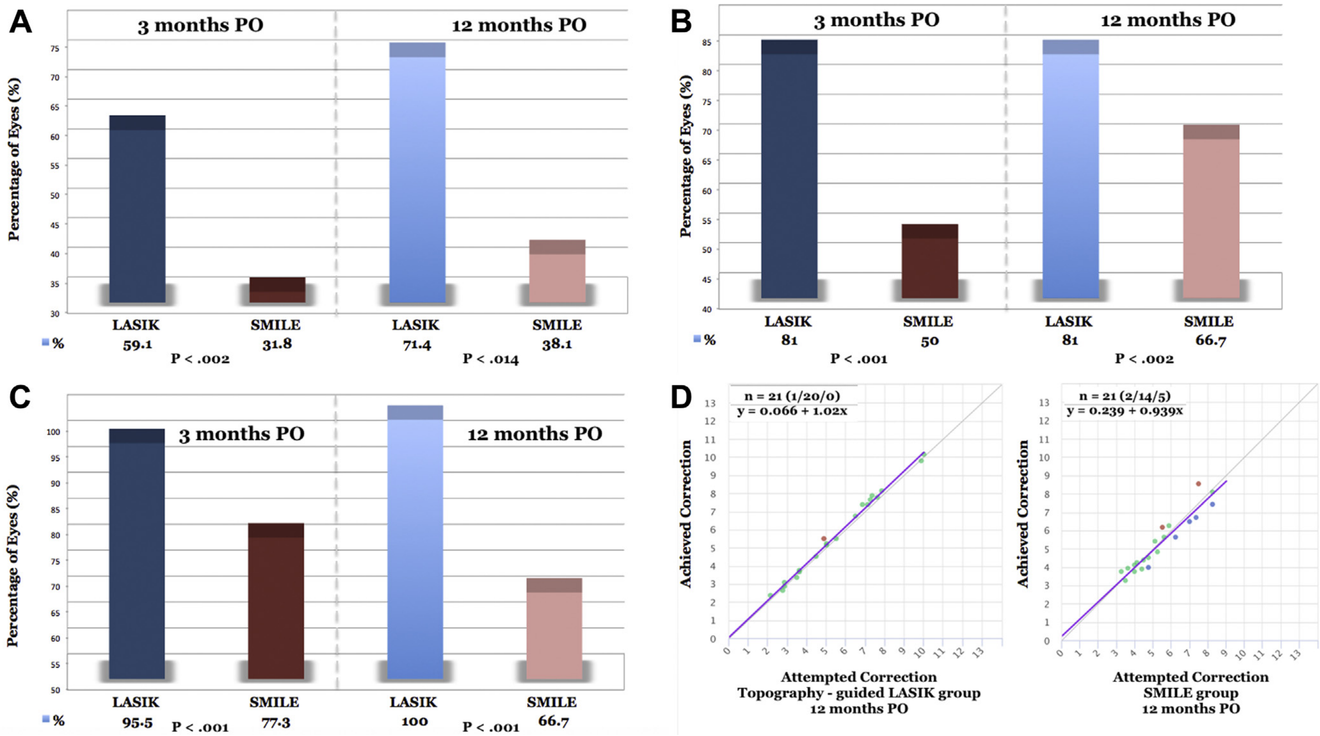

Figure 1. A, Visual outcomes for the topography-guided LASIK (blue) and small incision lenticule extraction (SMILE) (red) at 3 and 12 months, showing the change in 20/16 ft uncorrected distance visual acuity. **B,** Spherical equivalent refraction correction in ±0.5 diopters (D) for the topography-guided LASIK and SMILE groups at 3 and 12 months. **C,** Residual manifest refraction cylinder of less than 0.25 D for the topography-guided LASIK and SMILE groups at 3 and 12 months. **D,** Predictability graph with *red dots* showing overcorrection and blue dots showing undercorrection, with green dots within ±0.50 diopters for topography-guided LASIK and SMILE groups at 12 months postoperatively. PO = postoperatively.

In addition to this, both techniques compared here in a contralateral eye, randomized fashion show significant stability in the refractive error correction from essentially the first postoperative day in regard to LASIK eyes throughout the 1-year follow-up and from the first postoperative week in regard to the SMILE eyes throughout the 1-year follow-up (there does appear to be a difference in the first week visual acuity numbers for the SMILE eyes, which tend to improve dramatically within the first week). Nevertheless, topography-guided LASIK appeared to be more effective in all postoperative refractive parameters studied, both subjective and objective, in comparison with the SMILE eyes. The difference between the 2 techniques in astigmatic correction and in visual performance in regard to corrected and uncorrected distance visual acuity, objective scatter index, and low contrast sensitivity may derive from the fact that the topography-guided LASIK eyes did have the privilege of having topography-guided customization, cyclorotation compensation, and active tracking during the excimer ablation.

It seems that visual function data from both groups, LASIK and SMILE, improved significantly from the 3-month postoperative evaluation that we have previously reported to the 1-year mark, underlining the fact that both of these refractive procedures probably should be evaluated in a more long-term perspective than usually reported in the literature.

The refractive data collected were interesting, especially for the 20/16 uncorrected distance visual acuity improving from 59.1% for the LASIK eyes at 3 months to the impressive 71.4% at 1 year. Nevertheless, even in the SMILE eyes, there was significant improvement in this category, from 31.8% at 3 months to 38.1% at 1 year. This difference between the 2 groups was statistically significant ($P < 0.002$) (Fig 1A). In addition, the residual refraction cylinder ($\leq$0.25 D) was 81.0% at 3 and 12 months for the LASIK group, compared with 50% at 3 months to 66.7% at 12 months for the SMILE group. There was a statistically significant difference between the 2 groups ($P < 0.001$) (Fig 1B). There was an improvement in the residual manifest spherical equivalent of 0.0 ± 0.5 for LASIK eyes, from 95.5% to 100%, whereas SMILE eyes seemed to decrease a little from 77.3% to 66.7%, from 3 months to 1 year. The difference here is also statistically significant with $P < 0.002$ (Fig 1C, D). We already noted that the low-contrast sensitivity improved in both groups, albeit in a more impressive way for SMILE when comparing 3 months with 1 year (Fig S2, available at www.aaojournal.org), suggesting that there may be a lapse of postoperative scatter or healing because this procedure is different than LASIK; this could be due to a difference in the molecular healing level, the epithelial remodeling level, or just scatter, because there are 2 femtosecond laser passes to create the lenticule, or even to a difference of LASIK biomechanical effect or to a combination of these. As SMILE-like techniques and technology evolve, refractive outcomes are bound to improve further, so it is impressive that this procedure, even in our early clinical experience, renders results far superior than the Food and Drug Administration requirements.

Our study suggests that topography-guided LASIK resulted in superior refraction and visual performance outcomes. Nevertheless, contralateral-eye SMILE was safe and effective. Possible future addition of tracking or cyclorotation adjustment may enhance SMILE outcomes. Possible nomogram adjustments may result in improvement of refractive outcomes.

By the same token, a possible future advantage of SMILE to LASIK may be that the active tracking and the cyclorotation compensation only need to be active at the time of patient-interface engagement with the cornea surface, because after that, the eye remains fixated for the 2-femtosecond laser passes and side cut that create the lenticule. In LASIK, active tracking is required during the excimer laser ablation stage, and this can vary from a few seconds to more than 30 seconds in myopic corrections of approximately 10 diopters. Delivery of the ablation pattern, especially when somehow irregular and adjusted for angle kappa, when topography-guided treatments are used, significantly depends on effective active tracking and cyclorotation compensation.

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Presented in part at: the 2017 annual American Academy of Ophthalmology meeting, November 11−14, New Orleans, Louisiana.

Financial Disclosure(s): The author(s) have made the following disclosure(s): A.J.K.: Consultant – Alcon Laboratories, Inc., Avedro, Allergan, i-Optics, KeraMed, Inc., Carl Zeiss Meditec, ISP Surgical.

HUMAN SUBJECTS: This study includes human subject/tissues. No animal subjects were used in this study. IRB approval was done by the Laservision Clinical and Research Institute ethical committee. Informed consent was obtained from all human subjects. All tenets of the Declaration of Helsinki were followed.

Author Contributions:
Conception and design: Kanellopoulos
Data collection: Kanellopoulos
Analysis and interpretation: Kanellopoulos
Obtained funding: Not applicable
Overall responsibility: Kanellopoulos

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