Review of the FDA Premarket Approval Studies Comparing SMILE and LASIK

We have read with interest the review by Schallhorn et al. comparing the results obtained with small incision lenticule extraction (SMILE) and two excimer laser–based procedures in the correction of myopia with astigmatism. The problem with the conclusions of this article is that the populations in the different studies submitted to the U.S. Food and Drug Administration had significant differences in some preoperative features that may be clinically relevant (ie, amount of preoperative cylinder and corrected distance visual acuity (CDVA)). In addition, the postoperative uncorrected distance visual acuity (UDVA) is not recorded in the same way. In the SMILE study, data provided show the number of eyes obtaining up to only 20/16 UDVA, whereas the other two studies provide up to 20/12 UDVA, and this is relevant. In fact, in both the T-CAT and the iDesign studies, more than 20% of eyes reached UDVA of 20/12 or better 1 month after surgery, and 34% of the eyes achieved this level of UDVA in the T-CAT group at 1 year postoperatively. Unfortunately, no data about this level of UDVA were provided in the SMILE study. In a non-regulatory, real-world comparative study, the proportion of patients achieving 20/16 or better UDVA 6 months after surgery was three times more common after laser in situ keratomileusis than after SMILE. Furthermore, the number of eyes gaining lines of CDVA at 6 months postoperatively were different: 23% in the SMILE group, 36% in the T-CAT group, and 55% in the iDesign group.

In addition, the speed of UDVA recovery seems to be markedly slower in SMILE versus excimer laser–treated eyes. As an example, only 66% of the eyes in the SMILE group achieved 20/20 or better UDVA 1 month after surgery, whereas approximately 90% of eyes in the excimer laser group reached 20/20 or better UDVA at this time point. This means that some demanding patients might be concerned about their UDVA level at least for the first month after SMILE, and that the number of highly satisfied patients (so-called “ambassadors” in marketing terms) seems to be much higher if an excimer laser–based ablation is performed.

In other words, although the three technologies analyzed exceeded the minimum targets set by the U.S. Food and Drug Administration, the visual results (and the speed of visual recovery) seem to be clearly superior with excimer laser–based procedures than with SMILE. In addition, the theoretical advantage of SMILE in better preserving the corneal nerves seems not to be as clinically relevant, because 35% of the patients reported worse Ocular Surface Disease Index (OSDI) scores 6 months after SMILE.

SMILE seems to offer a slower visual recovery and a smaller percentage of eyes achieving “super vision” levels (20/12 or better) than modern excimer laser procedures. Additionally, after SMILE, a significant number of patients seem to suffer a self-perceived worsening in their dry eye symptoms. In other words, although the visual results of SMILE performed to correct myopia with astigmatism are good, modern excimer laser–based correction seems to obtain much earlier visual recovery and better UDVA.

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Dr. Teus reports grants from and is a lecturer and consultant for Alcon; reports grants from and is a consultant and lecturer for Allergan; is a consultant for Santen; reports grants from and is a lecturer and consultant for Novartis; is a lecturer and consultant for Glaukos; and reports grants from and is a lecturer for Johnson & Johnson Vision. The remaining authors have no financial or proprietary interest in the materials presented herein.

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Reply
We appreciate that the authors have read our study with such interest. As we stated in our article, the inclusion criteria between the studies were different, and as such they may have affected outcomes.

Our study was intended to compare the visual results of the premarket approval trials of these three laser vision techniques.
correction modalities. Indeed, as we note in the article, visual recovery for small incision lenticule extraction (SMILE) is slower than for both topography-guided and wavefront-guided laser in situ keratomileusis (LASIK). We were not interested in looking for the incidence of “ambassadors” or individuals with “super-vision.”

The question of dryness after laser vision correction is an interesting one. The premarket approval trial for SMILE used the Ocular Surface Disease Index (OSDI) as an outcome, as did the Patient-Reported Outcomes with LASIK (PROWL) study. In the PROWL study, 27% of patients reported worse symptoms at 3 months after surgery, similar to the SMILE study. However, the PROWL study was hampered by comparatively poor follow-up (only 89% of PROWL patients were available for follow-up at 3 months compared to 100% of SMILE patients), making direct comparisons difficult.

Unfortunately, the OSDI was not used in the premarket approval trials for either topography-guided or wavefront-guided LASIK, so we are not able to compare results between different modalities. Thus, it is impossible to say whether more, less, or the same amount of dry eye is induced by any of the modalities. SMILE does have a theoretical advantage of preservation of the anterior corneal nerve plexus, but we need more data before any conclusions can be drawn.

Direct comparability between clinical trials is significantly lacking in our field. Standardizing reportable outcomes would go a long way toward being able to compare different treatments to get a real answer as to which would serve our patients better. We strongly encourage anyone undertaking a clinical trial in refractive surgery to use standardized instruments in their study design, such as the OSDI and the PROWL questionnaire. This, in addition to ensuring proper patient follow-up and using the standardized visual outcomes that have been suggested, will help clinicians sift through the available evidence to make the best evidence-based decisions.

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doi:10.3928/1081597X-20191212-01

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