

# OCULAR SURGERY NEWS<sup>®</sup>

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COVER STORY

## With resurgence of LASIK, debate reemerges on femto vs. mechanical microkeratomes

If people with vision correction needs learned one thing during the COVID-19 pandemic, it was that masks and glasses do not mix.

However, foggy glasses are just one factor that has contributed to an uptick in LASIK and other laser vision correction procedures over the last 18 months.

"I've been doing LASIK since 1995 when it was approved by the FDA, and there is no doubt that there has been a huge surge in interest," **Mark Whitten, MD**, said. "I've attributed that to the fact that people couldn't go anywhere. They couldn't spend their money anywhere. Wearing a mask with glasses makes it hard to see, and if they wore contacts, they may have been questioning whether it was safe to put their fingers in their eyes."

**Ali Fadlallah, MD, MS, MPH**, who practices in the United Arab Emirates, said he has seen LASIK procedures grow by 35% since COVID. Although mask complaints were a major cause for many seeking the procedure, he said people were also spending their money in different ways.

"Patients were not spending their money on traveling," he said. "We saw COVID as a cause for patients spending their money elsewhere, which was mainly

*Cover story continues on page 10*



**LASIK treatments currently offer an "extraordinary level of safety and efficacy," according to Roy Rubinfeld, MD.**

Source: ReVision

## Screening needed for pentosan polysulfate sodium-associated maculopathy

Interstitial cystitis, also known as bladder pain syndrome, can be incapacitating for patients, keeping them up at night with constant feelings of urinary urgency.

Currently, the only approved medication for the condition is Elmiron (pentosan polysulfate so-

dium [PPS], Janssen). However, more than 20 years after its approval in 1996, a case series by investigators from Emory University found that chronic exposure to the drug may be associated with maculopathy in patients.

"They put together a retrospective case series of six patients and said, 'Hang on a second. Why are these people having pigmentary changes in their maculas?'" **Christina Y. Weng, MD, MBA**, of Baylor College of Medi-

cine, told *Ocular Surgery News*. "They finally realized that the unifying factor was that they were all on PPS treatment. That opened the community's eyes to the fact that the drug could potentially lead to this condition."

In most cases, retinal findings do not appear until a patient has been on the drug for 10 to 15 years, according to **Elliott Sohn, MD**, of the University of Iowa. Because patients

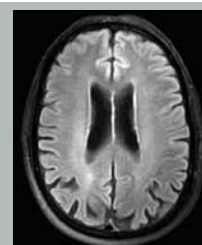
*Maculopathy continues on page 19*



Christina Y. Weng

**Grand Rounds at the New England Eye Center: Man presents with visual field changes over 1 year**

Left homonymous hemianopia was noted during examination. **26**



## COVER STORY

# In modern LASIK, both microkeratomes and femtosecond lasers get the job done

*continued from cover*

in the health sector. That meant more plastic surgeries and more LASIK.”

The gradual transition back to normal has not slowed this rise in LASIK either. According to the Refractive Surgery Council, laser vision correction procedures increased by nearly 200% in the second quarter of 2021 compared with the same time period in 2020 when the pandemic was still in the early stages. The council called the increase “the strongest H1 laser vision correction procedure volume growth in nearly a decade.”

“[Laser vision correction’s] current momentum is a reflection of consumers’ desire to take control of their vision in what has been an uncertain, yet optimistic, moment in time,” Jim Wachtman, chairman of the Refractive Surgery Council, said in a press release. “With the surge in travel and other pastimes, it’s clear life and lifestyle are firm priorities, and those dealing with vision correction issues are now unwilling to compromise with glasses or contacts.”

Another reason for increased LASIK volume is that masks make eyes dryer and more uncomfortable, reducing comfort and wear time of contact lenses, according to **Roy Rubinfeld, MD**.

With more people seeking LASIK treatments, surgeons have several methods to get the job done.

“As refractive surgeons, we have been hoping that more people would take advantage of these remarkable technologies because we are at a simply extraordinary level of safety and efficacy,” Rubinfeld said.

## Demand for ‘bladeless’ LASIK

The most critical step in the LASIK process is how patients pick their physician, according to **Mark S. Gorovoy, MD**. He said the three main avenues for patient choice are advertising, word of mouth and referral.

“I always warn patients that the advertising route is the least effective way of picking a doctor who is competent and caring,” he said. “In my practice, it’s all referral and zero advertising.”

The introduction of femtosecond

laser flap makers led to a rise in marketing for so-called “bladeless” LASIK, and “horror” stories from earlier days of older mechanical microkeratomes spread to potential patients.

In more than 20 years of practice,



**“Anything with LASIK, whether using the microkeratome or the femto, you have to get through the learning curve.”**

— MARK S. GOROVOY, MD

Rubinfeld said he has used more than a dozen different flap makers for LASIK procedures, including both femtosecond lasers and mechanical microkeratomes. While he has had good and bad experiences with both, he said the dogmatic push for bladeless LASIK is a bit unfounded.

“There were some really challenging early microkeratomes that produced a lot of abrasions and didn’t have great suction,” he said. “But people often tend to want to throw the baby out with the bath water when you start talking about mechanical microkeratomes. They might say all mechanical keratomes, including the advanced ones, are outdated, which is simply wrong.”

Rubinfeld is among a number of experienced laser refractive surgeons who have continued or resumed the use of mechanical microkeratomes to create LASIK flaps. Although surgeons have had good experiences with newer devices, there is still some trepidation

among squeamish patients when they think about blades near their eyes.

“One of the issues in all of this is that the manufacturers of the femto devices have done an excellent job marketing their instruments and then marketing the fact that you should have bladeless surgery, whereas the microkeratome people haven’t done much marketing at all,” Whitten said. “You have laser refractive providers telling patients that they are technically superior by using femto, but in fact, if you compare femto to a modern microkeratome, that’s just not true.”

In one study published in the *Chinese Medical Journal*, researchers compared LASIK flaps made with an IntraLase femtosecond laser (Johnson & Johnson Vision), a modern mechanical microkeratome (Moria One Use-Plus) and an older microkeratome.

They enrolled 161 eyes of 81 consecutive patients and randomly assigned them to treatment with one of the three devices. One month after surgery, investigators measured the flap thickness at 20 locations on each cornea.

The flaps created by IntraLase and One Use-Plus were more uniform, regular and accurate than those created by the older mechanical microkeratome.

Experts said such studies show that modern microkeratomes can do the job just as well as lasers in the hands of an experienced lamellar surgeon. For some, that experience with different devices has informed which side of the divide they currently fall on, and they hope patients can look past the marketing jargon.

“If you have appendicitis tonight and you go in for surgery, I don’t believe you’re going to ask the doctor whether he’s going to open your skin with a blade or a laser,” Whitten said. “What you do is look at the surgeon and say,



‘Please do your best job.’ Consequently, I don’t have a large discussion with my patients unless they ask me. If they do, I tell them the results are the same with both, and I choose what I think is best for them.”

### The case for femto

Femtosecond laser flap creation has backers, and Gorovoy is one of them. Although he had good results with a mechanical microkeratome for 25 years, Gorovoy made the switch to femto about 2 years ago when he upgraded to the Alcon LenSx femtosecond laser



**“You have laser refractive providers telling patients that they are technically superior by using femto, but in fact, if you compare femto to a modern microkeratome, that’s just not true.”**

— MARK WHITTEN, MD

system for cataract surgery. The device can also be used to create LASIK flaps.

“I know there are some disadvantages of the femto, and certainly the microkeratome is more efficient and less costly,” he said. “But I definitely saw some advantages of the femto, and I figured I would go with the newer technology.”

Some of the decision had to do with the local market in Fort Myers, Florida, where Gorovoy practices. Many practices advertise all-laser LASIK, and many more do PRK on nearly all of their patients. The decision to move toward femto was important to keep up.

“They’re not even making a flap, and they are able to say it’s all lasers and no blades,” Gorovoy said. “There is always a bit of peer pressure based on your market, as well.”

Because he originally bought the LenSx system for cataract surgery, Gorovoy said he had to dial it in for LASIK procedures. That meant tweaking the parameters and learning the best way to get a clean cut on the flap and avoid manual dissection.

“There was a bit of a learning curve with the laser just to get those parameters right,” Gorovoy said. “There is some inconsistency. Some flaps will just peel off with the laser, and others you’ve got to struggle with because the cuts are not confluent across the surface.”

In a study published in the *Journal of Refractive Surgery*, researchers assessed the safety and complication rate of femtosecond laser flap creation in more than 3,000 eyes. They observed several intraoperative complications, including flap tear, free cap, bubble escape and flap folds. However, the complication rate was low. The total complication rate was 0.63%, and the intraoperative complication rate was 0.33%. All of the intraoperative complications were managed on the same day.

There are two main factors that make a femtosecond laser a better option for LASIK flap creation, according to Gorovoy. First, it provides an exact diameter of the flap size, and second, it provides an exact depth.

“Microkeratome does fine for flap size,” he said. “If you have a flap that’s 9 mm vs. 8.8 mm or 9.2 mm, clinically that’s not going to make much of a difference for 99.9% of patients. However, the depth factor can be an issue in some cases, and there’s always a bit of fear because the microkeratome doesn’t cut to an exact depth.”

In addition, in the past, he had several issues with older models of microkeratomes, such as buttonholes and partial flaps, which also contributed to his transition to femtosecond flap creation.

There is a learning curve for any LASIK flap-making device.

“Anything with LASIK, whether using the microkeratome or the femto, you have to get through the learning curve,” Gorovoy said. “You have to have a certain volume. That’s why I think these other surgeons in my area are doing PRK. They don’t have a consistent volume, they’re younger, and they don’t have the learning curve.”

“I’m comfortable making corneal flaps, but for the average person who’s just a cataract surgeon or a young doctor who wants to get into this, they really need a mentor.”

### Mechanical microkeratomes

For surgeons who opt for the mechanical microkeratome route, they say the process is simple and repeatable and has few complications, particularly with newer advanced devices, such as the One Use-Plus.

“I started doing LASIK back in the day when we had nothing but micro-

## POINT / COUNTER

### What LASIK flap maker do you use, and why?

#### POINT

#### Advantages of femtosecond laser

I use the Ziemer CrystalLine femtosecond laser system to make my LASIK flaps because I think femto is the safest and most effective way to make those flaps.

When I first started in practice, the previous owner I worked with used a mechanical microkeratome, and I remember seeing how inconsistent it was in regards to flap thickness and diameter depending on the shape of the patient’s cornea. There seemed to be a lot of nuance and a steep learning curve required to determine exactly the best way to optimize it for different patients.

The biggest advantage of the femtosecond laser is consistency. Regardless of the shape of the cornea, the femtosecond laser makes a perfect flap with uniform thickness from the edge to the center of the flap almost every time. This results in a much lower incidence of free caps, partial flaps, buttonholes and epithelial defects.

Because of the smoothness of the bed, there is also some evidence, at least empirically, to suggest a lower rate of late flap dislocation for femto flaps compared with microkeratomes.

Because it is more precise, the femtosecond laser also allows you to make consistently thinner flaps. I routinely make 90- $\mu$ m flaps for my LASIK procedures. By doing that, you can conserve a lot more tissue than you could with a microkeratome. The flap centration is also adjustable after suction with some femtosecond lasers, which helps ensure ablation on the visual axis.

That is not to say that the femtosecond laser is without complications. I have had a small handful of buttonholes and free caps, but the chances of that happening overall are much rarer. The other complications specific to the femtosecond laser are related to the energy used to create the flap, including transient light syndrome, opaque bubble layer and anterior chamber bubbles. Fortunately, most of these are nuisances that resolve quickly and are not the kinds of complications that affect the patient’s ultimate visual outcome. Moreover, we used to think that the incidence of diffuse lamellar keratitis was maybe higher with femto, but the lower energy settings available today make this less likely. Of course, the femtosecond laser is an added cost, but if it were my eyes or my family’s eyes, I would want the safest and most effective device that we have. I think that is the femtosecond laser.

**Dagny Zhu, MD**, is from NVISION Eye Centers in California. Disclosure: Zhu reports she is a consultant for Alcon.



Dagny Zhu

#### COUNTER

#### Advantages of microkeratome

I brought a Zeiss VisuMax femtosecond laser into my practice in 2014, and now, I use it for about 60% of my LASIK cases. However, a good mechanical microkeratome is still an important part of any refractive surgeon’s toolkit.

Surgeons in the United States have been persuaded to think that femto is overwhelmingly better by successful marketing efforts of the femto manufacturers. However, we have learned through tracking surgical outcomes that both technologies yield comparable results with extremely low risk of unanticipated events such as buttonhole. Before surgery, we tell patients that procedures using femto might be slightly more comfortable and a few seconds shorter, but the statistical results of both systems are equivalent. Consistency of flap thickness is much tighter with femto than microkeratome, and this is a factor in counseling those with thinner corneas. Having the microkeratome allows us to offer LASIK at two different price points. For folks who may be economically challenged, either because of young age or the pandemic, it is a good option to help them afford LASIK if we can go the microkeratome route.

We also use microkeratomes in certain situations in which it might not be possible to use femto, including steep corneas above the manufacturer’s recommended range for specific platforms. We had an incident recently in which the air conditioning in our laser room failed on the day of surgery and the temperature rose to a point above which the use of the VisuMax is permitted. Because we had the mechanical microkeratome on hand, we were able to switch and salvage surgery for patients on that day. We did not have to disappoint them and crater a fairly significant surgical lineup.

I think the learning curve for microkeratomes is steeper than for femto. I make these choices from a position of significant volume, as well as accumulated comfort and experience.

**David Wallace, MD**, is from LA Sight in Los Angeles. Disclosure: Wallace reports no relevant financial disclosures.



David Wallace

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keratomes,” Neil Shmunes, MD, said. “But they started falling out of favor in America because we sell technology, and the thought was that the newer technology was better. The fact is, if you’re cutting, you’re cutting, whether it be a blade or a laser or whatever. There are a lot of ways to cut tissue.”

Shmunes said he used a femto flap maker for a period of time, but it never grew on him. He said it would cause



**“We saw COVID as a cause for patients spending their money elsewhere, which was mainly in the health sector. That meant more plastic surgeries and more LASIK.”**

— ALI FADLALLAH, MD, MS, MPH

tissue bridging issues that led to more manual dissections.

“I started doing side-by-side comparisons, and my complication rate with a femto flap was actually a little bit higher than what I was seeing with microkeratomes,” he said.

Fadlallah said many centers in his area made the switch to femtosecond lasers in 2006. However, in the last few years, there has been a near complete reversal in that trend, with most making the switch to a more modern mechanical microkeratome.

“The microkeratome industry has been able to improve the devices, making them easier, faster and more predictable,” he said. “The safety is extremely high, and I have never had a significant complication in 7 years with the Moria One Use-Plus.”

One of the chief concerns about using femtosecond flap makers is the potential for inflammation that can develop in the days after a LASIK procedure. Fadlallah said his incidence of lamellar keratitis is about 3% after LASIK with femtosecond laser flap creation. With modern mi-

crokeratomes, he said the incidence has been about one case per 1,000.

“The femto does a series of small cuts at 5  $\mu$ m to 7  $\mu$ m, and there can be a little difference from one point to another,” he said. “If this happens, we have to dissect these places, which can create a lot of inflammation. The blade is not doing this. It’s one cut, and I tell patients they can drive home in 4 hours.”

Rubinfeld said it is understandable that patients can be uncomfortable with the idea of a blade near their eye, but part of the surgeon’s job is to reassure and educate them about the safety of the procedure.

“I don’t lose patients because of technology,” he said. “I let them know all about my experiences and about how flaps are made. It often surprises people when I clarify that ‘bladeless LASIK’ also makes a cut. For many, the word ‘bladeless’ wrongly implies that no cutting or flap occurs. The real objective for a refractive surgeon is to get people to feel comfortable and to help them understand that a lot of what they’ve

heard through the grapevine about LASIK and refractive surgery are really myths.”

The One Use-Plus has been a game changer for some surgeons and represents an upgrade over what was in use in the earlier days of LASIK. Whitten said that even some of the most popular early microkeratomes did not work all that well.

“When some of the problems associated with some of the older blades started surfacing, the laser occurred right at that moment,” he said. “It was the single greatest reason people switched to the laser. It was absolutely a better device. If the Moria One Use-Plus was around before, there would be a lot less people using laser now.”

Whitten said the benefit of the One Use-Plus is its simplicity. There are no rotary blades. It makes one pass at the cornea to make a flap and comes right out.

“We don’t take the Gillette blade out and place it in the instrument like we did 30 years ago,” he said. “This is a completely sealed device, and the track

record is such with this instrument that I haven’t had a failure in 100,000 cases.”

Shmunes said that a lot of the debate about femtosecond vs. microkeratome flap makers comes down to selling technology. When he considers the factors, from costs to complications, he said he would rather use a straightforward device that gets the job done.


“You don’t need a rocket ship to go to the grocery store,” he said. “If I can do it with a blade and the complication rate is ridiculously low, that’s the way I’m going to go. I have the ability to use femto on patients that ask for it, but I

**“If I can do it with a blade and the complication rate is ridiculously low, that’s the way I’m going to go.”**

— NEIL SHMUNES, MD

generally try to talk them out of it because it will save them money.”

For patients looking to undergo a LASIK procedure, Whitten said they need to find the right surgeon.

“The most important thing they should do is find a doctor who has experience, get referrals from happy friends and meet with them before the procedure,” he said. “If they do those things, I think they’ll be happy with their choice.” — by Alex Young 

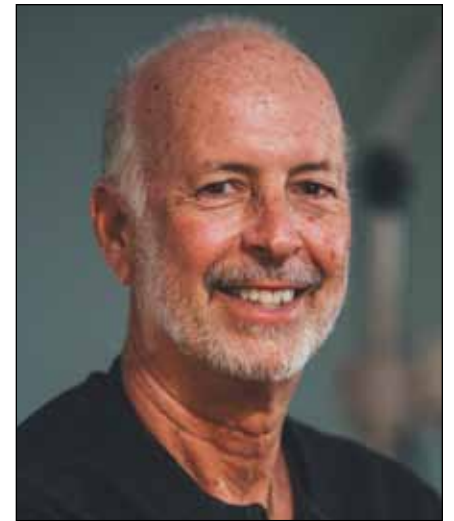
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