Known Risk Factors for Ectasia

What do we know so far?

BY WILLIAM B. TRATTLER, MD

By 2005, most LASIK surgeons have either seen one of their own patients develop ectasia or have examined patients who underwent LASIK elsewhere and have now developed ectasia. The number of post-LASIK ectasia cases continues to increase since this condition was first reported in 1998. Although we do not know the exact number of ectasia cases that have occurred, we do know that more than 200 post-LASIK ectasia eyes have already been treated with Intacs (Addition Technology Inc., Des Planes, IL).

Obviously, we as surgeons want to provide the best refractive surgery results for our patients, so identifying eyes that may be at increased risk for ectasia is a critical part of the preoperative evaluation process. The importance of staying up-to-date on the current understanding of risk factors for ectatic becomes crystal clear when a prominent surgeon loses a $7.25 million malpractice case for allegedly failing to recognize that an irregular corneal topography was a risk factor for ectasia. This article will not delve into what we knew in 2000 when the aforementioned case occurred, but will focus on our current understanding of why ectasia occurs as well as the risk factors for the pathology.

When reviewing cases of post-LASIK ectasia, it is clear that two broad groups of eyes appear to be at an increased risk for developing the complication. The first group contains normal eyes that were left with thin residual stromal beds after LASIK surgery. The second group includes eyes with decreased tensile strength (keratoconus, pellucid marginal degeneration, forme fruste keratoconus), whereby the creation of the lamellar flap appears to weaken the cornea and increase the risk for developing ectasia.

It seems that avoiding post-LASIK ectasia should be relatively easy by leaving the residual stromal bed with a certain thickness and by identifying patients who are at an increased risk for the complication based upon their preoperative examination. As we have learned more about ectasia, there are many gray areas when it comes to its causes. Even with careful preoperative testing and care to leave a sufficient residual stromal bed, a number of patients will still develop ectasia.[1]

To better understand why ectasia occurs after LASIK, there are a few basic facts we need to understand.

COLLAGEN STRENGTH

The corneal stroma is composed of planes of collagen lamellae. A network of collagen fibers runs obliquely through the anterior portion of the cornea and crosslink the collagen lamellae, mechanically stabilizing the cornea. The posterior portion of the cornea lacks these oblique collagen fibers and therefore has less structural support.[2]

LASIK FLAP STRENGTH OR LACK THEREOF

Because LASIK flaps can be easily lifted years after the original LASIK procedure, one wonders about the strength of its adherence to the underlying stroma. This information

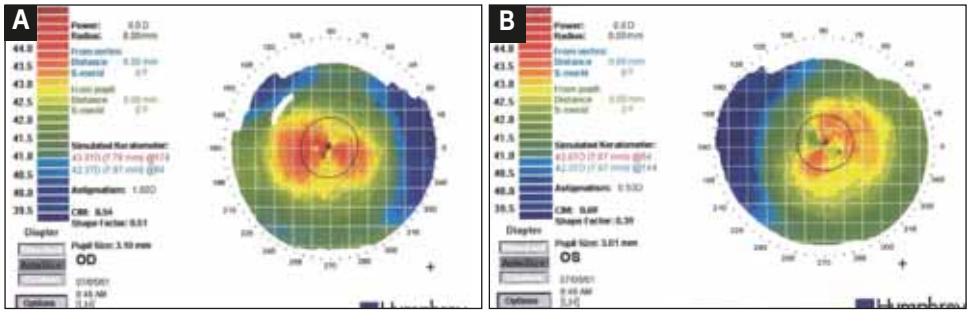

Figure 1. Preoperative corneal topography of an eye of an 18-year-old white male demonstrates a stable refraction. Noteworthy is the axis difference between his right eye (A) and left eye (B).

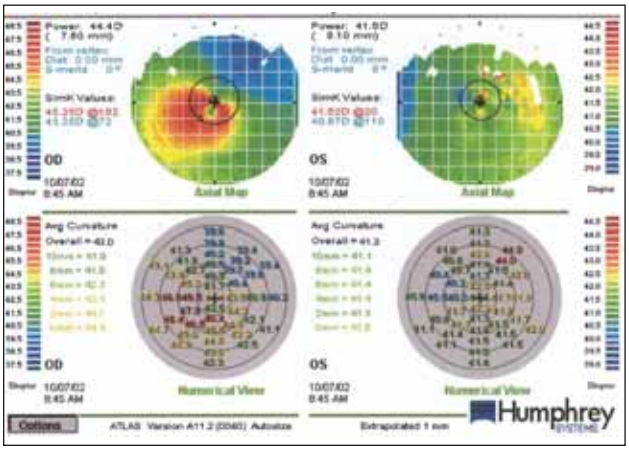

Figure 2. Fifteen months after LASIK, the patient developed ectasia.

is important to know both for advising patients on their risks of flap dislocations with blunt trauma and understanding the extent to which the flap contributes to the overall strength of the cornea.

Analysis of a corneal button in a post-LASIK ectatic eye that underwent a corneal transplant revealed that the flap interface was devoid of bridging collagen fibrils and cells. Electron microscopy showed that the surfaces were very smooth and that there is essentially no wound repair in the space between the flap and the underlying stroma.[3]

The actual reduction in corneal strength due to LASIK was recently determined in a study of 21 cadaver eyes at Emory University in Atlanta.[4] The researchers found that the adhesive strength of the LASIK flap was only 2.4% (±1.2%) compared with the normal interlamellar strength of a virgin cornea. In other words, the strength of the wound between the flap and the underlying stromal bed is reduced by 97.6% suggesting that the LASIK flap contributes little to the overall strength of the cornea after LASIK.

CLINICAL APPLICATIONS

The challenge to the refractive surgeon is leaving a sufficient stromal bed as well as identifying patients who may be at an increased risk for ectasia with LASIK. The biggest issues we have are (1) microkeratomes do not always cut a flap at the specified thickness and (2) there is no good test to measure a patient's corneal tensile strength. Instead, we must use tests such as intraoperative corneal pachymetry to determine exactly how deep of a flap we created, as well as preoperative corneal thickness, corneal topography, and Orbscan (Bausch & Lomb, Rochester, NY) to screen patients for signs of reduced corneal rigidity.

INTRAOPERATIVE PACHYMETRY

Some studies have shown that each microkeratome can have a wide range of actual flap thicknesses it produces.[5,6] Other studies have demonstrated that a stromal bed left too thin increases the risk for ectasia.[7,8] The recommended minimum residual stromal bed has been slowly increased over time to 250µm. Currently, the thickness considered prudent is in many cases more than 250µm, especially because patients who are under- or overcorrected typically need enough residual stromal bed in case they require additional treatment. Unpublished data from the 2005 Refractive Surgery Survey conducted by the Magill Research Center for Vision Correction found that only 34% of US refractive surgeons measure intraoperative pachymetry routinely. This step clearly makes sense to ensure that the LASIK flap was not accidentally created too thick. Furthermore, the investigators of the studies who used intraoperative pachymetry did not report any negative consequences from this step, nor did they report that performing intraoperative pachymetry affected the final visual outcome or increased the risk of infection.

CORNEAL TOPOGRAPHY AND ORBSCAN

Corneal topography allows the refractive surgeon to screen for changes in the shape of the cornea, which may suggest decreased corneal tensile strength (a factor that increases the risk of post-LASIK ectasia). The Orbscan topographer (Bausch & Lomb, Rochester, NY) uses slit-lamp technology to measure both the external and internal shape of the cornea. With this information, it can measure the corneal thickness in all parts of the cornea as well as the degree of posterior float elevation. One study has suggested that the posterior float may provide important information in deter-

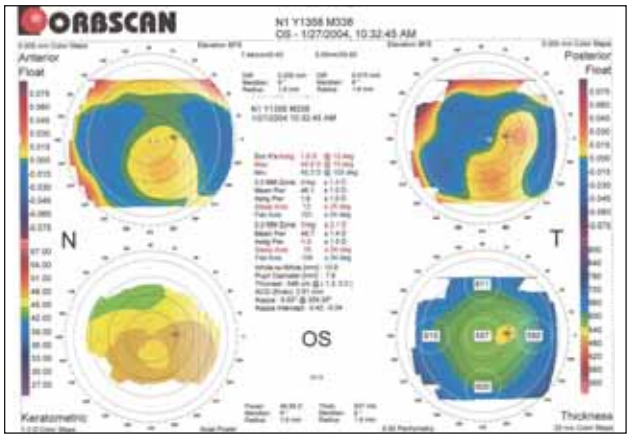

Figure 3. An Orbscan of the left eye of a female patient shows early pellucid marginal degeneration. Noteworthy is the lobster claw pattern, as well as the unelevated posterior float. Also, the pachymetry is relatively symmetrical.

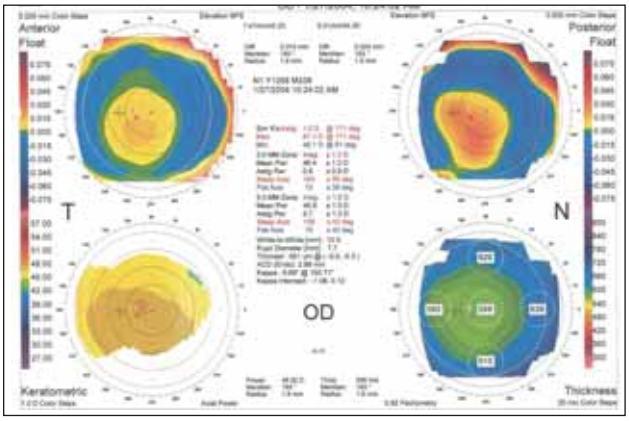

Figure 4. An Orbscan of the patient's eye showed a symmetrical pachymetry, an inferiorly displaced posterior float, and a relatively normal axial view.

mining who is at the highest risk for post-LASIK ectasia.[9]

Challenges to corneal topography exist, and situations such as dry eye, poor patient fixation, previous surgery, and warping of the cornea due to contact lens wear can all alter the measured topographic shape of the eye. Improving these conditions and then re-mapping the eye can help reveal the true shape of the cornea. In a similar fashion, corneal opacities and scars can affect the ability of the Orbscan to image the internal surface of the cornea, which produces inaccurate readings of the posterior float and compromises pachymetry readings.

It is important for surgeons to know that although many patients with keratoconus or pellucid marginal degeneration will present with topographic changes in their teens, other patients may not show signs of keratoconus on topography until their late 20s or 30s. This latter group of patients with normal topography, normal corneal thickness, etc., is still at risk for ectasia, and their course of presentation explains why occasionally some patients in their 20s with a perfectly normal preoperative examination who underwent LASIK later developed ectasia.

The refractive surgeon should be very suspicious of asymmetry between the eyes. Asymmetry of corneal topography can be a sign that one of the eyes is progressing toward keratoconus or pellucid marginal degeneration. Figure 1 shows the preoperative corneal topography of an 18-year-old patient with 10 years of documented refractive stability. His preoperative corneal thickness and refraction in the right eye were 524µm and -3.25 +2.00 X 120 = 20/20 respectively. The patient underwent LASIK in 2001, with a total ablation depth of 21µm and a predicted stromal bed of 353µm. This patient did not receive intraoperative pachymetry, so we do not know the actual flap thickness. Fifteen months later, the patient developed significant inferior steepening consistent with ectasia (Figure 2).

Pellucid marginal degeneration, typically a bilateral condition, is a major risk factor for post-LASIK ectasia. Occasionally, this condition can be unilateral, as Figure 3 shows. The Orbscan map of the left eye shows the classic lobster-claw appearance in the keratometric map (lower left cornea). Interestingly, the posterior float is normal in this eye with early pellucid marginal degeneration. Orbscan mapping and topography of the right eye (Figures 4 and 5, respectively) appear relatively normal, suggesting that this can be considered a topographically unilateral case of pellucid marginal degeneration. This information helps emphasize that there are eyes that have normal posterior floats but are not appropriate candidates for LASIK.

There are a variety of other warning signs for post-LASIK ectasia, in my opinion, that can be found on either topography or Orbscan. Steep corneal curvatures (49.00D or higher), a posterior float greater than 50µm, and significant variations between the superior and inferior corneal pachymetry I believe are all potential risk factors for early keratoconus or pellucid marginal degeneration, and thus potential risk factors for ectasia.

INFERIOR STEEPENING ON TOPOGRAPHY

Inferior steepening on corneal topography is a very common finding in patients considering refractive surgery. The surgeon must make a determination as to whether a patient with inferior steepening is at increased

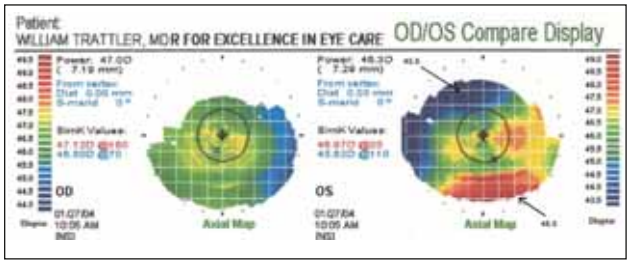

Figure 5. Topography of the patient shows a normal appearing right eye. The left eye has inferior steepening with a pellucid marginal degeneration-like pattern.

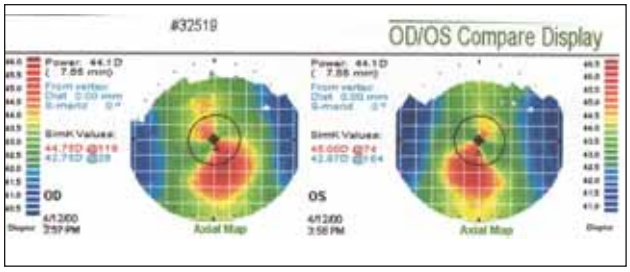

Figure 6. The patient had 3.00D of myopia in each eye and underwent LASIK with pachymetry measurements of 574µm OD and 573µm OS. The ablation depth OS was 31µm.

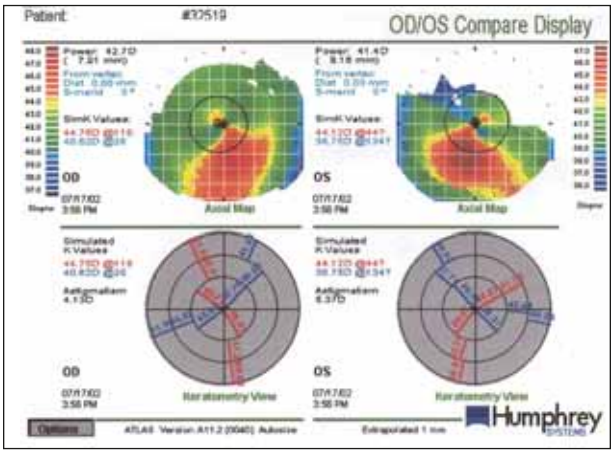

Figure 7. Two years after LASIK, postoperative topography reveals early ectasia in both eyes of the patient.

risk for ectasia. Clearly, if the amount of inferior steepening is severe, the cornea is thin, or there is a loss of BCVA, it is better to avoid LASIK. An Orbscan map can often provide additional information, such as the presence of an elevated posterior float or asymmetry in the corneal pachymetry.

A number of cases of post-LASIK ectasia have occurred in eyes with mild inferior steepening, excellent BCVA, and thick corneas. Figure 6 shows the preoperative topographies of just such a patient (surgery was performed before this center received an Orbscan), and Figure 7 shows the marked inferior steepening consistent with ectasia.

In cases of inferior steepening, an Orbscan map can be a very useful adjunctive test to try to determine whether the eye is at an increased risk for ectasia with LASIK. If the posterior float is elevated, most surgeons would recommend an alternative to LASIK. If it is normal, however, the situation gets murkier. Currently, there are no published articles on the risk for ectasia in eyes with inferior steepening but a normal posterior float. Without such a study, clinicians have to decide whether eyes with a normal posterior float can be considered candidates for LASIK, or whether an alternative refractive surgery should be offered. In my practice, I have seen a number of patients with keratoconus in one eye and signs of mild keratoconus in the second eye. The interesting finding in these second eyes is that the posterior float can be normal (Figure 8). In my practice, I therefore consider inferior steepening a potential risk factor for keratoconus and discuss the issues of ectasia in detail with these patients.

LASIK ENHANCEMENTS AS A RISK FACTOR FOR ECTASIA

It is not surprising that a solid number of patients who developed ectasia after LASIK first underwent a LASIK enhancement. Higher-risk eyes that do become ectatic drift toward more myopia and astigmatism, which may be interpreted as an undercorrection or regression instead of increasing myopic astigmatism due to ectasia. These patients are more likely to present for an enhancement, because their refractive results typically do not remain stable.

Therefore, another important safety step is to carefully monitor patients for refractive stability prior to an enhancement. As well, be vigilant about obtaining old records from patients who had LASIK elsewhere. If you suspect early ectasia, then a prudent alternative is to consider surface ablation on the flap (with haze prophylaxis steps), as thinning the flap would theoretically be unlikely to weaken the cornea further.

REFRACTIVE SURGICAL OPTIONS FOR NON-LASIK CANDIDATES

Thankfully, we have a number of excellent refractive surgery options for patients with a potential increased risk of ectasia, including advanced surface ablation, Intacs (for low myopia), and phakic IOLs.

A number of studies have looked at the safety of performing surface ablation in patients with forme fruste keratoconus. Percy Amoils, FRCS, presented the results of more than 70 eyes with an 8-year follow-up at the course "Risk Factors for Ectasia" at the ASCRS meeting in 2005.[10] He noted that in his series, eyes treated with PRK remained relatively stable. David Hardten, MD, and Richard Lindstrom, MD, have also discussed their results[11] of advanced surface ablation on eyes with forme fruste keratoconus, which similarly found that advanced surface ablation can work well for patients with forme

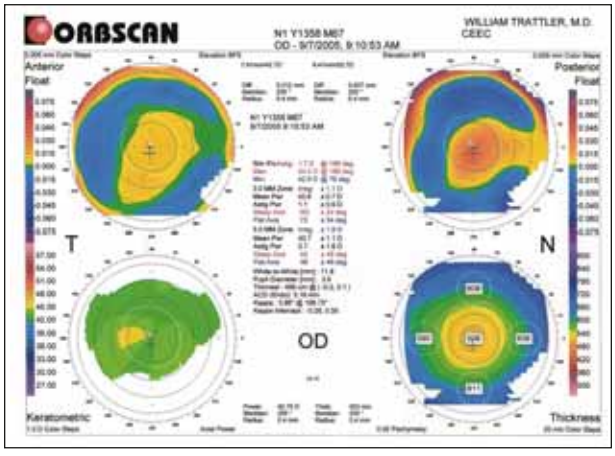

Figure 8. A patient interested in LASIK has early keratoconus in his left eye. Besides the axial power map's having some non-orthogonal astigmatism, the rest of the Orbscan is completely normal. The posterior float is under 50, and the pachymetry map shows a symmetrical distribution of corneal thickness.

fruste keratoconus. They have pointed out that advanced surface ablation does not halt the disease, so some patients potentially may still have some progression of their condition. The key issue is to identify borderline cases and discuss in detail the corneal findings and the patient's potential options. If proceeding with advanced surface ablation, it is critical to have a detailed and patient-specific informed consent.

SUMMARY

Refractive surgeons need to be extra diligent in their preoperative screening process to identify patients who may be at an increased risk for post-LASIK ectasia. Making the diagnosis of early keratoconus and early pellucid marginal degeneration can be challenging, since these conditions can only be picked up once there are changes on topography or an Orbscan map. In borderline cases, repeating topography and Orbscan maps can sometimes provide additional information. The bottom line is that for patients interested in refractive surgery who have borderline findings on their preoperative examination, one can provide a detailed discussion of the questionable findings and discuss other alternative refractive procedures. ■

William B. Trattler, MD, is a corneal specialist at the Center for Excellence in Eye Care in Miami and a volunteer assistant professor of ophthalmology at the Bascom Palmer Eye Institute in Miami. He states that he holds no financial interest in any product or company discussed herein. Dr. Trattler may be reached at (305) 598-2020; wtrattler@gmail.com.

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ADDRESSING POSTOPERATIVE ECTASIA

By Stephen G. Slade, MD, FACS

As usual, Dr. Trattler makes some excellent points. Simply put, there are patients that do not show any preoperative signs of developing ectasia after laser vision correction. These are also the same individuals who are at risk to develop the condition without any surgery. For them, laser vision correction may function as a "cardiac stress test" to reveal the ectasia that otherwise would not have appeared, if the surgery affects the process at all.

Conversely, some patients have multiple risk factors but do well with surgery. Doctors do not always agree on the mix of such factors to diagnose risk. There is no definitive science, "magic number," or genetic marker; no litmus test that can make the diagnosis for us. Instead, ophthalmologists are left with a diverse group of clinical signs to evaluate. For example, inferior steepening on topography associated with skewing of the mires can identify patients who are at risk but cannot make the diagnosis of keratoconus alone. Currently, there is no one device or brand of topographer that is universal and could be considered the standard for diagnosing a propensity for ectasia.

WHAT CAN BE DONE?

Surgical technique may reduce the risk of ectasia after laser vision correction. Lens-based surgery may be considered. The LASIK flap may be able to be customized to the eye and the planned ablation. Different treatment profiles, thinner- and smaller-diameter flaps, more accurate keratomes, and even-shaped edges all may contribute to a stronger cornea postoperatively. Dr. Trattler discusses measuring residual beds intraoperatively. This technique is potentially helpful and adds little risk of infection considering the bactericidal qualities of the subsequent ultraviolet irradiation, yet the majority of surgeons do not employ this method.

Organized ophthalmology is responding to the problem of postoperative ectasia as well. Recently, the AAO and the ASCRS formed a joint committee to investigate the matter. This committee, chaired by Perry Binder, MD, and Richard Lindstrom, MD, intends to provide a position statement to the membership as well as coordinate education on the issue in the future.

Certainly, we surgeons are in a learning process. Most importantly, we have treatment choices for ectatic eyes that provide excellent results. Our knowledge on this subject will continue to evolve, but absent any definitive diagnostic, genetic, or laboratory test, we will have to depend on the art as much as the science of medicine for some time.

Stephen G. Slade, MD, FACS, is in private practice in Houston. He states that he holds no financial interest in any product mentioned herein. Dr. Slade may be reached at (713) 626-5544; sgs@visiontexas.com.