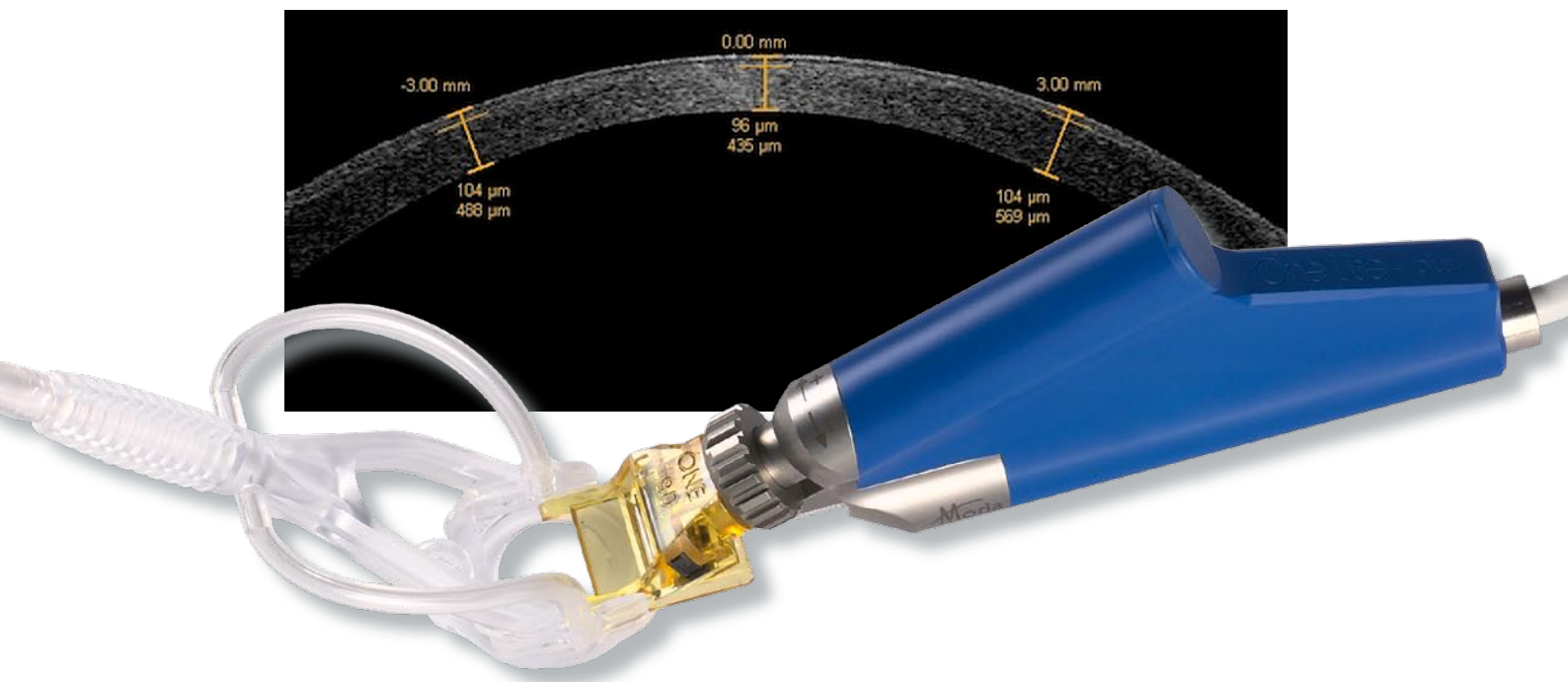


Patient and Practice Benefits of SBK

without the complications and cost of Femto-LASIK



Moria One Use-*Plus* SBK
compared to Femtosecond Lasers
in Thin-Flap LASIK (SBK)



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Why Mechanical Microkeratomes are here to stay.

My ideal femtosecond laser would:

- *Be small enough to fit under my excimer platform and eliminate the need to move patients from one device to another*
- *Rarely need service and when necessary the manufacturer could ship me a loaner unit overnight.*
- *Not leave tissue bridges and therefore allow me to lift all flaps atraumatically.*
- *Not leave air bubbles in the stroma or anterior chamber and would never produce a surgical delay or prevent iris registration.*
- *Produce almost no inflammation and would not require intensive topical steroids.*
- *Cost under \$40,000, would have an annual maintenance contract under \$4000, and cost less than under \$100 to operate per case.*
- *Consistently create perfect flaps between 95 and 105 microns with a 3.5 mm hinge and 8.5 mm diameter.*
- *Be almost devoid of DLK.*
- *Be disposable and portable.*
- *Not have a click fee.*

When they make my ideal femtosecond I will consider giving up my Moria One-Use-Plus SBK mechanical microkeratome. But I am not sure this will ever happen because during surgery, the flaps created by the Moria OUP SBK are thin, dry, resilient, and natural. The femtosecond flaps look oedematous, white, rubbery and unnatural. I believe the flaps created by finely honed steel are more physiologic than those generated from a series of tiny plasma explosions. I admit, we haven't yet found any clinical correlation to these findings.

The track record for steel is well established. There are many unknowns in the long term effects of femtosecond laser energy delivered to the cornea. I also doubt we will ever be free from a click fee. Years ago the Harvard Business Review suggested that industry "share in the surgeon's success" with laser vision correction. Most excimer laser companies and all femtosecond companies have strictly adhered to that recommendation.

I am loyal to my Moria, unmoved by marketing pressures, immune to industry propaganda, and ignoring the well-paid pundits. I am confident I am providing the best care, making the best flaps, respecting the integrity and physiology of corneal tissue. I am working cost-effectively without being victimized by yet another predatory click fee.

Those surgeons confident in their clinical skills, respectful of corneal tissue, and interested in controlling costs will stand firmly with Moria's OUP SBK. Mechanical microkeratomes are here to stay. I look forward to the next generation of Moria mechanical microkeratomes, perhaps with a choice of hinge positions.

Warm regards,

A handwritten signature in black ink that reads "James S. Lewis MD". The signature is written in a cursive, flowing style with a prominent flourish at the end.

James S. Lewis, MD

Lewis JS. Microkeratomes are here to stay. Ocular Surgery News SuperSite, March 1, 2009

Dear Doctor,

I hope you find the following roundtable discussion on sub-Bowman's keratomileusis (SBK) compelling. Seven surgeons from around the world share their experiences with SBK with an advanced mechanical microkeratome. These surgeons believe the best depth for LASIK is at approximately 100- μm , and that SBK or thin-flap LASIK will soon be the dominant choice of laser refractive surgeons.

David Leaming, MD, and Richard Duffey, MD, have been tracking and reporting on trends in refractive surgery for many years. In the latest survey, they sent questionnaires to 1,364 physician members of the International Society of Refractive Surgery of the American Academy of Ophthalmology (ISRS/AAO). Of those, 223 (16%) responded.

The 2008 survey results demonstrate a clear trend toward thinner LASIK flaps (Fig 1). Half of surgeons currently prefer a 120- to 130- μm flap. The percentage of those favoring a 100- μm flap jumped considerably in 2008, and has nearly doubled since 2006, while the share preferring a 150- μm or thicker flap has been dropping consistently. A thinner flap, of course, leaves more room for custom ablations and for the residual stromal bed. The survey data show that surgeons' comfort level with a 250- μm residual bed is decreasing. Nearly 40% of the survey respondents indicated they prefer to leave at least 275 μm of residual stroma (Fig 2).

There are many reasons to choose SBK, not the least of which is a reduced risk of corneal ectasia. And for those who want to make thinner flaps, it is important to know that there is an advanced microkeratome that performs as well as or better than femtosecond lasers for SBK. Please read the views and studies presented here for more information on this important topic.

Warm regards,



Fabienne Duclos
Moria VP International Marketing & Scientific Affairs

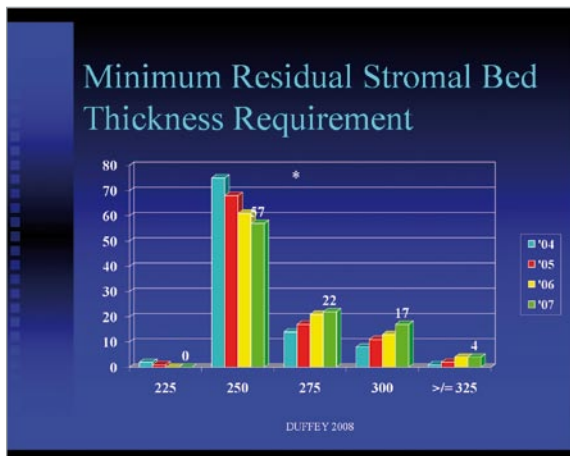
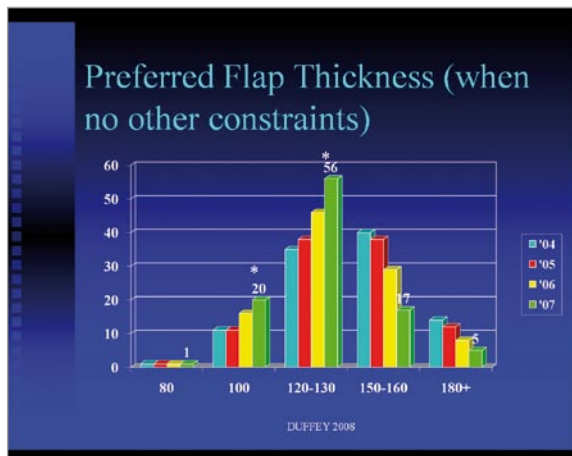


Fig.1 (left): 100-micron flap has doubled in practice in 3 years

Fig.2 (right): The barrier of untouched stroma increases:

- safety-conscious reasons
- case of future enhancement

Datas from US trends in Refractive Surgery: 2008 ASCRS Survey by Dr. Duffey

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Thin is In: SBK with an Advanced Mechanical Microkeratome

During the 2008 ESCRS and AAO meetings, experts from around the world discussed the rationale and best techniques for performing Sub-Bowman's Keratomileusis (SBK). They concluded that SBK offers many advantages over standard-flap LASIK. Performing SBK with an automated microkeratome achieves results that are as good as or better than those with any femtosecond laser, at a significantly lower cost.

The rationale for SBK

Moderator: What are the advantages of making thinner LASIK flaps?

Carlos Vergés, MD, PhD: The most important advantage is safety. From John Marshall's work, we know that the strongest parts of the cornea are the anterior, more peripheral layers¹. The greater the insult to these portions of the cornea, the greater the impact on the cornea's biomechanical integrity. Our comparative studies have demonstrated a 30% reduction in corneal strength with standard, thick-flap LASIK at three months compared to only a 17% reduction with SBK².

Surface ablation may be the safest way to perform refractive surgery, but LASIK clearly has advantages in terms of rapid visual recovery and patient comfort.

We conducted a 4-way comparison of standard flaps with the Moria M2 Single Use microkeratome, Sub-Bowman's Keratomileusis (SBK) flaps with the Moria One Use-Plus SBK microkeratome or the IntraLase* 60kHz femtosecond laser, and Epi-LASIK surface ablation². Both SBK procedures had about the same corneal hysteresis (CH) effect, a 16-17% reduction in corneal strength, compared to nearly 30% reduction

in corneal strength with standard thick-flap LASIK. These and other studies provide support for the growing consensus that thinner flaps are better. I personally no longer make standard flaps, but aim for about a 100- μ m flap in every LASIK case.

***"I personally no longer make standard flaps, but aim for about a 100- μ m flap in every LASIK case."
Dr Vergés***

Osama Ibrahim, MD, PhD: My colleague in Alexandria, Dr. Ahmed El-Massry, has shown an 18.65% reduction in corneal hysteresis (CH) at one month postop^{3,4}, which is very consistent with Dr. Vergés' results. By contrast, though, we saw a bigger reduction, of about 25%, in CH following femto-SBK⁵ (Fig 1).

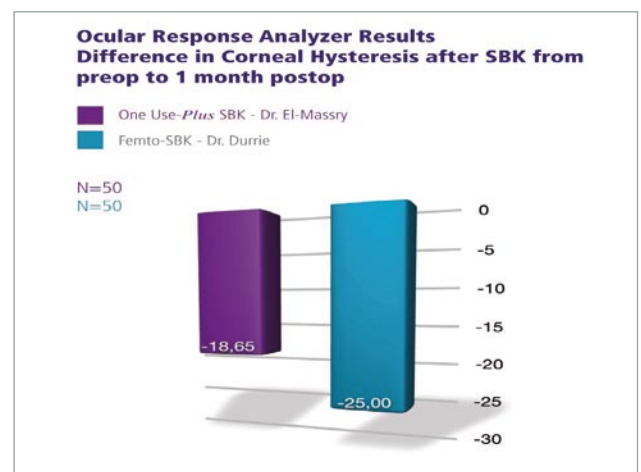


Fig.1: Better biomechanical stability with Moria One Use-Plus SBK than with Femto-SBK³⁻⁵

Richard J. Duffey, MD: I have also moved away from standard flaps. For the past five years, I've been making thin flaps in almost every LASIK case. Thinner

flaps expand the range of people we can treat, reduce the incidence of post-operative dry eye, and speed visual recovery⁶. They also produce more consistent flap thicknesses with a lower standard deviation compared to traditional LASIK flaps⁶.

James S. Lewis, MD: Sub-Bowman's keratomileusis (SBK) really combines the advantages of LASIK and surface ablation. Like surface ablation, SBK leaves the patient with more residual stromal tissue. And like standard LASIK, it offers patients quick, pain-free recovery. In fact, recovery may be even faster with SBK. The thinner flap absorbs much less fluid than a 130- to 150- μ m flap, and the endothelium is able to pump fluid out of the cornea more effectively and efficiently, so any corneal edema resolves very quickly. Immediately after SBK, patients can often see 20/30 to 20/60.

Another important issue is the difference in the quality of the stromal bed at the SBK depth. We know the cornea is not homogeneous. The collagen fibers are woven less tightly as one gets deeper into the cornea. An Epi-LASIK flap, at about 50 μ m, gives us the most pristine optical surface. Just below Bowman's, at 80-100 μ m where SBK is performed, the surface is still very smooth, but at 150 μ m, the traditional depth for LASIK, the collagen is rougher and the surface is not ideal for the carefully calibrated custom ablations we perform today⁷ (Fig 2).

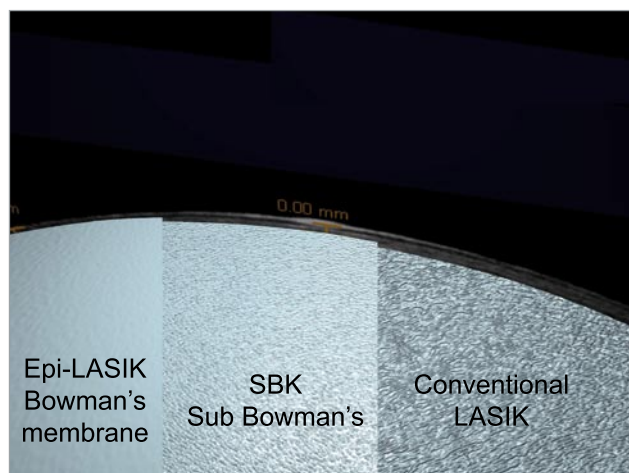


Fig 2: Bed smoothness related to flap thickness⁷

Ibrahim: We used to consider a thin flap to be a LASIK complication. I remember that surgeons were concerned that chord length disparity between the ablation zone and the flap could lead to the “cracked-mud” appearance of tiny folds in Bowman's membrane.

We worried that a thin flap would be more prone to wrinkling. Interestingly, though, quite the opposite is true, and the increased biomechanical strength of the cornea after SBK compared to standard LASIK makes it clear that SBK is the way to go.

“the increased biomechanical strength of the cornea after SBK compared to standard LASIK makes it clear that SBK is the way to go.”
Dr Ibrahim

Richard Norden, MD: Many people are surprised to find that striae are less of a problem with thinner flaps because less stroma is involved. I think the incidence of striae may be similar at all flap thicknesses, but a 40- μ m stromal wrinkle simply doesn't have the same visual significance as a 110- μ m stromal wrinkle.

Laurent Gauthier-Fournet, MD: The only advantage to making a thick flap is ease of handling. Delicate, thin flaps are slightly more challenging to handle, but one can readily adjust, given the potentially reduced risk of ectasia. I routinely perform SBK for all myopic LASIK cases. With thinner flaps, I can now perform LASIK up to about -12 D, which has greatly reduced the indication for phakic IOLs in my practice.

“I can now perform LASIK up to about -12 D, which has greatly reduced the indication for phakic IOLs in my practice.”
Dr Gauthier-Fournet

For hyperopic cases, I like to make a very large, 9-mm flap to allow space for the ablation, and these large flaps are easier to handle if they are a little thicker and more rigid. Of course, the hyperopic ablations remove less tissue and are performed in the periphery where the cornea is thicker, so the goal of preserving tissue is much less urgent in these cases compared to myopic ones.

Daniel Casado Rodríguez, MD: I began making thin flaps about a year ago and now prefer SBK for all my LASIK cases, regardless of refractive error or corneal thickness. The potential safety advantages are enormous. Anecdotally, I feel that my SBK patients achieve better quality of vision than with standard LASIK. We are seeing less dry eye and a lower rate of enhancement, as well.

SBK Technology

Moderator: Can you use a mechanical microkeratome for SBK? Some people claim that only a femtosecond laser can be used to perform thin-flap LASIK.

Lewis: That is a common misperception. Any flap that is 100 µm thick and about 8.5 mm in diameter should be considered an SBK flap. Patients may initially be attracted to the idea of “all-laser” LASIK, but my role as their surgeon is to educate them about the real advantages and disadvantages of various options. I think we have all had the experience of cataract patients who say: “You do the surgery with a laser, right, doctor?” When we tell them how the procedure is done, they don’t walk away just because there is no laser keratome involved.

“Patients may initially be attracted to the idea of “all-laser” LASIK [...] but they don’t walk away just because there is no laser keratome involved.”
Dr Lewis

Norden: The definition of SBK is vague. If you define it as cutting a flap just below Bowman’s layer, I think we can actually get closer to Bowman’s with a mechanical microkeratome than with a femtosecond laser. I have used both technologies for SBK and, in my hands, the only advantage of the femtosecond laser, despite the huge cost differential, is the nicely angled side cuts. I have not seen any advantage in centration, visual outcome, or the precision of the flap cut. And there are some real disadvantages to the femtosecond laser, including longer suction time and increased discomfort for patients.

“we can actually get closer to Bowman’s with a mechanical microkeratome than with a femtosecond laser”
Dr Norden

Ibrahim: I have used both the IntraLase* 60kHz femtosecond laser and the Moria One Use-Plus SBK system and prefer the latter. In my hands, the predictability of flap thickness is very similar—mean

thickness of 108 µm with the microkeratome versus 110 µm for IntraLase*, with similar standard deviations and ranges^{3,4}. The flap hinge location and side-cut angle are more customizable with the femtosecond laser, however, these are very minor advantages.

“I have used both the IntraLase 60kHz femtosecond laser and the Moria One Use-Plus SBK system and prefer the latter.”
Dr Ibrahim

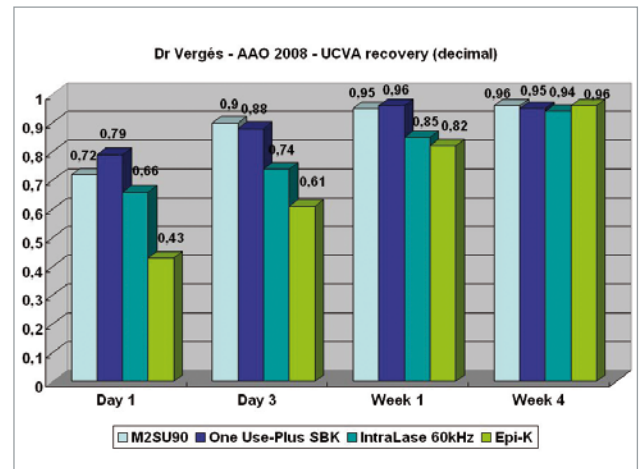


Fig.3: UCVA recovery depending on procedure²
26 eyes of 13 patients per group

Vergés: In our comparative study, the flap thickness and standard deviations were comparable for both SBK groups. Visual recovery, however, was considerably slower with the femtosecond laser and reached equivalence with to One Use-Plus SBK group only at Week 4 postop² (Fig 3). There was also more discomfort with the femtosecond laser. Over the first two days, the discomfort with femtosecond LASIK was closer to that of surface ablation than to microkeratome SBK or LASIK. The two methods of making thin flaps had a similar impact on postoperative higher-order aberrations.

“Visual recovery [...] was considerably slower with the femtosecond laser and reached equivalence with to One Use-Plus SBK group only at Week 4 postop”
Dr Vergés

Duffey: The postoperative Day 1 results I obtained in my first 50 cases with the Moria One Use-Plus SBK were a little better than I have been able to achieve in the past with the LSK One microkeratome⁶ and were considerably better than Day 1 results reported by Durrie et al using IntraLase* 60kHz and Ziemer Da Vinci*⁸, and Dishler et al using VisuMax* femtolasers⁹ (Fig 4). As Dr. Vergés also reported, I saw no clinically significant differences in induction of higher order aberrations (HOAs) between the two flap-making methods⁶.

There were significant differences in comfort, though. In a comparison study, I created thin flaps in 10 consecutive myopic eyes undergoing SBK with the IntraLase* FS 60-kHz and then 10 matched consecutive eyes with the Moria One Use-Plus SBK microkeratome⁶. All were treated with the same excimer laser.

The IntraLase* group tended to feel a sharp, aching pain in the early post-operative period versus more of a foreign body sensation in the microkeratome eyes. The femtosecond group reported about twice as much pain during surgery as the microkeratome group, although intraoperative discomfort was mild for both groups. The most intense pain was one to five hours after surgery, when the femtosecond group suffered more than three times the pain experienced by the microkeratome group (Fig 5). Beyond just the longer suction time during surgery, I think carbon dioxide diffusion through the corneal tissue may be responsible for the post-femtosecond discomfort (foreign body sensation).

“I think carbon dioxide diffusion through the corneal tissue may be responsible for the post-femtosecond discomfort”
Dr Duffey

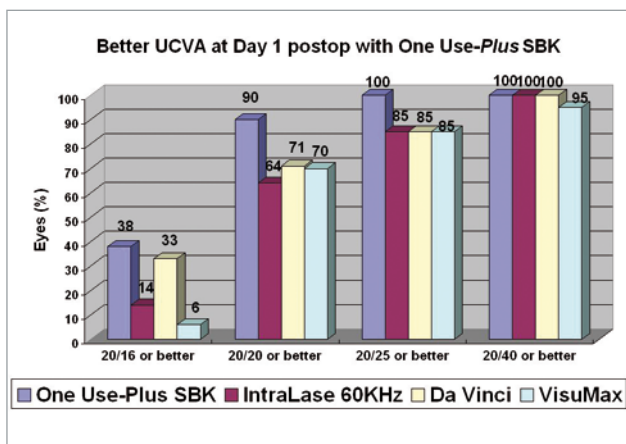


Fig.4: Faster visual recovery at Day 1 postop with Moria One Use-Plus SBK than with femtolasers^{6,8,9}

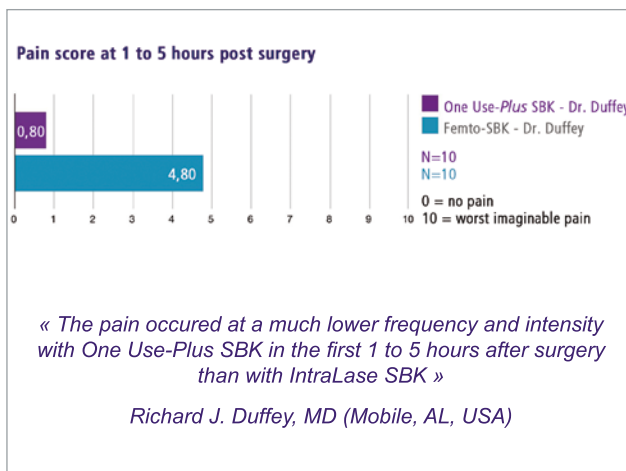


Fig.5: Greater patient comfort with One Use-Plus SBK than with Femto-SBK⁶

Ibrahim: There are also practical reasons to choose a mechanical microkeratome system over the femtosecond laser. The laser is bulky and may require another laser room, depending on the size and location of your excimer laser room. And even with the 60 kHz system, femtosecond laser procedures still take nearly twice as long as a microkeratome to create the flap. Of course, the cost differences are huge, both for the initial equipment investment and also for the per-patient consumables.

Moderator: Describe the Moria One Use-Plus SBK technology that you currently use.

Ibrahim: The One Use-Plus SBK is an advanced, fully automated, mechanical microkeratome. It runs on Moria’s Evolution3 and Evolution3E consoles, the same consoles that surgeons use for other Moria microkeratomes, as well as for Epi-K™ and the DSAEK system. The One Use-Plus SBK microkeratome has two independent motors and dual suction ports, so there is no loss of suction, even if one port becomes obstructed. A fully disposable plastic head with a pre-assembled metal blade is utilized for each patient (Fig 6). Surgeons have the option of either a single-use plastic ring (Fig 7) or a reusable metal ring (Fig 8).



Fig.6: The Moria One Use-Plus SBK single use head with pre-inserted blade



Fig.7: The Moria One Use-Plus SBK with a single-use plastic ring



Fig.8: The Moria One Use-Plus SBK with a reusable metal ring

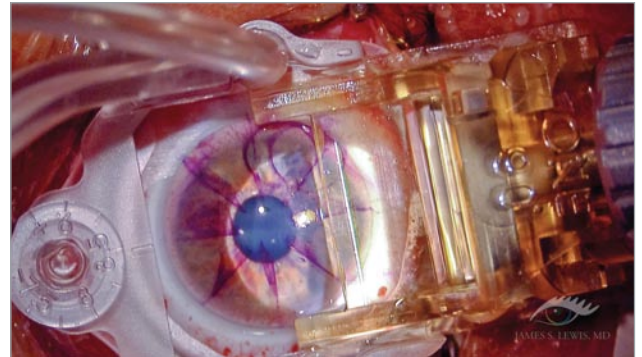


Fig.9: Excellent visualization through the single-use plastic ring for centration then confirmation of suction¹¹

Gauthier: I prefer the disposable plastic ring because it eliminates sterilization concerns and delays, and offers excellent visualization of the cornea through the transparent ring (Fig 9). The white ring of conjunctiva visible through the suction ring is proof that good suction is being maintained. I also like the fact that the ring diameter is small. It can be used in almost any eye without opening the lid speculum very wide, which increases patient comfort.

“I prefer the disposable plastic ring because it eliminates sterilization concerns and delays”
Dr Gauthier-Fournet

Casado: I have been comparing the plastic and metal rings in a prospective clinical study¹⁰. To date, we have treated 200 eyes of 117 patients (age 20-53 years), with 100 eyes in each group. Reproducibility of the flaps is similar for both groups. In all cases, the flaps have been of very high quality and there have been no flap complications in either group. I am comfortable using either type of ring and do not expect to see any significant differences between them when the study is complete. Certainly, the fully disposable (all plastic) option provides the highest degree of safety for each patient.

“Certainly, the fully disposable (all plastic) option provides the highest degree of safety for each patient.”
Dr Casado

Duffey: In addition to the safety advantages of a single-use head, it also cuts extremely smoothly. Blade imperfections and irregularities are almost non-existent because the heads are not subjected to autoclaving and repeated handling. Perhaps because of this, I have found them to be gentler to the epithelium than any other microkeratome I've used previously.

Lewis: I love the sterility of the fully disposable system. Because it comes sterile and pre-assembled, it cuts down on staff time—and on my dependence on staff to clean and assemble the head properly.

Clinical Experience and Results

Moderator: How predictable are the flaps made with the One Use-Plus SBK?

Lewis: I conducted a study of 300 eyes of 150 consecutive patients without prior refractive surgery¹¹. Flap measurements were done by an independent observer. As we have seen consistently in previous flap studies, the second eye usually had a slightly thinner flap when using the same blade for both eyes. With the One Use-Plus SBK, reproducibility is outstanding: the mean flap thickness was 99.22 μm in the right eyes and 97.15 μm in the left eyes, with a range of 80 to 120 μm . The central flap thickness did not correlate with age, spherical equivalent, average Ks, gender, or the surgeon's technique or experience level.

“With the One Use-Plus SBK, reproducibility is outstanding: the mean flap thickness was 99.22 μm in the right eyes and 97.15 μm in the left eyes, with a range of 80 to 120 μm ”
Dr Lewis

Norden: I typically get a thinner than 100- μm flap in eyes with very thin preoperative pachymetry, but I don't think this is a disadvantage. In fact, I think it may be an advantage over femtosecond lasers that definitely do not vary by preoperative pachymetry. Thinner corneas, especially if they are highly myopic, would have the greatest risk from a thick flap. We are better off to err on the thin side in such eyes.

Casado: In the study I mentioned earlier comparing the metal and plastic rings¹⁰, the median flap thickness was 99.7 μm in the metal group and 98.1 μm in the plastic group, with very tight standard deviations in both.

Duffey: The data gathered by the members of this panel and others (Table 1) demonstrate tremendous consistency in the results obtained with this microkeratome.

Gauthier: That is correct. I think we would be remiss not to point out what a huge change this is from the days of thick flaps when the standard deviations could be 25 μm or greater and one could sometimes—unpredictably—get a very thick flap.

Lewis: Some have questioned the role of blade technology in the evolving LASIK marketplace for this very reason. In the recent past, mechanical microkeratomes have been associated with a certain degree of unpredictability in flap thickness, ranging from 90 μm to more than 200 μm ¹²⁻¹⁴. But the new Moria One Use-Plus SBK microkeratome has consistently cut 100- μm flaps in clinical trials involving multiple investigators and more than 1000 eyes.

“Moria One Use-Plus SBK microkeratome has consistently cut 100- μm flaps in clinical trials involving multiple investigators and more than 1000 eyes.”
Dr Lewis

Moderator: Does the One Use-Plus SBK microkeratome make a planar or meniscus flap?

Duffey: We have always been taught that microkeratomes make a flap that is meniscus-shaped, or thicker in the periphery than in the center. Intuitively, it makes sense that this shape could eliminate the biomechanical advantages of a thin flap. But it is a mistake to conclude that all mechanical microkeratomes produce a meniscus-shaped flap. Longitudinal translational microkeratomes like the Moria LSK One and the Moria One Use-Plus SBK make very planar-shaped flaps⁶ (Fig 10). The microkeratome flap shallows (not deepens) only slightly in the far periphery as it nears its tapered edge.

Ibrahim: We certainly don't have any evidence that the One Use-Plus SBK flap, whatever its shape, results in lower corneal stability than a planar femtosecond flap. Dr. Vergés has already said that he found about the same impact on corneal hysteresis. As I noted earlier, Dr. El-Massry has actually demonstrated better biomechanical stability following One Use-Plus SBK than has been reported after femto-SBK^{3,4}.

Duffey: When I compare One Use-Plus SBK flaps to IntraLase* flaps, the two appear qualitatively to be similarly planar⁶ (Fig 10). Dr. Emrullah Tasindi of Turkey has also reported that flaps made with this SBK microkeratome appear to be planar¹⁵. He measured the thickness of each flap at various positions from the apex, nasally and temporally, using the OCT Visante*[®].



Fig.10: Flap thickness profiles: with One Use-Plus SBK



with IntraLase 60kHz at 1 month postop⁶

When I compare One Use-Plus SBK flaps to IntraLase flaps, the two appear qualitatively to be similarly planar
Dr Duffey

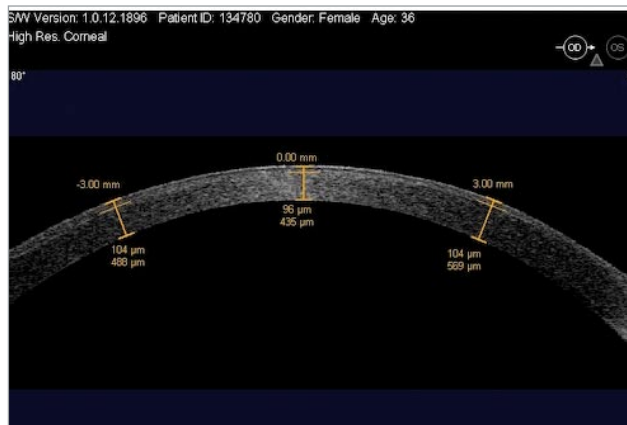


Fig.11: Anatomy of flaps created with Moria One Use-Plus SBK¹¹

However, the reality is that the Visante*[®] OCT system, while very helpful, isn't yet precise enough to measure flap thickness accurately. In our tests, a skilled technician attempting to place the cursor at the exact same location five times in a row obtained flap thickness measurements that differed by as much as 32 µm, with a standard deviation of 9.5 µm. This was true whether the flap was made with a microkeratome or a femtosecond laser. When you are talking about a 100-µm flap, that degree of imprecision can easily turn a planar flap into a meniscus one or vice versa.

Lewis: I consider the One Use-Plus SBK flap to be semi-planar, with only slightly thicker edges around the periphery compared to the center¹¹ (Fig 11). This shape actually gives the surgeon a "supportive skirt" for ease of handling and stability without intruding more than 100 µm on the thinner central cornea.

Gauthier: I think this emphasis on the subject of flap architecture may be misplaced. Regardless of its shape, the One Use-Plus SBK flap fits very nicely back in the bed as long as the surgeon repositions it with care. That's what everyone is really concerned about.

Lewis: I agree. Very little manipulation is required to obtain nearly perfect flap positioning.

Moderator: How is the quality of the stromal bed?

Casado: Using the Moria One Use-Plus SBK, I have been very impressed with the smoothness of the stromal bed. I think this is a combination of advanced

microkeratome technology and the more superficial location of the flap, as we discussed earlier. In any case, there are no peaks, lines or other irregularities on the stroma like we used to see with other microkeratomes. We have even stopped tracking “bed quality” in our outcomes database now because it is always of a perfect smoothness.

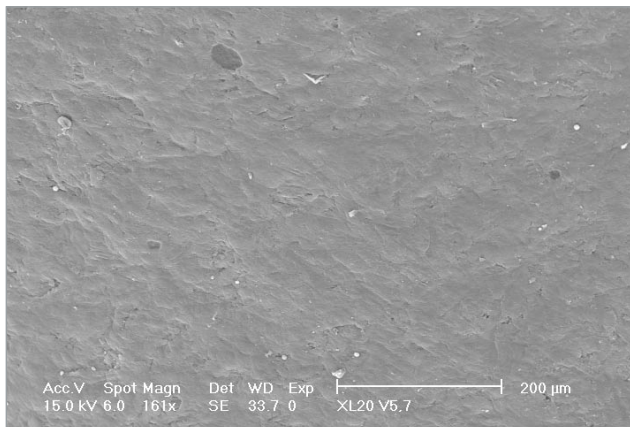
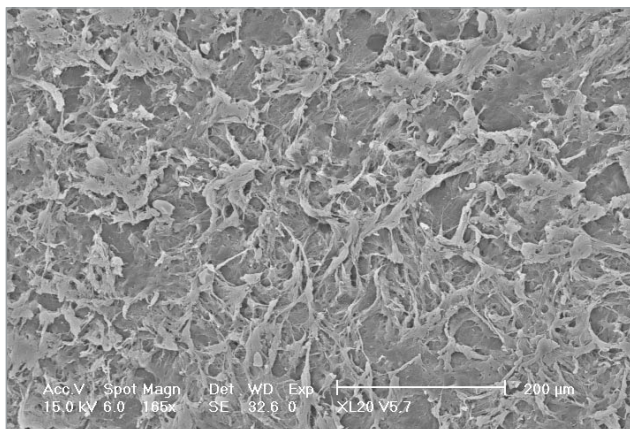


Fig.12: Scanning Electron Microscopy (x160)⁶:
Moria One Use-Plus SBK



IntraLase* 60kHz

Duffey: Many of us have had the clinical impression that the stromal beds with this SBK microkeratome are much smoother than any we have seen before, including those of femtosecond laser flaps. I decided to test this impression in the laboratory. We obtained four human cadaver eyes (two paired sets) that were all less than five days post-mortem and unsuitable for corneal transplantation. Flaps were made with the Moria One Use-Plus SBK on one eye from each pair, and with the IntraLase* 60-kHz femtosecond laser on the second eye of each pair. I aimed for a 9-mm, 100-μm flap in all eyes⁶.

After amputating the flaps, we performed scanning electron microscopy (SEM) at increasingly higher resolutions. The scans were rated from 0 (polished glass-smooth) to 4 (very rough) by 10 masked observers. The cumulative mean score was 2.24 for the One Use-Plus SBK and 3.78 for the IntraLase*. At all magnifications, the femtosecond beds appeared considerably rougher than the microkeratome beds (Fig 12). I think this roughness comes from the forceful breaking of the adhesions at the flap-bed interface when the surgeon peels back the flap.

“At all magnifications, the femtosecond beds appeared considerably rougher than the microkeratome beds”
Dr Duffey

Moderator: What are the visual acuity outcomes you have achieved, and how quickly does the vision recover?

Lewis: As Dr. Duffey just noted, when one lifts a femtosecond flap, considerable force is needed to break the adhesions, risking the migration of opaque bubbles and plasma gases into adjacent corneal tissue. An One Use-Plus SBK flap, by contrast, is less traumatic to the tissue. There is minimal postoperative inflammation, less swelling, less need for topical steroids, and therefore, faster visual recovery. In our study, all the subjects were 20/25 or better and 92% were 20/20 or better uncorrected on Day 1 postop¹¹.

“when one lifts a femtosecond flap, considerable force is needed to break the adhesions, risking the migration of opaque bubbles and plasma gases into adjacent corneal tissue”
Dr Lewis

Duffey: The smooth, dry bed that we have been discussing here is an ideal surface for excimer laser ablation (Fig 13). I think this is certainly a contributing factor to the outstanding visual acuity results and low enhancement rates. On the first postoperative day, we have considerably more patients seeing 20/20 or better than we’ve seen reported with femtosecond lasers^{6,8,9} (Fig 4). Even at the one-month mark,

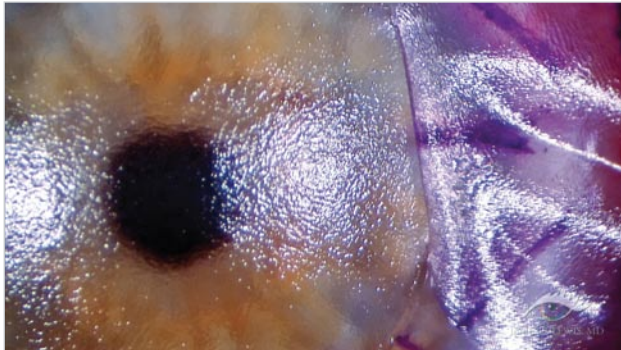


Fig.13: Extreme smoothness of the stromal bed and backside of the flap after Moria One Use-Plus SBK flap creation¹¹

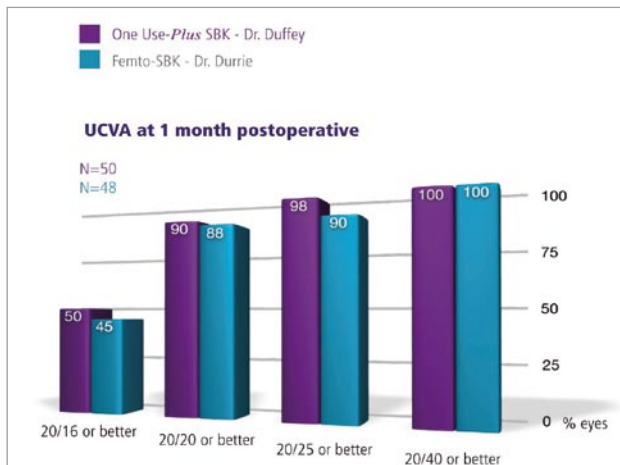


Fig.14: Equivalent visual outcomes to Femto-SBK at 1 month postop^{5,6}

when any effects of edema or inflammation would be expected to have resolved, our results have been better than those reported for the IntraLase* 60kHz^{5,6} (Fig 14).

“On the first postoperative day, we have considerably more patients seeing 20/20 or better than we’ve seen reported with femtosecond lasers”
Dr Duffey

Vergés: In our comparison study, visual acuity in the One Use-Plus SBK group was excellent. The mean UCVA on Day 1 was 20/25, compared to just 20/30 in the femtosecond group. In fact, uncorrected acuity was superior in the One Use-Plus SBK group all the way out to Week 4 postop, when both the femtosecond and microkeratome SBK groups were about the same² (Fig 3).

Moderator: What kinds of flap-related complications have you encountered?

Gauthier: The risk of microkeratome complications is often overstated. In more than 18,000 cases using linear keratomes for LASIK or SBK, I have not had a single buttonhole. In the past 2,000 SBK cases, I have had no significant epithelial defects, no loss of suction during a case, and no microkeratome complications that resulted in a loss of BCVA. I have had one incomplete flap and two or three free caps, but since I prefer very narrow hinges, an occasional free cap is not surprising.

Duffey: I agree. Looking back over the past 10 years, I’ve had one free cap (in a hyperope when I didn’t set a stop) and not a single buttonhole, even in very steep corneas.

Ibrahim: I had one buttonhole with the One Use-Plus SBK. However, this occurred in a post-penetrating keratoplasty patient with a very steep cornea, so it was not at all surprising. In addition to that buttonhole, I have had one free cap, and a 0.06% rate of partial flaps in the past 5,000 eyes treated with a mechanical microkeratome (both SBK and standard flaps). I already had very low rates of epithelial slides (2%) and epithelial defects (0.3%), as well. In our SBK study, 20 eyes (15%) had slight irregularities at the edge of the bed near the hinge but these were of no clinical importance^{3,4}.

I think we have to acknowledge that with either such an advanced microkeratome or a femtosecond laser, one can expect very few flap complications. Femtosecond lasers have introduced other types of complications, such as higher rates of DLK and transient light sensitivity (TLS). Also, there is always gas transmission into adjacent stroma. In some cases, the gas bubbles obstruct pupil tracking or iris registration and they can migrate into the anterior chamber.

“Femtosecond lasers have introduced other types of complications, such as higher rates of DLK and transient light sensitivity (TLS).”
Dr Ibrahim

Casado: Dr. Jérôme Vryghem and colleagues recently reported on their experience with the Ziemer Da Vinci* femtosecond laser in 500 eyes¹⁶. They reported some epithelial defects, bubbles in corneal stroma, difficulty lifting the flap atraumatically in 5.6% of eyes, microstriae in 0.4% of eyes, and partial flaps requiring manual cuts in 0.4% of eyes. Interestingly, Dr. Pansatiakul reported at the last AAO in Atlanta 3.8% occurrence of microstriae when using IntraLase* 60kHz for 120-micron LASIK in 133 eyes; but that rate of complications increased up to 44% when using IntraLase* 60kHz for SBK in 50 eyes¹⁷. We have not seen any of these complications with the One Use-Plus SBK. The longitudinal movement of this microkeratome has virtually eliminated the risk of buttonholes, obstructions, or of the head colliding with the lid speculum, so to me it represents a great improvement over my previous microkeratomes.

In the past, for example, shifting to a larger ring for a hyperopic or large eye increased the risk of a buttonhole, but that is not the case with the One Use-Plus SBK. The only risk we have now in going larger is some bleeding in the periphery, which is very manageable and therefore not a significant concern.

Duffey: In our series, we had no epithelial defects or slides. There were no flap complications, including striae, microstriae, slipped flaps, free caps, buttonholes, DLK, or epithelial ingrowth. Pupil tracking was successful in all procedures and the beds were smooth and dry⁶.

Norden: I had just one small epithelial defect in an eye with mild epithelial basement membrane dystrophy. It healed the following day.

Moderator: There have been some reports of early flap dislocation with thin microkeratome flaps. Have you seen this problem?

Gauthier: We have not seen anything like this with the Moria SBK system. Dr. Kovalev from Ukraine recently reported on dislocations at 20-30 minutes postop using 90-micron blades with the Zyoptix XP* microkeratome¹⁸. It was surprising that they experienced dislocations, especially given that the flaps had a superior hinge, which usually protects against dislocation. This complication can be managed fairly easily with a bandage contact lens, but I think we'd all like to avoid bandage lenses when possible.

In fact, with the One Use-Plus SBK, the flap actually adheres much better to the stromal bed. The osmotic tension of the thin flap favors adhesion. The analogy I like to use is that a wet piece of paper sticks to a surface much better than a wet piece of cardboard.

Vergés: Another speaker at the 2008 AAO meeting in Atlanta, Dr. Luis Felipe Vejarano from Colombia, noted that he doesn't even consider a free cap to be a complication anymore¹⁹. In the past, when he had a thin free cap, he needed to use a bandage contact lens, as in the report above. But now the bandage lens is not necessary, according to Dr. Vejarano, because the One Use-Plus SBK adheres so tightly to the dry, perfectly smooth stromal bed.

Moderator: Can you offer any technique pearls for SBK with the One Use-Plus?

Lewis: I don't perform standard LASIK now that SBK with a mechanical microkeratome is available. I apply the suction ring to the eye first with attention to flap position and visual axis. Once suction is achieved I place the head in the tracks and begin translation. Another pearl is to skip the lid speculum in small eyes and in tiny orbits. The One Use-Plus SBK functions well in these problem patients.

Duffey: For the ideal fit in the bed, I use a "whale's tail" sponge to stretch the flap out as I reposition it on the stroma (Fig 15). Wet the tip of a spear-shaped Murocel sponge so that it spreads out just slightly at the tip for gentler stretching of the flap edge. This technique is useful in all thin-flap cases, microkeratome or femtosecond, because it virtually

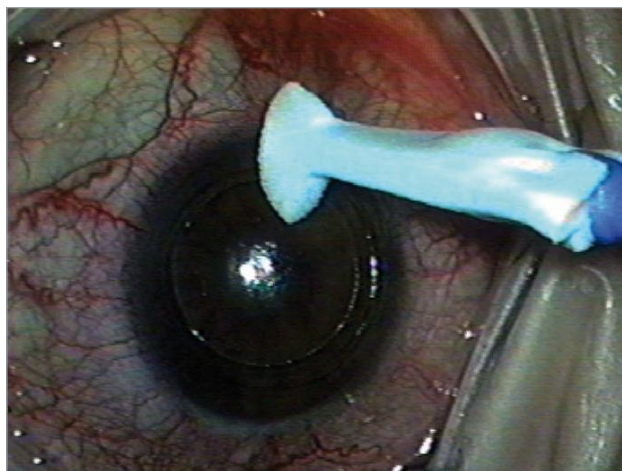


Fig.15: Use of a whale's tail sponge to stretch the flap⁶

eliminates microstriae and greatly reduces the chance of epithelial ingrowth. It also contributes to improved visual clarity on postoperative Day 1.

Casado: If the ablation diameter is large, I slightly decenter the ring nasally; the hinge will be a little smaller in these cases. The microkeratome has two advancement speeds. My default is the higher speed, but in cases where we have obtained a flap thickness <90 µm in the first eye, we switch to the lower speed for the second eye. I have also increased the drying time from 2 minutes to 2.5 minutes.

Gauthier: I have recently performed several retreatments on high myopes who had primary LASIK procedures about 10 years ago with very thick flaps at that time. For the enhancement, I have been able to cut a new, more superficial, flap within the old flap²⁰ (Fig 16). By doing this, I can improve their myopic correction without taking any more tissue at all. There are so many other patients with thick flaps who are potential candidates for this intra-flap approach in the future. This can only be done with a very precise mechanical microkeratome like the Moria One Use-Plus SBK, and remains impossible with any femtosecond laser.

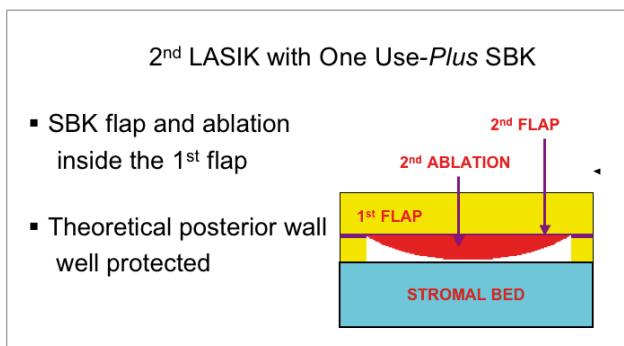


Fig 16: Retreatment of high myope having a very thick existing flap²⁰

“For the enhancement, I [...] cut a new, more superficial, flap within the old flap [...]. There are so many other patients with thick flaps who are potential candidates for this intra-flap approach in the future. This can only be done with a very precise mechanical microkeratome like the Moria One Use-Plus SBK, and remains impossible with any femtosecond laser.”
Dr Gauthier-Fournet

Moderator: How do you see SBK fitting into your overall refractive surgery practice? Is it your first choice or one of many options?

Casado: Like many of my colleagues, I have been getting more conservative every year about recommending LASIK. I opt for surface ablation if the topographies are asymmetrical or irregular, if there is significant dry eye, if I see red or yellow indices on the Pentacam* exam, or if the central pachymetry is <500 µm. I also prefer surface for those individuals who play contact sports or have a higher risk of trauma that could dislodge the flap in the future. Currently, about 60% of my patients have thin-flap LASIK, 30% surface ablation (primarily Epi-LASIK), and about 10% a phakic IOL. When I perform a LASIK procedure, I feel that SBK is simply the safest way to do it.

Lewis: For the majority of our patients, LASIK will probably always trump surface ablation, due to its comfort and rapid visual recovery. SBK is the LASIK procedure all patients should have.

Casado: I totally agree. The best LASIK procedure I can offer my patients is a SBK flap created with the Moria One Use-Plus SBK microkeratome. Although femtosecond laser is a promising technology, I do not think all its problems have yet been resolved.

“The best LASIK procedure I can offer my patients is a SBK flap created with the Moria One Use-Plus SBK microkeratome”
Dr Casado

Duffey: For me and for most refractive surgeons, I think the negatives of femtosecond technology still outweigh the positives. But that shouldn't be taken as an indictment of SBK in any way. The Moria One Use-Plus SBK allows us to achieve all the benefits of thin-flap LASIK, including reduced risk of ectasia, broadening the pool of candidates, and better, faster visual recovery, with the bladed microkeratome technology that has served us so well.

“the negatives of femtosecond technology still outweigh the positives”
Dr Duffey

Table 1: Flap Thickness Studies

The flap accuracy, predictability, and reproducibility of the Moria One Use-Plus SBK is equal to or better than reported results for any femtosecond laser platforms used to perform SBK.

Study author	#Eyes # Patients	Mean Flap Thickness (μm)	SD (μm)	Range (μm)	Vertical Diameter (mm)
Moria One Use-Plus SBK Microkeratome					
Ibrahim O. ^{3,4}	151 eyes of 83 patients	108	11	77-123	9.1 \pm 0.28
Duffey RJ. ⁶	50 eyes of 25 patients	103	9	83-123	9.3 \pm 0.3
Casado RD. ¹⁰	200 eyes of 117 patients	99.7 (metal) 98.1 (plastic)	13.2 (metal) 10.7 (plastic)	73-135 (metal) 77-122 (plastic)	9.5 \pm 0.2 (metal) 9.0 \pm 0.3 (plastic)
Lewis JS. ¹¹	300 eyes of 150 patients	99.22 OD 97.15 OS	8.87 OD 10.39 OS	83-125	8.45
Tasindi E. ¹⁵	18 eyes	105.40	5.66	99-111	N/A
Gauthier-Fournet L. ²⁰	63 eyes	102.87	13.8	75-132	N/A
Norden RA. ²¹	50 eyes of 25 patients	97.98	12.187	73-128	8.77 \pm 0.30
Chen YG, Bai J. ²²	72 eyes of 36 patients	95	7.1	83-118	8.72 \pm 0.27
Zeiss Visumax* Femtosecond Laser					
Reinstein DZ. ²³	24 eyes of 12 patients	112.3 (intended 110)	7.89	102.6-132.9	N/A
Ziemer Da Vinci* Femtosecond Laser					
Vryghem JC. ¹⁶	500 eyes	100.87 (intended 110) 88.94 (intended 90)	9.16 12.29	69-135 61-125	
Seiler T. ²⁴	200 eyes	114	13	91-135	N/A
Stodulka P. ²⁵	200 eyes	102	9	N/A	N/A
AMO IntraLase* 60kHz Femtosecond Laser					
Kezirian G. ²⁶	N/A	109	10	Max 131	N/A
Updegraff SA. ²⁷	164 eyes	112.9	17.1	72-165	N/A

For patient-friendly information about SBK and Epi-LASIK, visit the new Refractive Patient Network blog at www.refractivepatientnetwork.com.

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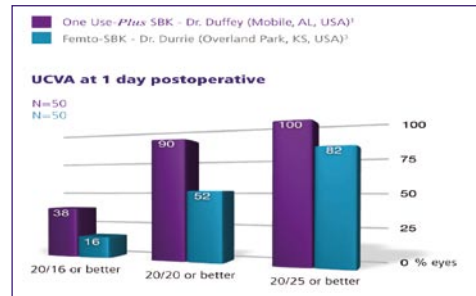
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Think Thin

One Use-Plus SBK

	One Use-Plus SBK Flap thickness using ultrasound pachymetry ¹	Flap thickness with Femto-SBK 60 kHz ²
Surgeon	Richard Duffey, MD (Mobile, AL, USA)	Guy Kerizian, MD (Paradise Valley, AZ, USA)
Intended thickness	100 microns	100 microns
Average	103 microns	109 microns
Standard Deviation	9 microns	10 microns
Minimum	83 microns	N/A
Maximum	123 microns	131 microns



Think Thin

Recent research has demonstrated that because it does not cut into the weaker posterior stroma, Sub Bowman's Keratomileusis results in less weakening of corneal biomechanics than conventional LASIK.⁴ Thinner flaps expand the range of patients that can be treated, reduce the incidence of dry eye, and speed visual recovery.¹ They also produce more consistent flap thicknesses with lower standard deviations.¹

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4 Marshall J. Wound healing and biomechanics of corneal flap creation. 24th ESCRS meeting; Sept 10th, 2006; London, UK

One Use-Plus SBK

- Thin, 100-micron, planar flaps
- Accuracy and predictability equivalent to Femto-SBK
- Smoother stromal bed
- No femto-complications
- ... At a fraction of the cost

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Roundtable with 7 international SBK experts

The participants have no financial interest in Moria and are not paid consultants for the company.



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