

Laser Versus Manual Keratectomy

This clinician wanted to know which flap-making method was better for his patients.

By Daniel S. Durrie, MD

SINCE THE ADVENT OF THE INTRALASE FS femtosecond laser (IntraLase Corp., Irvine, CA), some anecdotal reports have indicated both advantages and potential disadvantages with the device's flap-cutting capabilities compared with mechanical microkeratomes. Some of these reports cited more predictable flap thicknesses and fewer epithelial defects, but also a slower visual recovery, at least for the first few postoperative days, as well as some diffuse lamellar keratitis.

As a result, many ophthalmologists requested that IntraLase Corp. conduct a randomized, prospective study at an independent center that would compare a mechanical microkeratome's flap in one eye with an IntraLase flap in the other. I was the principal investigator for this study, which used the Hansatome microkeratome (Bausch & Lomb, Rochester, NY) in the patients' contralateral eyes. Although the Hansatome has been around for a long time and its safety profile is established, the device has been associated with occasional epithelial defects, and surgeons well know that microkeratomes can create buttonholes or an incomplete cut.

STUDY DESIGN

My colleagues and I conducted a randomized, prospective study with 51 patients (102 eyes). We kept the parameters of the study as close as possible in order to keep the cutting device as the only variable. We randomized the patients by drawing a card that told us which eye would receive which treatment. The patients were masked from the treatment. The observer was independent but could not be masked, because when he looked at the eye he could tell the difference (the IntraLase flaps are perfectly round). I performed all of the surgeries, and I did so with customized ablation using the LADARVision CustomCornea Wavefront System (Alcon Laboratories, Inc., Fort Worth, TX) (Read Dr. Durrie's discussion of his latest CustomCornea data on page 23). No one had previ-

ously reported results using customized wavefront-guided ablation with the INTRALASE FS laser.

PARAMETERS

In the study, we examined many surgical parameters to determine whether we could identify a difference between the INTRALASE FS laser and the Hansatome microkeratome. In addition to visual acuity, we evaluated flap-thickness predictability, contrast sensitivity, and pre- and postoperative wavefront measurements. We also performed dry eye testing with a Schirmer's test and conducted Lissamine Green staining (Accutome, Malvern, PA). Finally, we tested quality of vision under certain lighting situations using a subjective patient questionnaire. The questionnaire asked the patients to rate which eye saw better under certain conditions.

FINDINGS

At the 2003 AAO Meeting in Anaheim, California, I presented the first visual acuity results of the study.¹

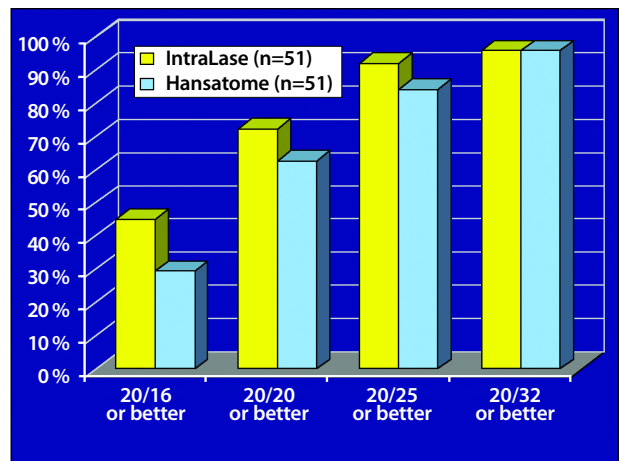


Figure 1. This graph shows the percentage of cumulative UCVA for each modality on the first postoperative day.

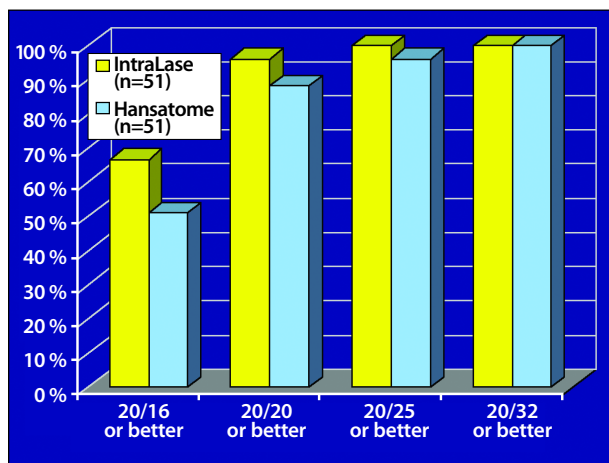


Figure 2. This figure shows the percentage ($P < .005$) of cumulative UCVA for each modality at the first postoperative month.

There was 100% follow-up at all visits through 3 months. The outcomes in both groups were extremely good, but we found that, contrary to what had been previously reported, the INTRALASE FS laser produced better vision, even at 1 day and continuing through 1 week, 1 month, and 3 months postoperatively (Figure 1). Additionally, patients' visual acuity was statistically significantly better at all levels in the eyes that had undergone IntraLase. Moreover, the patients' vision in their IntraLase eye was extremely good: above 90% achieved 20/20, and above 75% achieved 20/16 at 1 month (Figure 2). These results were better than those I had achieved using LADARVision CustomCornea in the CustomCornea clinical trials.

In addition, the contrast sensitivity data were better in the IntraLase eyes; the patients responded in the questionnaires that they preferred their IntraLase eye for quality of vision. Further, when we looked at the Schirmer's test results, the tear film levels were statistically significantly better in the IntraLase eyes. Recently, we analyzed the higher-order aberrations induced by each device. The total amount of higher-order aberrations postoperatively, particularly coma, was statistically significantly lower in the IntraLase eyes.

THE WINNER IS . . .

In summary, the INTRALASE FS laser was at least equal to or better than the Hansatome in every category. I consider these results impressive across the board, and they may make surgeons realize that the IntraLase procedure is better than they might have expected. It is more predictable with flap thickness, it is a very safe device, and it

produces statistically significantly better visual results while preserving the tear film. Moreover, in this study, the patients were happier with IntraLase's outcomes versus the mechanical microkeratome cut. The only disadvantages that we found with IntraLase are that the device is expensive, it slows the procedure, and it requires more staff and OR space. Surgeons interested in adopting this technology will have to strike a balance between its scientifically proven better quality of vision and better patient satisfaction versus its expense and the awkwardness of implementing the device into their normal surgical routine. Already, many physicians who want to offer cutting-edge technology are seriously considering adopting the IntraLase technology.

Because this study was randomized and prospective, I entered into it without any expectations for which procedure would prevail. I simply was interested in the results because I had been using the INTRALASE FS laser and the Hansatome microkeratome interchangeably. Since the study's conclusion, I have switched to using the INTRALASE FS laser exclusively in all my refractive cases, unless there is some medical reason to use the microkeratome. My microkeratome of preference is still the Hansatome, but now I think that making a flap with the laser is safer. Looking back, researchers spent 15 years trying to make excimer lasers more accurate, and customization has certainly improved the quality of vision outcomes and raised the bar. Until now, however, we have not concentrated on how the flap may improve patients' vision; we have only focused on how to make flaps more safely. The INTRALASE FS laser has perhaps redirected our thinking on this subject.

Surgeons cannot provide customized LASIK with IntraLase for less than \$2,000 per eye, so they will have to judge whether this technology will fit with their business model. Many clinicians are adopting it, however. My patients do not complain about the price; they will gladly pay more for a safer procedure that yields better-quality vision. ■

Daniel S. Durrie, MD, is Director of Durrie Vision in Overland Park, Kansas, and is Clinical Assistant Professor of Ophthalmology at the Kansas University Medical Center in Kansas City, Kansas. He is a paid clinical investigator for both IntraLase Corp. and Bausch & Lomb. Dr. Durrie may be reached at (913) 497-3737; ddurrie@durrievision.com.

1. Durrie DS. A randomized, prospective clinical study of LASIK performed with mechanical vs IntraLase FS laser keratomes. Paper presented at: The ISRS/AAO Subspecialty Day at the Annual AAO Meeting; November 14, 2003; Anaheim, California.