Inaccuracies in Reporting the Accuracy of Flap Creating Devices

To the Editor:

We read with interest the article by Ju et al published in the February issue of the Journal of Refractive Surgery, which reported the thickness profile of flaps created with the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) using optical coherence tomography (OCT). The authors are to be congratulated on a well-executed study. Interestingly, a similar article was published in the same month in the Journal of Cataract & Refractive Surgery that compared the flap thickness profile using three femtosecond lasers, which also used OCT to measure flap thickness.

We wish to point out that determining the original flap thickness profile generated cannot be accurately performed by using the full flap thickness measurement postoperatively due to changes in the epithelium. Therefore, it might be expected that the epithelium can be as much as 6 µm thicker centrally than postoperatively due to changes in the epithelium.

The study by Ju et al used the Visante OCT (Carl Zeiss Meditec) and measured the flap thickness at 10 points over the cornea (central, 1.5-mm, and 3.0-mm radii) 1 week and 1 month after LASIK for myopia up to ~8.38 diopters (D) spherical equivalent refraction. The flap thickness profile was reported to be of uniform thickness because no statistically significant differences were noted in mean flap thickness among any of the 10 measurement locations. However, the measurements were not adjusted to account for the lenticular epithelial thickness changes that are known to occur after myopic excimer laser ablation. We have found the epithelium after myopic ablation to be similar in thickness within the central 1.5-mm radius before becoming progressively thinner centrifugally. For a ~4.00-D correction, the epithelium can be as much as 6 µm thicker centrally than at the 3-mm radius. Therefore, it might be expected that the central and 1.5-mm flap thickness measurements by OCT overestimate the actual flap thickness at the time of creation. This suggests that a finding of uniform flap thickness might actually mean that the true flap thickness profile was thinner centrally than paracentrally. Epithelial thickness changes are also correlated to the amount of myopia treated with more central epithelial thickening for higher corrections, which means that the error introduced into flap thickness measurements will vary among eyes.

The study by Ahn et al used the RTVue Fourier-domain OCT (Optovue Inc, Fremont, California) and measured the flap thickness at 14 points over the cornea 2 months after LASIK for myopia (although the amount of myopia treated was not reported). This study reported a uniform flap thickness profile for both the IntraLase (Abbott Medical Optics Inc, Santa Ana, California) and VisuMax femtosecond laser platforms. Again, because epithelial thickness changes were not accounted for by the postoperative OCT flap thickness measurements, it is likely that the central flap thickness measurements overestimated the true flap thickness. The same assumption has also been made in other studies where a uniform flap thickness has been reported for femtosecond laser systems.

Flap thickness accuracy is considered on the order of microns. Most surgeons expect the reproducibility of flap thickness (one standard deviation) to be on the order of 5 to 15 µm. The changes in the epithelial thickness profile after LASIK can be up to 18 µm for myopia and 24 µm for hyperopia. Therefore, the only way of usefully and accurately determining the actual original flap thickness created by a microkeratome or a femtosecond laser is to employ temporally displaced measurements of the epithelial thickness preoperatively and the stromal component of the flap postoperatively (once all edema has subsided). This method has been described previously using Artemis very high-frequency digital ultrasound with an epithelial thickness repeatability of 0.58 µm and a flap thickness repeatability of 1.68 µm.

One final point is that as a general rule, given that 99% of measurements are within three standard deviations of the mean, the repeatability of the measuring tool should ideally be at least one-third of the reproducibility of the data set to enable distinct measurements to be made on the scale required. In the study by Ju et al, the flap thickness reproducibility is reported to be 3.9 µm, but the measurement device being used has been reported to have a repeatability of 8.7 µm and therefore can only be expected to determine flap thickness with confidence to within 17.4 µm (two standard deviations).

Dan Z. Reinstein, MD, MA(Cantab), FRCS, FRCOphth
Marine Gobbe, MST(Optom), PhD
Timothy J. Archer, BA(Oxon), DipCompSci(Cantab)
London, United Kingdom

Dr Reinstein is a consultant for Carl Zeiss Meditec (Jena, Germany) and has a proprietary interest in the Artemis technology (ArcScan Inc, Morrison, Colorado) and is an author of patents related to VHF digital ultrasound administered by the Cornell Research Foundation, Ithaca, New York. The remaining authors have no proprietary or financial interest in the materials presented herein.

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