AS SEEN IN
www.eyeworld.org
EyeWorld
The News Magazine of the American Society of Cataract and Refractive Surgery
REPRINTED FROM MARCH 2006 VOLUME 11, NUMBER 3

Point: Should We Abandon Mechanical Microkeratomes?

by Y. Ralph Chu, M.D.

Mechanical microkeratomes are a time-proven technology that over the years have evolved in safety for patients, predictability in flap creation, and simplicity of use.

Having an instrument you are comfortable with that makes safe, effective flaps is part of providing patients with a high level of quality care. I have had successful experience using the Amadeus II (Advanced Medical Optics, Santa Ana, Calif.) microkeratome for seven years and find that this new generation of microkeratomes offers surgeons features that dramatically surpass previous technology.

With recent upgrades surgeons can now customize LASIK flaps for each individual eye with the use of variable head and ring sizes, automated suction control, computerized safety checks, and electronic voice confirmations that inform the surgeon he or she can proceed with the procedure, all improvements that make the most challenging part of LASIK simpler.

Recently, the creation of lamellar flaps with a femtosecond laser has received much attention, with the overriding message that this instrument provides better visual acuity outcomes, fewer complications, and considerable improvements on the reproducibility of flap thickness.

Head-to head studies comparing mechanical microkeratomes to the femtosecond laser have had conflicting results about which technology is favored for use in LASIK.

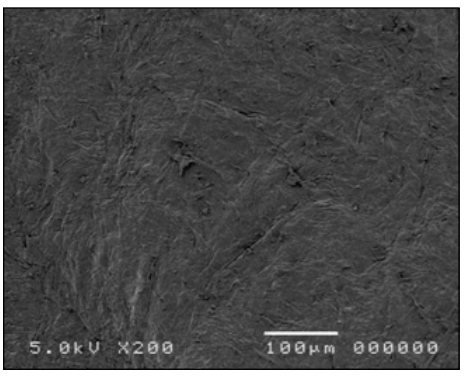
Many studies have shown similar visual acuity results between the two types of microkeratomes. The devices' flap thickness variations and complication rates also are similar in several studies.

However, there are two areas in which the mechanical microkeratome has advantages over the femtosecond laser: an increased length of time to create a flap with the femtosecond laser and cost savings—utilizing the femtosecond laser is a more expensive procedure overall.

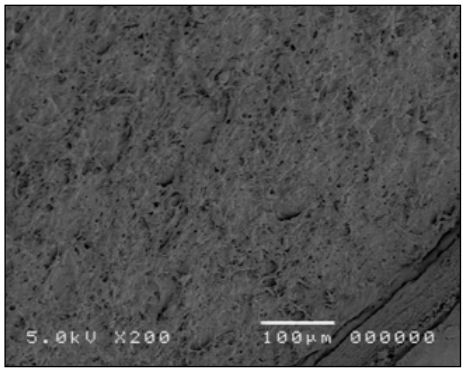
I will acknowledge that all-laser LASIK might create some initial buzz around your practice, but with patients paying out of pocket for additional femtosecond laser costs—which could be hundreds of dollars more per procedure depending on the volume of a practice—this could discourage some potential patients.

Visual acuity outcomes

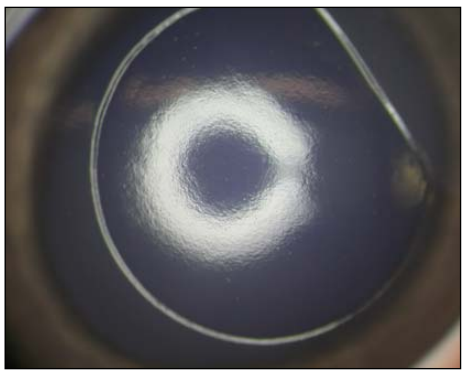
Results from a study conducted by **Trevor Woodhams**,(**M.D.**, Atlanta),



Stromal bed has mild areas of surface irregularity with significant smooth areas. Individual keratocytes can be visualized.



Stromal bed appears to have course sponge-like appearance with multiple crevices and irregularities.



This Epi-LASIK flap was created by the Amadeus microkeratome

Source: AMO

that compared patients who underwent LASIK with both the Amadeus II and a femtosecond microkeratome showed that visual acuity at three months post-op were actually greater in those who had the procedure with the Amadeus II. More than 90% of patients saw 20/20 after surgery with the mechanical microkeratome vs. 80% of patients who had surgery with the femtosecond laser at three months post-op.

As we increase our precision with wavefront ablations, the impact of any induced aberrations during lamellar surgery becomes a more important factor to consider. **Kerry Assil (M.D.**, Santa Monica, Calif.), addressed the importance of implementing wavefront-neutral lamellar technology and techniques in a recent study to determine if lamellar surgery induces significant higher-order aberrations.

Results of this preliminary study have shown that changes in HOA after the creation of a flap with the Amadeus II microkeratome are minimal and should not result in any negative impact to the refractive correction.

Flap quality

In another study, Renee Solomon (**M.D.**, Long Island, N.Y.), compared the flap creations of femtosecond laser vs. microkeratome lamellar keratectomy. A SEM analysis of the beds and edges of the keratectomy specimens was performed and surface and cut-edge characteristics of the keratectomies were analyzed. The stromal beds of the mechanical microkeratome and the femtosecond keratome were compared. Results showed the microkeratome and femtosecond laser have different morphologic features when they create a lamellar flap (see figure 1). In addition, greater surface irregularity is found in the bed of lamellar keratectomies created with the femtosecond laser.

In a study presented at the most recent American Academy of Ophthalmology meeting by Lee, H.M., et.al., comparing the Hansotome XP to IntraLase found the microkeratome to be statistically significantly more accurate with respect to intended flap thickness(116 vs. 152).

The microkeratome produced, on average, thinner corneal flaps with respect to intended flap thickness(-4,-11 vs. +32,+17), had a comparable standard deviation in flap thickness (16.1 vs. 14.4), and demonstrated equivalent UCVA, BCVA under high and low contrast conditions at one month (92% vs. 87%).

Safety

Another important consideration not to be overlooked has been the improved safety and consistency of mechanical microkeratomes. The microkeratome's evolution consistently has helped surgeons meet their intraoperative needs by creating viable flaps for LASIK patients.

Also, the Amadeus II now includes the ability to make Epi-LASIK flaps (see figure 2). This has allowed patients who previously may not have been the best candidates for LASIK to undergo a modern surface ablation procedure. Patients with dry eye, thin corneas, mildly asymmetrical astigmatism, or anterior basement membrane corneal dystrophy are candidates for Epi-LASIK. This "two-in-one" capability has improved safety for patients.

Patient complications

Safety is a critical concern of LASIK surgeons.

Any surgical procedure has potential complications. The creation of a lamellar flap is a surgical procedure and has certain risks whether the flap is made with a laser or a blade.

No instrument, whether a laser or a mechanical microkeratome, is complication free. I think the complications between two different devices may also be different, but to infer that a laser device is complication free is implausible. Complications such as ectasia, buttonholes, and DLK are risks with both femtosecond and mechanical microkeratomes. Others such as transient light sensitivity (TLS), are specific to the femtosecond microkeratome.

One area of recent debate is the development of thin flap LASIK. Some report that by using the femtosecond laser (IntraLase, Irvine, Calif.) surgeons can create a thinner flap than a mechanical microkeratome and avoid some of the potential complications associated with creating thicker flaps with a mechanical microkeratome.

However, I would argue that whether a flap is thick or thin, the creation of a flap is still surgical incision and, therefore, still has the potential for complications such as dry eye and ectasia. If there is any concern about creating a flap, I believe surface ablation should be performed. I think thin-flap LASIK should be "no-flap" LASIK.

Conclusion

Mechanical microkeratomes have evolved in their safety, predictability, and simplicity in creating lamellar flaps for the LASIK procedure. Also, with the increased use of surface ablation procedures through Epi-LASIK, having a device that can create both lamellar and epithelial flaps is not only convenient but also critical. From my perspective, this raises the bar for new technologies such as the femtosecond laser as they enter the microkeratome market.

ABOUT THE AUTHOR

Dr. Chu *is medical director,Chu Vision Institute, Edina, Minn. Contact him at 952-835-0965, yrchu@Chuvision.com.*

Advanced Medical Optics (Santa Ana, Calif.) arranged for this article

Counterpoint: The case for all-laser LASIK

by Louis Probst, M.D.

Two years ago I was pretty pleased with how my refractive surgery practice was going and the technology that I was using to treat patients.

I had performed more than 55,000 procedures with mechanical microkeratomes with minimal complications and pretty good results. I really did not see a reason to switch to the femtosecond laser, despite watching many of my colleagues make the jump and sing its praises. Then a couple of situations happened to change my mind. Today, I do 100% all-laser LASIK at two centers where I operate, and we're about to purchase one for our third center. Here's why I think all refractive surgeons should do the same.

Patients Really Do Care

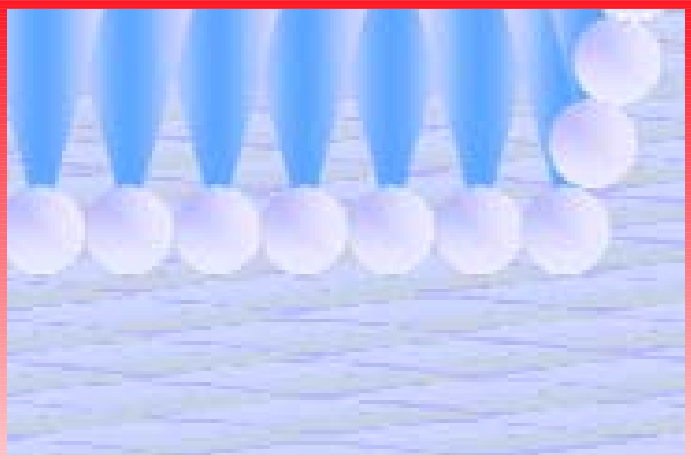
At one of the centers where I do refractive surgery, a competitor bought an IntraLase Laser (IntraLase Corp., Irvine, Calif.). 'Good for him,' we thought. I asked our referring physicians and optometrists if they thought it was hurting business—everyone said no.

We told ourselves that patients couldn't fully discern the difference between a flap created with a mechanical microkeratome and the laser. We told ourselves that we were providing the best service, plus we weren't too thrilled at making the investment in the femtosecond laser. We maintained the status quo.

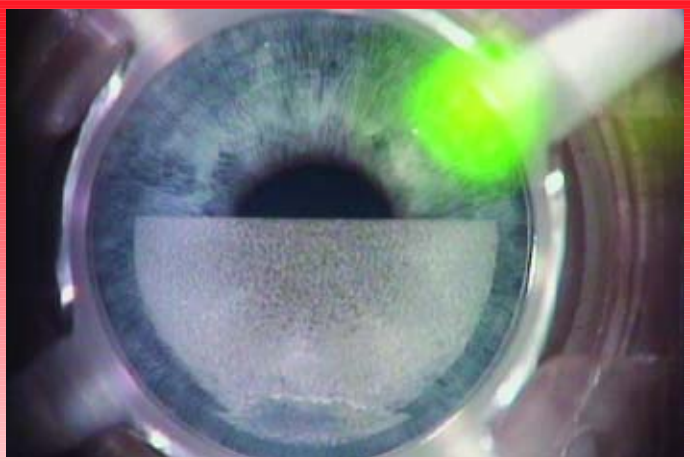
Then one day three potential patients came for evaluations. They were friends of one of our staff members, so we assumed conversion would be straightforward. But they also went to see the guy down the street with the femtosecond laser. Guess where they decided to have their LASIK done.

Shocked by the decision, we called the three patients and asked why they opted to go elsewhere.

Each said he was impressed by our facility, by the staff and the presentation, as well as the qualifications of the surgeon. Still they opted to go with the other refractive surgeon because they simply

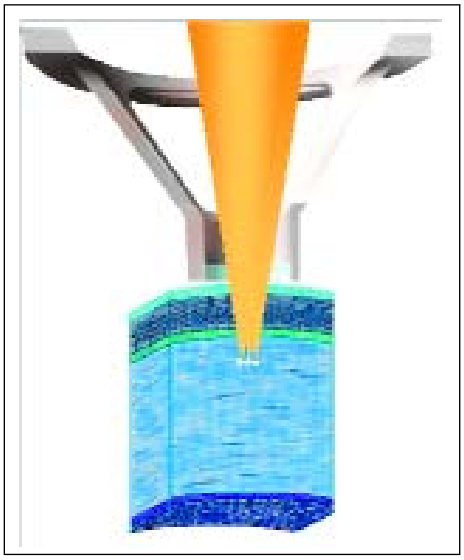


Disposable docking cone used for the application of cornea for application of the Intralase FS laser.



Horizontal spot pattern used by the Intralase FS laser to create the flap.

Source: Louis Probst, M.D.



Flap creation using the 30 KHz Intralase FS laser.

felt safer knowing that a laser was going to be used to cut the flap.

That was $12,000 in lost revenue that could not be ignored. The reality is that when a patient is sitting in that exam chair listening to you explain the LASIK procedure, he will understand the difference between a metal blade and a laser being used to create the flap. The patient may not understand the custom LASIK procedure, but how he can comprehend how the flap is created.

Shifting Sands

The second thing that happened in my practice that really crystallized my feelings about the benefits of all-laser LASIK were outbreaks of Sands of Sahara at the second center where I operate.

We had never experienced complications with the Hansatome Microkeratome (Bausch & Lomb, Rochester, N.Y.), but about two years ago, we had 15 patients develop Sands of Sahara.

I had to relift the flaps, irrigate, and treat the patients with topical steroids. Most responded well, but two patients developed grade 4Sands with central scarring of the cornea. It was extremely stressful for everyone involved, and the staff really worried about who was going to be next. We followed all the recommended protocols for getting rid of it, but six months later there was another outbreak. That was the breaking point.

With the IntraLase laser, you don't have to worry about something like Sands of Sahara because you can make it a completely disposable procedure. The applanation mask is disposable, and I use disposable instruments made by Moira, which means contamination should be almost non-existent.

In addition to less worry about contamination and infection, we also see fewer flap complications with the IntraLase. You can avoid buttonholes because you can visualize the flap as it's being created.

Some people have raised concerns about DLK, slipped flaps, and delayed visual recovery, citing them as reasons not to get an IntraLase. I honestly can say that after performing some 2,000 procedures with this laser the safety risks are the same as with a microkeratome, maybe even less with the laser.

A Joy to Use

Economics and safety certainly are two of the most critical factors in considering the switch to all-laser LASIK. However, I also think you need to consider ease of use as well as clinical results.

I first saw the femtosecond laser in 1999, when it was in the developmental stage. At the time it took two minutes to create the flap and additional time to life the flap. This seemed like a very long time, and I wondered how the patient would tolerate it.

Three years later IntraLase asked us to be one of the first centers to get the laser. By this time it was a 15-kHz laser, and the flap creation time had dropped to one minute. When the technology was presented to the optometric board, the members turned it down because they were suspicious of this new technology and didn't see the need.

Of course, things change, and now we have two 30-kHz IntraLase lasers that take just 35 seconds to create the flap. This laser is a joy to use. With the arrival of the 60-kHz laser, flap creation time will drop to 20 seconds, almost equalling the time it takes to create a flap with a mechanical microkeratome.

In terms of improved results with the IntraLase Laser, I was pleasantly surprised when I asked TLC for an analysis that compared custom LASIK results with a mechanical microkeratome to custom LASIK results with IntraLase. It turns out that there really is a difference.

In the IntraLase custom LASIK group, almost 20% of patients achieved a UCVA of 20/15 or better compared to 13% in the mechanical microkeratome group. Ninety-eight percent had a UCVA of 20/40 or better in the IntraLase group compared to 96% in the mechanical group. Certainly, the results for IntraLase are comparable, if not slightly better, than the mechanical microkeratome.

In the centers where I have IntraLase lasers, I still have mechanical microkeratomes, but now they sit idle. When I compare the two technologies, it makes no sense to use the mechanical microkeratome. Nowadays when I use an all-laser, custom LASIK procedure, it is one of the most satisfying procedures for me because I know I am providing state-of-the-art technology and state-of-the-art care for every patient.

ABOUT THE AUTHOR

***Dr. Probst** is the Medical Director for TLC Chicagoland in Windsor, Ontario, and Madison, Wis. He can be reached at (708) 562-2020 or louisprobst@comcast.net. Intralase (Irvine, Calif.) arranged for this article.*