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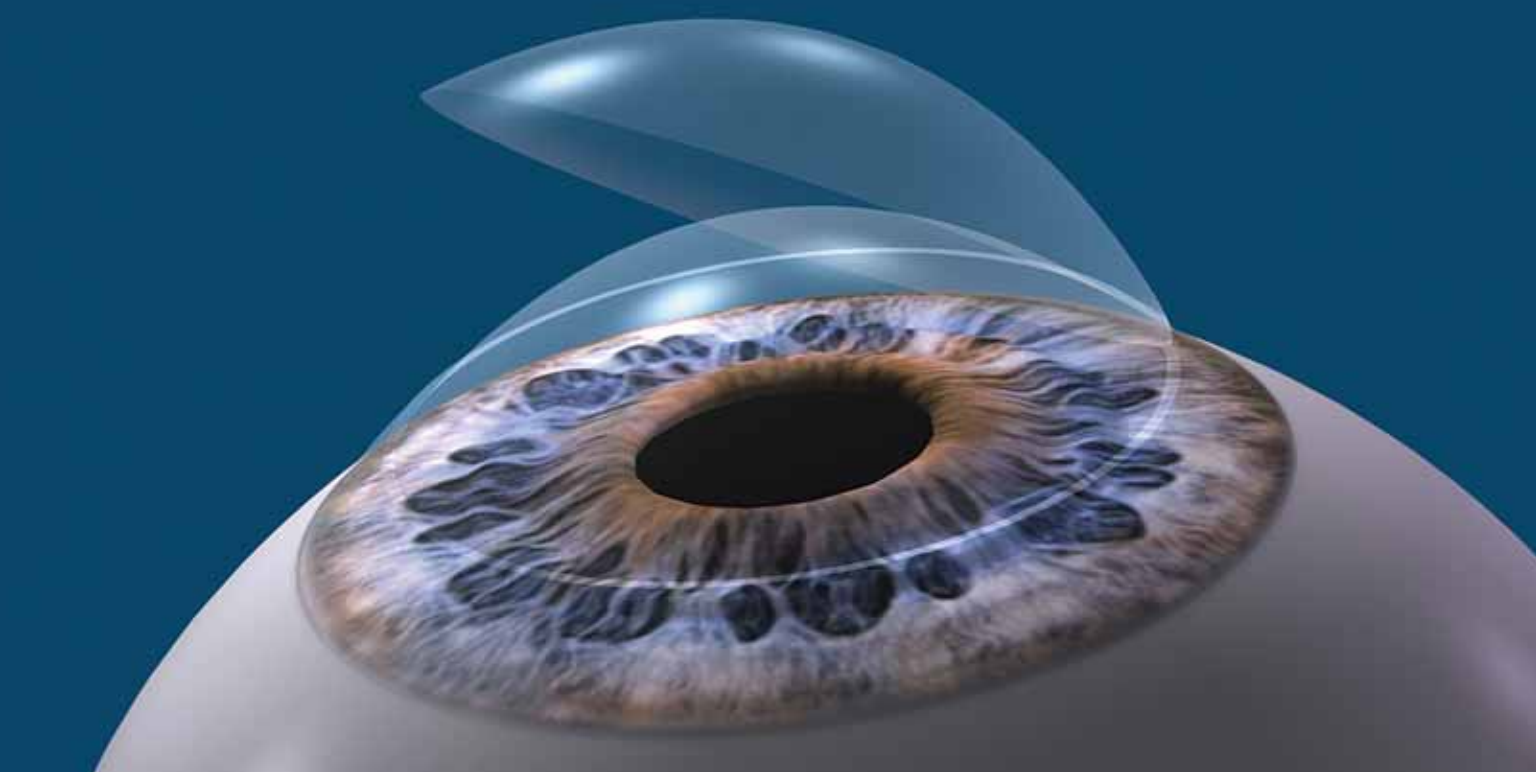
Hansatome Versus Intralase



Controversies in Flap Creation

Hansatome Versus Intralase

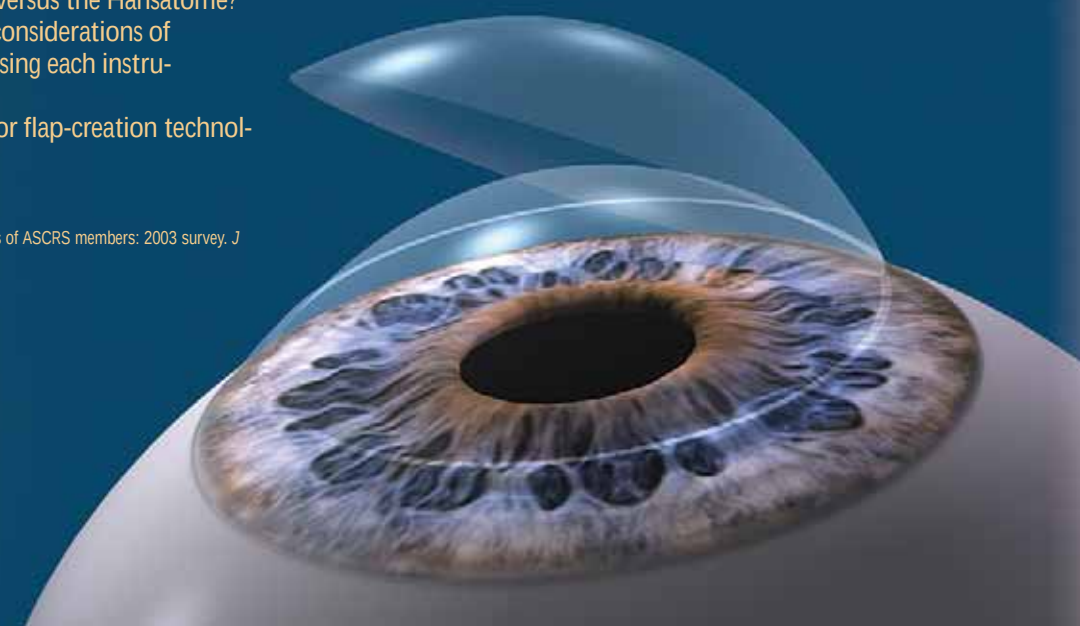
The advantages of a mechanical microkeratome system.

There is no question about the current dominance of LASIK as the procedure of choice for both refractive surgeons and patients who seek laser vision correction. Mechanical microkeratomes have been used almost exclusively to create the LASIK flap in the more than 5 million cases performed since 1997.[1]

The Hansatome microkeratome (Bausch & Lomb, Rochester, NY) has been used safely in millions of LASIK cases over the last 6 years and is currently the most widely used microkeratome technology throughout the world.[2] Today, there are two classes of instruments used in flap creation: mechanical microkeratomes (such as the Hansatome) and the femtosecond laser (Intralase FS; Intralase Corp., Irvine, CA). These options leave surgeons who are either launching a refractive surgical practice or re-equipping an existing practice an important—and one potentially quite expensive—choice.

In this monograph, experienced surgeons who have used both mechanical microkeratomes and the femtosecond laser will present their opinions so that the reader may answer the following questions:

- How does the clinical performance of each instrument differ in terms of LASIK flap creation?
- What differences in outcomes (recovery of vision, final visual acuity, postoperative inflammation, etc.) have been noted?
- Are there any complications or undesirable effects associated with the Intralase FS laser versus the Hansatome?
- What are the economic considerations of acquiring, maintaining, and using each instrument?
- What is the best choice for flap-creation technology in my practice today?



1. Bausch & Lomb. Data on file.
2. Leaming DV. Practice styles and preferences of ASCRS members: 2003 survey. *J Cataract Refract Surg*. 2004;30:892-900.

Not All Flaps Are Created Equal

Flap-creation technology exerts many influences on LASIK results.

Every LASIK procedure requires the creation of a corneal flap, but not all corneal flaps are created equal. Some of the differences between flaps made with mechanical microkeratomes versus a femtosecond laser are beginning to emerge.

FLAP THICKNESS

The Hansatome microkeratome has gained wide acceptance among surgeons based on its ability to (1) create a corneal flap with clean, even edges and thereby leave a smooth stromal bed and (2) make flap cuts that are actually thinner than nominal and thus reduce the risk of corneal ectasia.[1-5] One of the appeals of the Intralase FS femtosecond laser has been its predictability in terms of flap thickness.[6] However, the new Zero Compression Head available for the Hansatome Excellus microkeratome has improved the repeatability of the thickness of mechanically created flaps.

PROCEDURAL TIME

One important difference in the intraoperative performance between the two instruments is that flap creation with the Intralase FS laser is measured in minutes, as opposed to seconds as with the Hansatome microkeratome. This variance translates directly into a longer procedure with the Intralase FS laser. Perry S. Binder, MD, of San Diego, California, Co-Medical Director of Intralase, has noted that, in his practice, "The [Intralase] laser has increased the total procedural time to about 8 minutes."[7] The loss of suction fixation that sometimes occurs with the Intralase FS laser has also been observed to prolong flap-creation time and cause significant patient discomfort.[8,9]

FLAP LIFTING

Eric D. Donnenfeld, MD, of Long Island, New York, and others have noted that the microablation action of the Intralase FS laser, which creates thousands of cavitation bubbles within the cornea, destroys tissue and thus creates an uneven stromal bed.[10,11,2] The resultant flap sticks to the corneal bed with microadhesions.[12] Before applying the excimer ablation pattern, the flap must be lifted to tear the remaining collagen fibrils that the cavitation bubbles missed.

Even Intralase proponents say that lifting the flap after the laser's initial cut can be more difficult than with a microkeratome's cut. Dr. Binder has acknowledged this difficulty during the learning period with these instruments.[13]

EFFECTS ON LASIK

Beyond the issues of the ease of lifting the flap and the learning curve involved with the Intralase FS laser is the question of how flap lifting itself may affect the results of LASIK. Scott M. MacRae, MD, of Rochester, New York, recently reported on the results of a study in which pre- and postoperative wavefront, corneal topography, and visual acuity measurements were compared in patients who had a LASIK flap created but not lifted, and patients who had a flap created and then lifted, all using a Hansatome microkeratome.[14]

In his lecture at the 2004 joint meeting of the ASCRS/ASOA, Dr. MacRae said that, "Creation of the flap via microkeratome did not increase higher-order aberrations. The other group of patients who had their flaps lifted and a sham ablation performed for 2 minutes had a 30% increase in higher-order aberrations, however." Both patient groups also exhibited an increase in spherical aberration after the LASIK ablation was subsequently performed, with the amount of induced aberration proportional to the amount of correction.

The study thus links flap lifting—not simply flap creation—with the increase in higher-order aberrations that has previously been associated with LASIK. Dr. MacRae recommended that, in order to minimize induced aberrations, surgeons should keep the flap relatively dry once it is made and

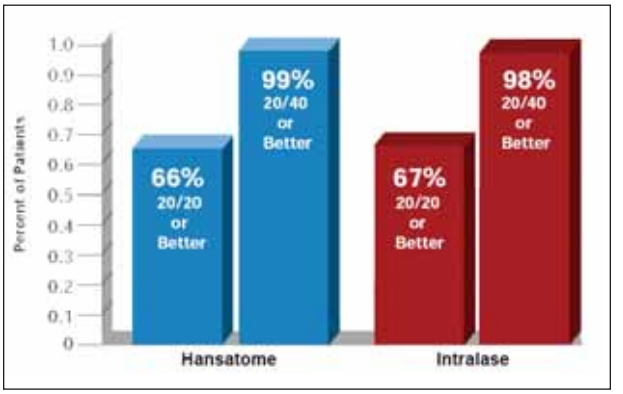


Figure 1. Data from a retrospective analysis comparing the uncorrected distance visual acuity (Snellen) outcomes of LASIK performed using the Hansatome (left) and the Intralase FS laser (right) found no statistically significant differences between results at 3 months after surgery.

DIFFERENCES IN POSTOPERATIVE HIGHER-ORDER ABERRATIONS BETWEEN HANSATOME AND INTRALASE ARE CLINICALLY MINIMAL

By Scott M. MacRae, MD

In a study on which he reported at the 5th International Congress on Wavefront Sensing and Optimized Refractive Correction in Whistler, Ontario, Canada, Daniel S. Durrie, MD, noted that eyes treated with the Intralase FS laser and customized ablation had a 0.05-µm RMS increase in higher-order aberrations, whereas contralateral eyes treated with the Hansatome had a 0.1-µm RMS increase.[1]

Although this difference in higher-order aberration was statistically significant, it was clinically minimal. The difference in higher-order aberrations between the Intralase FS laser and Hansatome eyes was equivalent to one-quarter of a click on the phoropter. That is, an increase in 0.2µm RMS of defocus (sphere) with a 6-mm pupil equals 0.25D of defocus or one click on the phoropter.

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1. Durrie DS. Wavefront outcomes of IntraLase vs. Hansatome LASIK. Paper presented at: The 5th International Congress on Wavefront Sensing and Optimized Refractive Correction; February 22, 2004; Whistler, Ontario, Canada.

take special care in repositioning it symmetrically after ablation. He further recommends gently but firmly stretching the flap back into position (using two Merocel sponges [Medtronic Ophthalmics, Jacksonville, FL] slightly moistened with Celluvisc [Allergan, Inc., Irvine, CA]) to minimize the gap between the cut flap and uncut corneal edges.

Although there have not yet been any similar studies using the Intralase FS laser, the additional manipulation required to lift flaps created by the laser may have an effect on postoperative higher-order aberrations. Flap repositioning may also play a special role with the Intralase FS laser.

Because the Intralase FS laser's flap is created by the removal of tissue within the stroma and around its circumference, the flap is also smaller than the stromal bed.[11,12] This size difference requires a period of postoperative "reseating" of the Intralase FS laser's flap that does not occur with mechanical microkeratome flaps, according to Dr. Donnenfeld. Daniel B. Goldberg, MD, of Little Silver, New Jersey, has also said that, "Patients may experience slightly more postoperative discomfort with IntraLASIK than with mechanical LASIK procedures due to the different flap and edge anatomy."[12]

CONCLUSIONS

At this time, the accuracy and repeatability of the Intralase FS laser have not been found conclusively to lead to better results. In a paper presented at the 5th International Congress on Wavefront Sensing and Optimized Refractive Correction, Daniel S. Durrie, MD, noted that 73% of the eyes in the customized Intralase FS laser group saw 20/16 UCVA postoperatively, whereas 55% of the eyes in the Hansatome group achieved that same level of UCVA.[15] He also noted that sphere was undercorrected by 0.14D more in the Hansatome group than in the Intralase FS laser group, and cylinder was undercorrected as well. These findings suggest that different nomogram adjustments are needed when using a laser versus a mechanical keratome system to create a flap. Furthermore, a contralateral eye study of 21 closely matched myopes using the Hansatome with Zero Compression Head in one eye and the Intralase FS laser in the other found no statistically significant differences in UCVA or residual higher-order aberrations at 1 week and 1 month postoperatively,[16] and a retrospective analysis of outcomes with the Hansatome and Intralase FS laser showed no statistically significant differences in UCVA at 3 months (Figure 1).[6] ■

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6. Kezirian GM, Stonecipher KG. Comparison of the IntraLase femtosecond laser and mechanical keratomes for laser in situ keratomileusis. *J Cataract Refract Surg*. 2004;30:804-811.
7. Schena LB. IntraLASIK's pros and cons. *EyeNet*. 2004;5-6.
8. Assil KK. Understanding your keratome options. *Ophthalmology Management*. 2004;(suppl):4-6.
9. Woodhams TJ. Does a better flap improve outcomes? *Ophthalmology Management*. 2004;(suppl):7-9.
10. Biser SA, Bloom AH, Donnenfeld ED, et al. Flap folds after femtosecond LASIK. *Eye Contact Lens*. 2003;29:252-254.
11. Donnenfeld ED. FS laser: Not ready for prime time. *Ophthalmology Management*. 200;8(suppl):10-12.
12. Goldberg DB. The IntraLASIK learning curve. *Cataract & Refractive Surgery Today*. 2004;4:24-428.
13. Samalonis LB. What happened to flap complications? *Review of Ophthalmology*. 2004;11:53-55.
14. MacRae SM, Porter J, Yoon G-Y, et al. Causes of the increase in higher-order aberrations after LASIK. Paper presented at: The ASCRS/ASOA Symposium on Cataract, IOL, and Refractive Surgery; May 3, 2004;San Diego, CA.
15. Durrie DS. Wavefront outcomes of IntraLase vs. Hansatome LASIK. Paper presented at: The 5th International Congress on Wavefront Sensing and Optimized Refractive Correction; February. 22, 2004; Whistler, Ontario, Canada.
16. Cox IG. The Hansatome vs. the femtosecond laser: Equivalent results after LASIK [white paper]. Bausch & Lomb; April 2004.

Making the Choice

When choosing between the Hansatome microkeratome and the Intralase FS laser, proven results are persuasive.

Because the ideal refractive surgical procedure has yet to be invented, every advancement in technique and technology forces refractive surgeons to choose whether to incorporate the new tool into their practices based on its potential advantages and attendant risks. The choice between LASIK flap-creation technologies is particularly difficult, because the results are excellent with both technologies. However, there are some differences between them.

CONSIDERATIONS

The wide adoption of the Hansatome microkeratome by refractive surgeons[1] has created a large pool of data confirming the safety and efficacy of the device.[2-7] Any new flap-creation technology developed subsequently will need to achieve or exceed these levels of safety and effectiveness in order to be considered for use in clinical practice.

Surgeons have found more postoperative inflammation with the Intralase FS laser than in Hansatome cases. Postoperative care after LASIK with a mechanical microkeratome most often includes a 2- to 3-day course of topical steroids. A more prolonged use of postoperative steroids is required after LASIK with an Intralase FS laser flap.[6,8,9]

At the 2003 meeting of the ASCRS, Jonathan D. Christenbury, MD, reported on a series of 933 cases of LASIK performed with the Intralase FS laser.[8] Dr. Christenbury said that he had converted to using the Intralase FS laser for flap creation in the majority of his LASIK cases and that the results were equivalent to his experience using a mechanical microkeratome. In an earlier news article published on his paper, Dr. Christenbury described complications with using the Intralase FS laser, including epithelial ingrowth, epithelial defect/abrasion, striae/wrinkles, and interface debris.[10] He also noted occasional patient complaints of ocular irritation and burning postoperatively, as well as some cases of photophobia.

The incidence of photophobia relative to use of the Intralase FS laser may be related to a syndrome that has only recently been recognized. Recently, a unique phenomenon associated with using the Intralase FS laser has been reported by surgeons, including Brian R. Will, MD, of Vancouver.[11] Dr. Will described a phenomenon he called *track-related iridocyclitis and scleritis*. This complication of LASIK performed with the Intralase FS laser is

COMPLICATION PROFILE, RESULTS, AND ECONOMICS MAKE HANSATOME PREFERABLE TO INTRALASE

By Elizabeth A. Davis, MD, FACS

I have not yet had any personal experience with the Intralase FS femtosecond laser, specifically because, every time my colleagues and I have considered buying one, we have investigated and researched the system's outcomes and found them to be inferior to results with the Hansatome microkeratome. Several surgeons from my group and I have spent a day observing a surgeon who uses the Intralase FS laser, and we were quite unimpressed. We observed poor flaps, prolonged surgical time, inefficient patient flow, patient discomfort, prolonged flap edema, and delayed visual recovery.

The Intralase FS laser does not eliminate the risk of a problem with the flap. A surgeon may still get short flaps, buttonholes, etc. Furthermore, the Intralase FS laser's flap bed is not as smooth as with a Hansatome, because the connecting bands of stroma that remain at the end of the laser's pass must be broken with a mechanical instrument prior to lifting the flap.

Additionally, with the substantial expense of the Intralase FS laser and the significantly increased surgical time required to perform a case, an Intralase surgeon's revenue per hour will dramatically drop with this technology.

At the moment, my colleagues and I see no distinct advantage to using the Intralase FS laser over the Hansatome, and we even see some disadvantages. Hence, we have yet to purchase the device. We will, however, continue to re-evaluate the Intralase FS laser from time to time, and if these concerns are addressed, we would be amenable to examining it for consideration again.

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TABLE 1. INITIAL COSTS FOR HANSATOME VERSUS INTRALASE

	Hansatome	Intralase	Difference
Cost of Acquisition	$49,500	$300,000	$250,500
Annual Service Cost	$7,000	$50,000	$43,000
Disposables (Single Use)/Intralase User Fee	$65	$150	$85

characterized by eyes that have good visual acuity and no apparent clinical signs upon examination, but in which the patient complains of debilitating photophobia beginning 6 weeks or longer after surgery. A pathogenetic theory for this syndrome has been proposed (See "Flap Technologies Aim for Safety," on page 7.), but the manufacturer and Intralase users are still investigating it. ■

1. Learning DV. Practice styles and preferences of ASCRS members: 2003 survey. *J Cataract Refract Surg* 2004;30:892-900.
2. Samalonis LB. What happened to flap complications? *Review of Ophthalmology.* 2004;11:53-55.
3. Randleman JB, Russell B, Ward MA, et al. Risk factors and prognosis for corneal ectasia after LASIK. *Ophthalmology*. 2003;110:267-275.
4. Tham VM, Maloney RK. Microkeratome complications of laser in situ keratomileusis. *Ophthalmology*. 2000;107:920-924.
5. Yildirim R, Devranoglu K, Ozdamar A, et al. Flap complications in our learning curve of laser in situ keratomileusis using the Hansatome microkeratome. *Eur J Ophthalmol*. 2001;11:328-332.
6. Kezirian GM, Stonecipher KG. Comparison of the IntraLase femtosecond laser and mechanical keratomes for laser in situ keratomileusis. *J Cataract Refract Surg.* 2004;30:804-811.
7. Cox IG. The Hansatome vs. the femtosecond laser: Equivalent results after LASIK [white paper]. Bausch & Lomb; April 2004.
8. Christenbury JD. Clinical outcomes of 933 LASIK cases using the IntraLase FS laser keratome. Paper presented at: The ASCRS/ASOA Symposium on Cataract, IOL, and Refractive Surgery; April 14, 2003; San Francisco, CA.
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11. Will BR. Track-related iridocyclitis and scleritis associated with use of the IntraLase for LASIK. Paper presented at: The ASCRS/ASOA Symposium on Cataract, IOL, and Refractive Surgery; May 4, 2004; San Diego.

Money Matters

The economics of choosing Hansatome over Intralase.

Given the significant capital costs of starting up and maintaining a laser vision correction practice, selecting the Hansatome Excellus microkeratome may be much more economical than acquiring, using, and servicing the Intralase FS laser system. The initial 5-year cost for the Intralase FS laser is three times that of the Hansatome Excellus once acquisition, annual service, and disposables are added up.

Table 1 shows the costs for acquisition, service, and disposables for each instrument. Figure 1 shows the total "hard" costs for a practice using each system for a 5-year period. These costs include (1) initial acquisition, (2) cost of annual service over 5 years, and (3) cost of single-use disposables (Hansatome) and user fees (Intralase) in 500 cases per year for 5 years.

Use of the Intralase FS laser is three times more expensive than that of the Hansatome, costing the practice an additional $890,000 in the first 5 years of use. The $356 difference in cost per case ($164 per case for the Hansatome compared with $520 per case with the Intralase FS laser) would have to be passed along to the patient. This cost could certainly place a refractive surgery practice at a competitive disadvantage in a market in which microkeratomes such as the Hansatome Excellus are widely used.

The differences in cost per case between the two devices is magnified by the fact that more LASIK cases can be performed using a microkeratome compared with the Intralase FS laser. Thus, the Hansatome allows greater patient volume.[1,2] One surgeon who has used the Intralase FS laser in his refractive surgical practice has even stated that, "We've come to terms with the con-

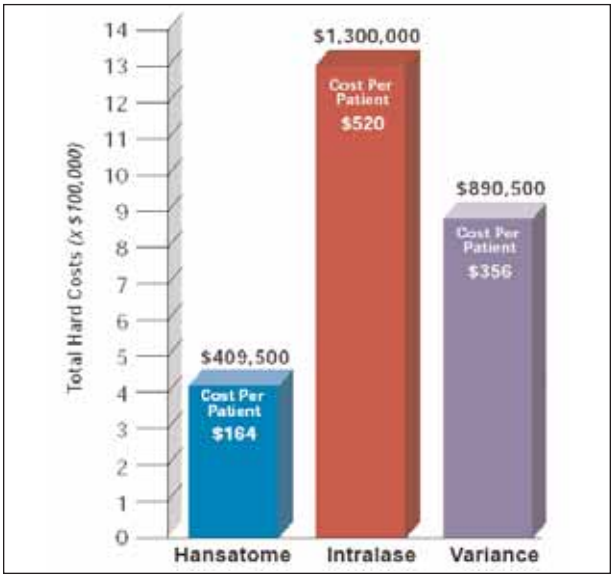

Figure 1. Total hard costs (acquisition, annual service, and disposables) in the first 5 years of use for Hansatome (blue) versus Intralase (red) and the difference between the two (lavender).

HAVING BOTH A MECHANICAL AND LASER MICROKERATOME IS IDEAL

By Stephen G. Slade, MD, FACS

I currently have an Intralase FS laser in my refractive surgical practice. Lee Nordan, MD, of Carlsbad, California, and I received the very first units, and I have now used mine for more than 6 years.

My colleagues and I conducted a contralateral eye study comparing the Intralase FS laser to the Hansatome microkeratome[1] and found no statistically significant differences in the results between the two technologies. I believe the very early postoperative results tend to be better with the Hansatome, but then the outcomes become equivalent.

I currently use both keratomes in my practice, and I consider that the ideal situation. There are patients whom I prefer to treat with the Intralase FS laser, and some whom I would rather treat with the Hansatome. If a surgeon could have only one flap-creation technology, then the choice would depend on the budget of the practice and what the other surgeons in the local refractive surgery market have.

I have never marketed the Intralase FS laser, but I do see the potential for surgeons marketing the availability of the unit. The first surgeons in a market to advertise a technology seem to have an advantage over those who try later.

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1. Cox I. Evaluation of LASIK Flaps Created With a Microkeratome Versus a Femtosecond Laser. Paper presented at: The ASCRS/ASOA Symposium on Cataract, IOL, and Refractive Surgery; May 3, 2004; San Diego, CA.

cept that the device may never pay for itself."[3]

Another comparative advantage to using the Hansatome is patients' "wow" factor of rapid visual recovery, often in the immediate postoperative period. Visual recovery is slower after procedures involving an Intralase FS laser flap.[1,3] ■

1. Donnenfeld ED. FS laser: Not ready for prime time. *Ophthalmology Management.* 200;8(suppl):10-12.
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Flap Technologies Aim for Safety

How close do they come?

Patient safety is the foremost concern in medicine, and the highest levels of safety are required of elective procedures such as laser vision correction. Because flap creation is the most potentially dangerous step of LASIK, the technology used to create the flap must prove itself safe and reliable. The safety profile of any flap-creation technology comprises both intraoperative problems that could lead to the abandonment of the procedure[1] as well as factors such as a tendency to create a thick flap and thin stromal bed that lead to postoperative complications (in this example, corneal ectasia).[2]

RECORDS OF SAFETY

The Hansatome

The Hansatome microkeratome has a long record of clinical success. Recently, Daniel Durrie, MD, reported that, in more than 13,000 procedures with the Hansatome in his practice, there were no major complications.[3] Also, a study of flap complications among a group of novice LASIK surgeons reported that "the Hansatome had an easy learning curve without any of the serious complications that frequently occur in this phase."[4]

The most recent evolution of the Hansatome microkeratome incorporates the Zero Compression Head, which is designed to further improve on the device's safety results. The new Excellus model Hansatome in conjunction with the Zero Compression Head creates flaps that are actually thinner than nominal, reducing the likelihood of postoperative ectasia.

The Intralase FS Laser

The Intralase FS laser was developed as a technology to create flaps more safely and predictably. A review of the early literature on its clinical results in LASIK found that the laser was able to cut flaps of uniform thickness.[5] One potential problem, however, is that the suction ring of the Intralase FS laser remains on the eye for 40 to 60 seconds, which is much longer than required by mechanical microkeratomes. This duration can lead to the loss of suction during flap creation,[6-8] which has resulted in cases of significant patient discomfort and postoperative conjunctival injection. Some physicians have adopted the use of preoperative vasoconstrictors to prevent the problem.[6,9]

SAFETY ISSUES SUPPORT THE CHOICE OF A MECHANICAL MICROKERATOME

By Robert K. Maloney, MD

Although the Intralase FS laser is an interesting piece of technology, I think that some surgeons are expecting it to solve a problem that has no perfect solution: how to make a perfect flap.

Flap complications are rare with both laser and mechanical keratome technologies, but they do occur. My personal feeling is that choosing between the Hansatome microkeratome and the Intralase FS laser is a matter of choosing which type of complication the surgeon would prefer to have when it does occur. A refractive surgeon who finds it easier to manage buttonhole flaps, as I do, will fare better with a mechanical microkeratome. One who prefers to deal with flap tears, however, may want to consider the Intralase FS laser. Tears are probably more likely to cause irregular astigmatism, and are almost certainly more likely to lead to epithelial ingrowth, however.

The Intralase procedure is less comfortable for the patient, because instead of taking 4 minutes from beginning to end, as with a microkeratome, LASIK with the Intralase FS laser takes 30 minutes in two ORs. The procedure requires the application of suction for a much longer time compared with a microkeratome, and loss of suction occurs in about 1 in 50 Intralase cases.[1] In contrast, loss of suction with mechanical microkeratomes is very rare; in my experience, about 1 in every 1,850 eyes. So to achieve minimal pain and maximum ease for the patient, the Hansatome is preferable.

Patients who have had a flap made with the Intralase FS laser typically have had a slower visual recovery, with visual acuities of 20/20 to 20/30 on the first day after surgery versus 20/15 to 20/20 in cases where a mechanical microkeratome was used. Further study is needed to determine what long-term visual acuity differences may exist between the two devices.

The newly recognized phenomenon of track-related iridocyclitis and scleritis (TRISC) following LASIK with the Intralase FS laser is an area of great concern. The syndrome is extremely disabling for patients, who often have such severe photophobia that they need to wear sunglasses indoors. This effect can last for 3 to 6 months, and the aggressive steroid therapy being used to treat TRISC is risky. IOP may be elevated after LASIK, and the presence of a fluid pocket under the flap can lead to falsely low pressure measurements. I have seen four patients in my practice who sustained significant visual loss from optic nerve damage after using steroids post-LASIK, and they never had high IOP readings.

There has been some perceived marketing advantage to physicians' abilities to offer patients an "all-laser" LASIK procedure. Even in Los Angeles, where I practice and where the Intralase procedure has been heavily publicized, I have found very few refractive surgery patients who understand the concept of the procedure or have even heard of Intralase. The technology was introduced as a safer way to make a flap, but we are finding that it has similar complication rates to mechanical microkeratomes, and the laser may be associated with other problems such as TRISC. Surgeons making a choice between the two flap-creation technologies need to consider these factors.

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1. Nordan LT, Slade SG, Baker RN, et al. Femtosecond laser flap creation for laser in situ keratomileusis: Six-month follow-up of initial U.S. clinical series. *J Refract Surg.* 2003;19:8-14.

FURTHER REPORTS

As described elsewhere in this monograph (See "Not All Flaps Are Created Equal," on page 3.), the fact that the Intralase FS laser works by removing corneal tissue means that the resultant flap is smaller than the stromal bed. This fact can result in the occurrence of postoperative flap folds that may resist treatment by flap repositioning and require suturing to reduce symptoms and improve visual acuity.[10]

Postoperative flap interface inflammation has also been reported to occur after LASIK with the Intralase FS laser.[6,7,11,12] Although changing the laser's parameters may be sufficient to address this problem,[11] a new postoperative syndrome associated with the laser has appeared. At the 2004 meeting of the ASCRS, Brian R. Will, MD, described a phenomenon he called *track-related iridocyclitis and scleritis*.[13] This complication of using the Intralase FS laser in LASIK is characterized by eyes that have good

visual acuity and no apparent clinical signs upon examination, but in which the patient complains of debilitating photophobia starting 6 weeks or longer after surgery. Dr. Will found that a course of topical steroid treatment was effective in resolving the syndrome. He theorized that the syndrome was a result of inflammatory cytokines being produced in a "track" created by the Intralase FS laser between the LASIK flap interface and the sclera, which allowed the cytokines to pass into the perilimbal sclera and iris base.

A subsequent news report on Dr. Will's paper cited several different names for this syndrome, which had been observed by a number of Intralase users and was being studied by the laser manufacturer.[14] All of the surgeons interviewed for that article described a similar presentation of the syndrome, but had different accounts of the incidence. One surgeon estimated the incidence to be as much as 10% to 20%, although most others saw much less. All the surgeons used steroids to treat the condition, and some added Restasis (cyclosporine A; Allergan, Inc., Irvine, CA).

To date, there is only one published head-to-head clinical study comparing the Hansatome (and one other mechanical microkeratome) with the Intralase FS laser.[15] That comparison, which was made using the Hansatome without the new Zero Compression Head, found that the laser produced thinner flaps than the Intralase FS laser and did not disturb the corneal epithelium. No major flap complications were reported for any of the devices studied, and there were no statistically significant differences in postoperative UCVA, or any loss of BCVA.

A white paper prepared by Bausch & Lomb summarized data on refraction and higher-order aberrations after LASIK with the Hansatome versus the Intralase FS laser.[16] This study, conducted by Stephen G. Slade, MD, of Houston used the Hansatome with the Zero Compression Head in 21 myopes with closely matched manifest spherical refraction. Dr. Slade and his co-investigators performed same-day bilateral LASIK in one eye with the Hansatome and in the fellow eye with the Intralase FS laser. At 1 day, 1 week, and 1 month postoperatively, there were no statistically significant differences in manifest refraction or RMS values for total aberrations or individual higher-order aberrations. Postoperative pachymetry found that the Intralase FS laser flaps were thicker than nominal, whereas the Hansatome flaps were thinner.

In summary, the most recent data indicate that there are no significant advantages to using the Intralase FS laser versus the Hansatome, and case reports and personal anecdotes indicate that some unrecognized problems may occur after flap creation with the Intralase FS laser. Surgeons who are considering their options for upgrading or adopting new flap-creation technology into their refractive surgical practices should take all of these factors into account. ■

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Mechanical Microkeratomes Versus Intralase

Where technology stands today.

The information on LASIK flap-creation technology presented in this monograph from both clinical studies and anecdotal reports is diverse and challenging to interpret. In summary, a side-by-side comparison of the Hansatome and the Intralase FS laser (Intralase Corp., Irvine, CA) yields the following main points.

Flap Creation: The Hansatome creates flaps in seconds. The Intralase FS laser creates flaps in minutes, with the potential for loss of suction that may lead to patient discomfort and conjunctival hemorrhage.[1-4]

Postoperative Steroids: The Hansatome requires 2 to 3 days of postoperative steroids, whereas the Intralase FS laser necessitates their prolonged use.[5-7]

Cut: The Hansatome creates a smooth stromal bed; the Intralase FS laser microablates multiple spots that result in tissue removal by cavitation bubbles.[8-10]

Flap Edge: The Hansatome produces clean, even flap edges, whereas the Intralase FS laser creates a flap diameter that is smaller than that of the stromal bed. It may require "reseating,"[8,9] and could potentially create a "track" for cytokine migration.[11,12]

Flap Thickness: With the new Zero Compression Head, the Hansatome Excellus' flap cuts are thinner than nominal, whereas the Intralase FS laser's flap cuts are thicker than nominal.[13]

Flap Lifting: The Hansatome's flap cut is made cleanly from the stromal bed, making lifting easy. The Intralase FS laser's flap sticks to the bed via collagen fibrils that are not broken by the cavitation bubbles. Flap lifting is difficult, especially in initial cases.[1,14]

Cost: The Hansatome has a lower cost per case; the Intralase FS laser's is higher.

Safety and Efficacy: The Hansatome has well-established safety and efficacy, whereas there is emerging knowledge regarding an Intralase FS-laser-specific postoperative syndrome.[11,12]

Outcomes: There are no statistically significant differences in postoperative vision, higher-order aberrations, or complications found in direct clinical comparisons of the latest-generation microkeratome instruments.

All of these data show that the Hansatome is:

- proven to be efficacious in a clinical setting;
- a safe technology with few complications; and
- an economically sound investment compared with the Intralase FS laser (lower initial acquisition cost, lower maintenance costs, lower disposables cost versus user fee-per-case, etc.).

Mechanical microkeratomes thus appear to be the standard of care in refractive surgical practices today and for the near future. ■

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TODAY'S PREFERRED CHOICE: MECHANICAL MICROKERATOMES

By Richard L. Lindstrom, MD

Mechanical microkeratomes, specifically the Hansatome, represent the standard of care in my practice for the creation of LASIK flaps. This decision is based on this microkeratome's ability to produce outcomes that are equivalent to those achieved with the Intralase FS laser, but with greater efficiency and lower cost.

My own review of the literature confirmed that overall visual acuity outcomes are similar with mechanical microkeratomes and the Intralase FS laser, and the rates of occurrence of epithelial ingrowth are similar for both.

The Intralase FS laser is less likely to create an inadequate flap or to create flaps with epithelial defects, and it is more precise in achieving the desired flap thickness (±14µm, versus ±19µm with mechanical microkeratomes). There are more cases of diffuse lamellar keratitis, photophobia syndrome, and slipped flaps with the Intralase FS laser, however.

In terms of economics and logistics, the Intralase FS laser has a greater cost per case, and its longer operative time reduces patient throughput. More cases per hour can be performed with the Hansatome.

Surgeons who are considering whether to acquire the Intralase FS laser or a new model mechanical microkeratome, such as the Hansatome Excellus, are well advised to conduct a cost/benefit analysis that takes all of these factors into account. In my practice, such an analysis has established mechanical microkeratomes as the preferable alternative.

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