

Avoiding Flap Complications

Advanced surface ablation procedures combine the effectiveness of LASIK with greatly improved safety.

BY TERRENCE P. O'BRIEN, MD; MARK VOLPICELLI, MD; ERIC D. DONNENFELD, MD;
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Laser vision correction has come full circle from its beginnings with surface phototherapeutic keratectomy and PRK. The field advanced to lamellar refractive surgery with LASIK emerging as the dominant procedure. Today, interest in advanced surface ablation has re-emerged with LASEK and other methods.

Surface procedures offer several advantages compared with lamellar methods, particularly because the former avert rare but potentially devastating complications. Creating the permanent LASIK flap has been associated with the induction of higher-order aberrations and decreased corneal sensitivity as well as an increase in dry eye syndrome, striae, diffuse lamellar keratitis, infection, epithelial in-growth, and other intraoperative hurdles. Fortunately, the likelihood of visual loss from LASIK is very small. According to the Eye Surgery Education Council of the ASCRS Foundation, to date, less than 1% of LASIK patients have experienced serious vision-threatening problems.

LASEK, an alternative to LASIK, provides little added benefit due to the cytotoxic effects of alcohol used as a softening solution applied to the ocular surface. Alcohol causes swelling of the cornea and results in discomfort, sensitivity to light, and delayed healing. Clearly, there is a need for procedures that provide the vision correction benefits of LASEK or LASIK but that avoid complications arising from alcohol use or excessive manipulation of the corneal lamellar flap.

—Terrence P. O'Brien, MD



NORWOOD EYECARE EPIKERATOME Mark Volpicelli, MD

An increasingly popular and rapidly growing technique in refractive surgery is Epi-LASIK. Ioannis Pallikaris, MD, PhD, of Crete, Greece, origi-

nally introduced this procedure to ophthalmologists in the US as an alternative to LASEK. The Norwood Epikeratome (Norwood Eyecare, Inc., Duluth, GA) is a fully automated, precision-engineered mechanical separator that does not use a metal blade. The device is unique in that it employs a polymethylmethacrylate plastic separator that mechanically cleaves the lamina densa epithelial basement layer from Bowman's membrane, thus leaving a glassy smooth Bowman's layer exposed for ablation (Figure 1). It is ergonomically

designed with good "surgeon feel" with two differently sized rings to be used for variously sized eyes, similar to a true microkeratome design used for traditional LASIK.

The Epikeratome system has a well-defined geometry and is made of lightweight titanium, including a posterior appplanation separator platform, which allows for reliable and predictable epithelial delamination. Because of its advanced castellation/fenestrations and differently sized rings, it achieves excellent and consistent vacuum, making the accidental loss of suction almost impossible.



Figure 1. Because the Norwood Eyecare Epi-LASIK separator travels across the eye more slowly than microkeratomes, it provides better control over the separation.

EPIKERATOME CANDIDATES

Patients with flat, steep, or thin corneas, older patients whose epithelium has the potential for an "epithelial slide" with LASIK, and patients with

basement membrane dystrophies are ideal candidates for Epi-LASIK with the Epikeratome. My colleagues and I are witnessing vision recovery that is faster at 1 month postoperatively compared with our PRK and traditional alcohol-treated LASEK eyes. This is probably due to the more rapid epithelial remodeling afforded by eliminating alcohol in LASEK. In addition, by providing an epithelial bandage contact lens, we can inhibit cytokine release and epithelial growth factor mediators, which may provoke epithelial haze during a more prolonged recovery process. So far, with the Epikeratome device in wavefront-customized ablations, all of our patients have returned to BSCVA by 1 month, and 74% have a UCVA of 20/20 or better at 1 month, with 84% of our patients within $\pm 0.50D$ of their intended correction.

COMFORT

Of course, when compared to LASIK, Epi-LASIK is less comfortable. In our group's experience, however, it is less painful than PRK, and it has resulted in little-to-no postoperative haze. We are currently participating in a multicenter prospective clinical trial to further elucidate and determine the optimal pre- and postoperative regimen for patients undergoing Epi-LASIK. Currently, the perfect niche for this device is in patients who might otherwise not be good candidates for LASIK due to the corneal anatomy noted earlier.

THE FUTURE OF EPI-LASIK

For Epi-LASIK to replace LASIK 100%, its slight delay in visual recovery and postoperative comfort issues would have to be resolved. Additional clinical investigations are underway to resolve this issue and to determine the best regimen of adjunctive pharmacotherapy to accelerate the recovery of these patients.

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EPILIFT

Terrence P. O'Brien, MD

A new technique employing a customized keratome device separates the epithelium mechanically, delaminates the corneal epithelium precisely, and exposes a smooth Bowman's membrane layer for standard or customized laser ablation. The Epilift System (Advanced Refractive Technologies, San Clemente, CA) is a fully automated, precision-engineered mechanical tissue separator. It uses a metal blade with a specially designed geometry, including a bar applanator, to reliably achieve epithelial delamination. The Epilift console incorporates a vacuum system, software, and controls for setting tissue

cleavage parameters. A dual-motorized handpiece powers the oscillation and translation of the cutting blade across the cleavage plane (Figure 2). A precisely machined separator regulates the depth of the delamination. The system offers a choice of suction rings to meet individual patients' needs, and it is designed for use with disposable tubing sets.

HOW IT WORKS

The Epilift System was granted 510(k) status by the FDA in September 2004. It cleanly separates the epithelium between the Bowman's layer and the basement membrane, thus leaving an intact sheet of viable tissue, which is lifted from the cornea in preparation for laser reshaping. Histopathologic studies demonstrate that the device creates a cleavage plane below lamina densa while preserving stratification of the basement membrane portion of the epithelial layer.¹ Because the procedure does not involve cutting the cornea or creating a permanent flap, the epithelium can be repositioned to restore integrity to the ocular surface. As with LASEK, visual improvement is relatively rapid, yet slightly longer than with LASIK.

Preliminary experience (personal communication, Professor Chris Lohmann, MD, February 2005) suggests that the Epilift reliably and reproducibly creates epithelial flaps with good integrity and proper dimensions for customized wavefront-guided treatment. However, more research is needed.

SUMMARY

Although LASIK currently dominates and defines refractive surgery from the patient's perspective, many individuals avoid lamellar procedures due to their small but measurable inherent risk. The Epilift offers certain advantages over PRK and LASEK, especially with respect to flap-related complications, iatrogenic ectasia, and alcohol-induced cytotoxicity. Questions remain about corneal wound healing after Epi-LASIK. Additional clinical investigations are needed to resolve this issue and to determine the best regimen of adjunctive pharmacotherapy to accelerate recovery without haze formation.

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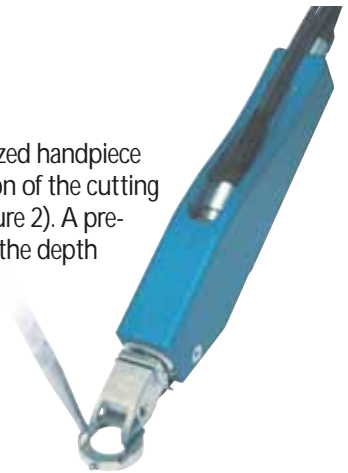


Figure 2. The Epilift System is equipped with a handpiece that has dual-motorized power.

THE LASITOME MICROKERATOME

By Roberto Pinelli, MD

Gebauer Medizintechnik GmbH (Neuhausen, Germany) introduced the Lasitome microkeratome to the European market in 2003. Unlike the company's EpiLift, which is designed solely for use during Epi-LASIK, the Lasitome may be employed during both Epi-LASIK and LASIK. The former has received 510(k) approval, but the latter is not available in the US. My 2 years' experience with the Lasitome has shown the microkeratome to be safe, accurate, and consistent.

LONGITUDINAL ASSESSMENT

Background

The Lasitome has five cutting heads available: the S160, S130, S100, H130, and H100. The numbers specify the cutting depth of each head. The letters refer to the flap's diameter; *S* designates heads that can create a maximal flap diameter of 9.5mm, and *H* indicates that the head can make a larger flap.

My colleagues and I at the Istituto Laser Microchirurgia Oculare in Brescia, Italy, undertook a longitudinal comparison of the S160 and S130 heads between May 2003 and 2004. The study included 500 eyes of 250 patients undergoing LASIK. The surgery on 300 eyes involved the 160- μ m head, whereas LASIK on the other 200 used the 130- μ m head. We estimated the flaps' thickness by subtracting the mean preoperative pachymetry reading from the mean pachymetry measurement of the residual bed.

Results

The mean flap thickness was 148 μ m (range, 140 to 156 μ m) for the S160 and 110 μ m (range, 100 to 120 μ m) for the S130 head. No flap was thicker than expected, but flaps were 8% to 10% thinner than the anticipated value in most cases. No intra-operative complications occurred. The only problem we encountered was that the suction ring became decentered on some hyperopic corneas upon the application of suction.

The microkeratome's blade and head cease moving upon the loss of suction. In addition, the Lasitome's grip on the cornea reduces the influence of K values on the regularity of the thickness of the flap. The device seems to be an excellent choice in hyperopic eyes with very low or high K values, as may be present after corneal transplantation.

CONCLUSION

In our experience, the Lasitome grips versus holds the eye well and makes a regular lateral cut, which we can visualize during its creation through a translucent applanation window. The lateral cut and nasal hinge seem to reduce the incidence of postoperative dry eye in our patients. That the LASIK flaps tend to be thinner than desired has not negatively affected our final surgical outcomes.

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AMADEUS II

Eric D. Donnenfeld, MD

The Amadeus II microkeratome (Advanced Medical Optics, Inc., Santa Ana, CA) is a nondisposable microkeratome that can create conventional LASIK flaps and also perform Epi-LASIK. The addition of a PMMA Epi-LASIK blade allows this surgical transformation to occur. With the Amadeus II microkeratome, there is no need for surgeons to purchase a separate Epi-LASIK delaminator or to use a disposable microkeratome with reduced mechanical tolerances. Histopathology of the intact epithelial sheet using the Amadeus II reveals the epithelium to be viable and the separation plane to be at the level of the epithelial basement membrane with Bowman's membrane left intact. Pathologic studies of eyes undergoing Epi-LASIK with the Amadeus II microkeratome prior to corneal transplantation reveal a smooth Bowman's membrane with a regular cleavage plane and the absence of residual epithelium. This is an ideal surface on which to perform excimer laser wavefront photoablation.

HOW IT WORKS

The Amadeus II is made of titanium and creates a nasal-hinge flap. It has a variable hinge width, translation speed, oscillation speed, flap size, spacer, and suction (Figure 3). The hinge width can vary between 0.4 and 2.0mm. For Epi-LASIK my colleagues and I recommend a wider hinge than for conventional LASIK and have been performing Epi-LASIK with a hinge width of between 1.0 and 1.2mm depending on corneal curvature. The translation speed is decreased to 1.5mm per second and the oscillation speed is slightly increased to 11,000 oscillations per second. The microkeratome comes with four different ring sizes: 8.5, 9.0, 9.5, and 10.0mm. We

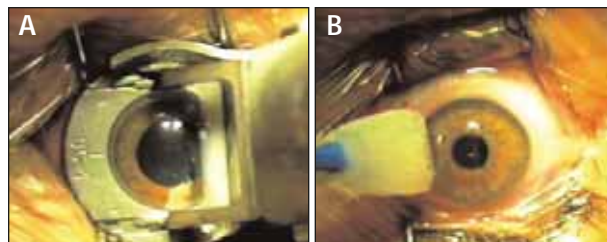


Figure 3. The Epi-LASIK procedure with the Amadeus II microkeratome uses a PMMA epithelial delaminator (A). Following the surface ablation, the epithelial flap is replaced (B).

have found larger ring sizes advantageous and perform most of our cases with the 9.5-mm ring. Finally, we reduce the suction level. The PMMA blade ensures a regular epithelial sheet without incursion into Bowman's membrane.

CONCLUSION

During the last several years, there has been a significant movement to surface ablation. This trend for a variety of reasons will continue to accelerate. Amadeus II Epi-LASIK offers several advantages compared with PRK and LASEK. There is a more regular epithelial debridement and no alcohol-induced cytotoxicity with this system. Early studies show less pain and photophobia than with PRK. We look forward to further studies on haze formation and the rapidity of visual rehabilitation with Amadeus II Epi-LASIK.

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MORIA EPI-K

Barrie Soloway, MD, FACS

THE PROCEDURE

In an Epi-LASIK procedure, an epikeratome is utilized to mechanically separate the epithelial layer of the cornea from Bowman's membrane. The epithelial flap is folded back prior to laser reshaping of the cornea and subsequently returned to its original position.

By creating a viable epithelial flap, the Moria Epi-K (Moria, Antony, France) produces better wound healing, faster visual recovery, and less haze compared with surface ablation procedures such as PRK and LASEK.

THE SYSTEM

The Epi-K System, approved by the FDA in March 2005, has a metal separator with optimal edge geometry for cleaving rather than cutting corneal tissue. Separation occurs along the natural cleavage plane between the basement membrane and Bowman's layer. To minimize the risk of inadvertently cutting stroma, the separator is encased in a disposable plastic head that contains an applanation plate (Figure 4).

The Epi-K handpiece is specifically calibrated to advance at an appropriate speed for epithelial separation. Two independent motors in the handpiece drive the separator oscillation and advancement of the head.

The Epi-K is driven by the Evolution control unit, which also operates all Moria's automated (LASIK) microkeratomes. The system includes a low-vacuum option on the reverse pass to minimize overall suction time and maximize patients' comfort.



Figure 4. The Epi-K mechanically cleaves the epithelium from the Bowman's membrane, leaving a pristine optical zone for ablation.

CLINICAL STUDIES

The safety and efficacy of Epi-LASIK with the Epi-K have been demonstrated in clinical trials of 530 eyes in 14 centers in nine countries.¹ The investigators reported that the device produced excellent epithelial flaps. Visual outcomes were similar to those of other laser vision correction procedures, and there was no significant incidence of haze. Postoperative pain was less and visual recovery faster than that typically associated with PRK or LASEK. Eighty-eight percent of patients at the New York Eye and Ear Infirmary were able to return to work within 3 days of surgery.

SUMMARY

In recent years, refractive surgery has experienced a growing trend toward surface ablation, due to its inherent safety, as well as the prospect of better visual outcomes. This movement has been tempered by the disadvantages of the current surface ablation procedures, PRK and LASEK. Epi-LASIK produces significantly better results than those procedures with regard to wound healing, visual recovery, and haze. Clearly, Epi-LASIK will become the procedure of choice for surface ablation, and most refractive surgeons will want to offer their patients both LASIK and Epi-LASIK.

LASIK is a mature technology with little room for further advancement. Thus, the flap effects inherent in the procedure may not be amenable to significant improvement. Now that we have an effective epikeratome, and as we continue to improve the procedure, it is conceivable that Epi-LASIK may one day become the corneal refractive procedure of choice.

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