SMILE and LASIK in Low Myopia

To the Editor:

We read with great interest the article by Reinstein et al. about the clinical outcomes of small incision lenticule extraction (SMILE) in low myopia published in the December 2014 issue.1 We have believed for a long time that refractive surgery to correct small refractive errors, such as low myopia, is extremely demanding. Usually preoperative uncorrected visual acuity is reasonably good; therefore, patients with these small defects need a surgical technique that is not only precise (ie, low percentage of eyes with significant postoperative refractive error), but also safe, because even a small decrease in visual acuity will be noticed by the patient.

In fact, we published some years ago an article that analyzed the visual outcomes of both LASIK and surface ablation in patients with low myopia and low astigmatism.2 It is interesting that only two studies (ours and Reinstein et al.’s) have been published in peer-reviewed journals about this interesting subject, as the authors correctly point out in their article.

Unfortunately, we strongly disagree with the main conclusion of the article by Reinstein et al.: that SMILE for low myopia was found to be safe and effective with outcomes similar to those previously reported for LASIK. We believe that this conclusion does not follow the results of the study and the comparison with the peer-reviewed literature. The percentage of eyes within 0.5 diopter (D) of emmetropia postoperatively was, in our study, 96.16% after LASIK and 98.7% after surface ablation, not 95% and 91%, as Reinstein et al. incorrectly quote (original data shown in Figure 4, page 143 of our article). In their article, only 84% of eyes after SMILE were within 0.5 D of emmetropia. Furthermore, in our study only 1.26% of eyes had a postoperative spherical equivalent higher than -0.5 D after LASIK, compared to 10% of eyes after SMILE in their article. In our opinion, such significant differences in predictability between excimer laser and SMILE procedures make excimer laser clearly superior in this population.

However, it is not only the predictability that matters. The speed of visual recovery is clearly faster in LASIK, and the amount of tissue removed to correct these small refractive defects was reported by Reinstein et al. as 79 µm on average and ranging from 51 to 108 µm with SMILE, compared to the average of 25 to 30 µm in excimer laser ablation for low myopia. In our opinion, all of these differences make the potential (clinically still unproven) advantage of reduced risk of postoperative ectasia after SMILE clearly not reason enough to currently choose this technique over excimer laser, at least for the correction of low myopia.

Reply:

We would like to thank Prof. Teus and Dr. de Benitos-Llopis for their letter and for raising these issues, and we apologize for misquoting the results from their previous study1—we had misinterpreted the labels on the predictability histogram. However, we do not agree with the comments made in relation to comparing small incision lenticule extraction (SMILE) and LASIK for low myopia.

Prof. Teus and Dr. de Benitos-Llopis assert that excimer laser corneal refractive surgery is “clearly superior” to the results that we reported for SMILE for low myopia.2 We acknowledge that their publication comparing LASIK and surface ablation for low myopic corrections1 reported that the spherical equivalent refraction was within ±0.50 diopters (D) in 96.2% of LASIK eyes and 98.7% of surface ablation cases, whereas we reported 84% for SMILE.2 However, our conclusion that “SMILE for low myopia appears to be to be as effective and safe as LASIK” was not just based on this one study. We also reviewed and extracted data for low myopia from the six U.S. Food and Drug Administration (FDA) pre-market approval studies since 2002, using modern excimer lasers.2 For these studies, the percentage of eyes with spherical equivalent refraction within ±0.50 D ranged between 81% and 93%. Our SMILE results are within this range and therefore can be said to be similar to LASIK. As we said in our article, “FDA studies provide a robust benchmark” because they are run to the most rigorous scientific standards; they are prospective, controlled trials, monitored by a Contract Research Organization, as well as being monitored and audited by the FDA itself.

When performing our review of the literature, we had found one further study by Katz et al.2 that reported the results of low myopic LASIK for sphere between -0.25 and -2.75 D and refractive cylinder of 0.75 D or less. However, we had decided to exclude it because the results were a significant outlier compared to the

REFERENCES


Miguel A. Teus, MD, PhD
Laura de Benito-Llopis, MRCOphth, PhD
Madrid, Spain

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Laura de Benito-Llopis, MRCOphth, PhD
Madrid, Spain

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Laura de Benito-Llopis, MRCOphth, PhD
Madrid, Spain

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other studies; combining all groups, 67% of eyes were within ±0.50 D. This is significantly lower than all of the other studies, including our SMILE results.

It appears that the predictability of LASIK for low myopia covers a wide range from 67% to 96% (or 99% for surface ablation), but if anything the study by de Benito-Llopis et al.\(^1\) represents the outlier in this data. What seems more likely is that much of the variation between studies is due to the difficulty in comparing results between different clinical settings, in particular the method used for manifest refraction. We use a standardized technique for manifest refraction, which we have validated between 2 surgeons and 7 optometrists, finding that the interobserver mean total dioptic power was 0.19 D, with a difference of 0.50 D or less in 94% of cases.\(^4\) This level is similar to that found for repeatability studies in controlled conditions. We believe that for studies where refractive predictability is within or better than the range expected due to measurement variation, it seems more likely that there was some bias in the measurement.

To put our SMILE results into context of a comparable clinical setting, we randomly generated a refraction-matched LASIK population from our database. In this group, 86% of eyes had spherical equivalent refraction within ±0.50 D, and there was no statistically significant difference between this group and the previously reported 84% for the SMILE group. It would therefore be of interest to obtain the outcomes of low myopic SMILE within the Prof. Teus and Dr. de Benito-Llopis clinical setting for direct comparison.

Taking all this into consideration, we believe it is difficult to claim that LASIK is “clearly superior” to SMILE, and we stand by our conclusion that given the currently available evidence, LASIK and SMILE provide similar outcomes for low myopia.

We agree that the amount of stromal tissue removed for the refractive correction was significantly greater in SMILE than LASIK, but this is ignoring the stroma included as part of the flap. In the study by de Benitos-Llopis et al.,\(^1\) the flap was created using a Moria M2 microkeratome (Moria SA, Antony, France), which has a published mean ± standard flap thickness of 134 ± 23 µm when using the 110 head (intended flap thickness: 130 µm).\(^5\) Therefore, the flap was incorporating 81 µm of stroma on average (assuming an epithelial thickness of 53 µm), but as much as 150 µm in the 0.5% (three standard deviations) of flaps that would be as thick as 203 µm. Therefore, there was actually less stromal tissue “removed” in SMILE (mean: 79 µm) than by LASIK with the Moria M2 microkeratome (mean: 106 µm; 81 µm for the flap plus 25 µm for the ablation). Of course, modern LASIK is performed using a femtosecond laser, allowing thin flaps and less flap thickness variability. Probably the most common flap thickness currently used is 110 µm, in which case the average tissue removal would be 82 µm (57 µm flap plus 25 µm ablation), which is still greater than the mean of 79 µm that we reported for SMILE.

This is without considering the further benefit that SMILE conserves the stronger anterior stromal lamellae by performing the refractive correction intrastromally.\(^6\) This factor also sets SMILE apart from photorefractive keratectomy (PRK); we have previously modeled that there is less reduction in total tensile strength after SMILE compared to PKR for equivalent tissue removal due to the fact that the PRK ablation occurs within the strongest anterior stroma.\(^6\) The difference in how the structural integrity of the stroma is affected enables a larger optical zone to be used in SMILE.

**REFERENCES**


Dan Z. Reinstein, MD, MA(Cantab), FRCOphth
Glenn I. Carp, MBBCh, FCOpth (SA)
Timothy J. Archer, MA(Oxon), DipCompSci(Cantab)
Marine Gobbe, PhD, MSTOptom
London, United Kingdom

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