REFRACTIVE SURGERY

Easy Calculation Evaluates Post-LASIK Ectasia Risk

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Although few patients with normal corneal topography develop post-LASIK ectasia, this surprise complication remains one of the most feared in laser refractive surgery, thanks to its potential to cause visual catastrophe. "Ectasia is the nightmare scenario in refractive surgery," said Kevin M. Miller, MD, at the Jules Stein Eye Institute in Los Angeles. "We're always on the lookout for it."

Against this backdrop, refractive surgeons are reacting positively to a proposed new formula—the "percent tissue altered" (PTA) metric—for identifying at-risk eyes.

How It Works

The metric consists of an equation that calculates the proportion of the cornea that will be impacted by LASIK. The surgeon adds the expected flap thickness (FT) to the planned ablation depth (AD), and then divides the sum by the eye's central corneal thickness (CCT). Thus, percent tissue altered is derived from (FT + AD) ÷ CCT.

Critical variable. Last summer, a joint Brazilian-U.S. group reported that a PTA of greater than 40 percent was the most significant independent variable associated with post-LASIK ectasia in eyes with normal-appearing corneas before surgery.[1,2]

PTA correlated more strongly with ectasia incidence than did the previously known risk factors, including patient age, residual stromal bed (RSB) thickness, the Ectasia Risk Scoring System (ERSS), and CCT, the researchers found. The mean PTA in affected eyes (n = 30) was 45.1 percent ± 3.9. This compared with a mean PTA of 31.9 percent ± 5.8 in 174 control eyes that came through LASIK with no problems.

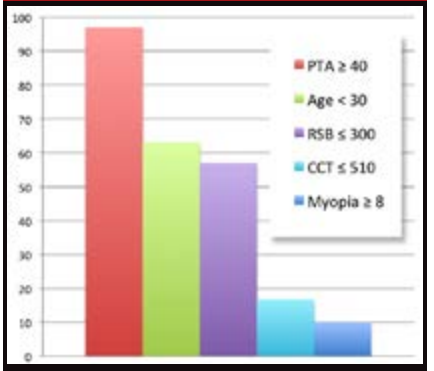
Many of the patients in the study who developed ectasia would have been considered at low risk if other measurements (notably RSB or CCT) had provided the sole guidance, said principal investigator Marcony R. Santhiago, MD, PhD. But as it turned out, all of them had a high PTA. "The association is more robust than all the variables isolated, and I use the formula with my patients every day," said Dr. Santhiago, at the Federal University of Rio de Janeiro.

User friendly. Further research is needed, but the early evidence suggests that calculating the PTA is a user-friendly way to look beyond normal topography and identify at-risk eyes, said George O. Waring IV, MD, FACS, at the Medical University of South Carolina in Charleston.

"PTA gives a more holistic view of the factors that seem to matter, and it tends to be the most predictive metric we have so far," Dr. Waring said. "Also, it is very easy to calculate. You're not having to do a lot of mathematical gymnastics in your head when you're sitting in the lane or when you're counseling the patient preoperatively."

Teasing out nuances. Dr. Miller said that he is "generally in agreement with the PTA concept" because it can enable surgeons to recognize corneas in which the usual minimum values for RSB and CCT values would not suffice. "Typically, we'll say that we want to leave a 250-µm residual stromal bed and then the patient will be safe. Well, not really. For instance, if you have a very thick cornea and you take away three-quarters of it, a 250-µm bed probably won't be good enough. PTA is a better metric in a case like this."

Rating Risk



ROBUST ASSOCIATION. PTA proved to be the most prevalent risk factor for post-LASIK ectasia when individual variables were investigated. All eyes had normal corneal topography prior to LASIK.

Considering Biomechanics

The anterior cornea's role. Post-LASIK corneal ectasia is thought to occur when the surgery reduces the stroma's structural integrity to a level too low to maintain corneal shape and curvature.[1] The anterior 40 percent

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of the cornea has significantly more cohesive tensile strength than the posterior 60 percent.[3]

Furthermore, the extent of the weakening depends not just on a single parameter, such as RSB, but also on flap thickness and the depth of the refractive ablation, Dr. Santhiago and his colleagues found.

A combined look at risk. The PTA equation accounts for the biomechanical effects of a combination of risk factors, unlike a potentially "oversimplified" approach of looking at risk factors individually, Dr. Waring said.

"In the past, risk factors have been largely considered independently and with equal weight. But we know that the whole eye is a very complex, dynamic, and fluid biomechanical system," Dr. Waring said. For instance, he said, "You can have patients with thin corneas that are strong, and you can have patients with thick corneas that are weak. Patients with thick corneas can develop ectasia," particularly if they are young and have "thick flaps and large ablations."

Dr. Santhiago agreed. "As compared to specific residual stromal bed or CCT values, PTA likely provides a more individualized measure of biomechanical alteration because it considers the relationship between thickness, tissue altered through ablation and flap creation, and ultimate residual stromal bed thickness."

PTA's Weaknesses

Despite its advantages, PTA does have certain drawbacks.

No direct measurement of corneal strength. The ideal approach to preventing post-LASIK ectasia would be to directly measure the structural integrity of the preoperative cornea, which PTA does not do, Dr. Waring said. "At the end of the day, PTA is still a surrogate. It's not a direct measurement." Meanwhile, he and other researchers are helping to validate diagnostic technology to directly measure corneal strength.

Same numerator, different outcomes. A patient with a thick flap and a small ablation may have the same numerator in the PTA ratio as a patient with the thin flap/large ablation combination, Dr. Waring said. "But a thick flap may bear a more significant effect on the resulting biomechanics of the cornea than a thin flap would." This would be particularly true in instances in which an older mechanical microkeratome was used. These microkeratomes produce "a meniscus flap architecture [that is] thicker in the periphery, where the biomechanical properties of the cornea may be more adversely affected," he said.

Dr. Santhiago is currently investigating the relative contribution of flap thickness and ablation depth within the PTA. Referring to research that is expected to be published this year, he said, "We showed that the LASIK flap had greater impact than ablation depth. However, thicker flaps alone were insufficient to create ectasia unless coupled with greater ablation depths—and thus high PTA values. PTA was still a more significant factor than the variables that comprise it."

Some eyes don't fit the model. "A few eyes do not develop ectasia despite having PTA values greater than 40 percent," Dr. Miller said. However, this does not negate the need for caution in all high-PTA eyes, Dr. Santhiago said. "The weakening predicted by a high PTA does not mean ectasia will necessarily occur, merely that these eyes carry increased risk. Given the elective nature of LASIK, it seems logical that the balance of risk acceptance should be weighted toward minimizing risk, especially when other procedures are available for refractive correction."

In Decline?

Reported rates of post-LASIK ectasia in eyes without identified risk factors have declined in recent years:

- In 2006, Klein et al. reported eight cases (1.8 percent), out of 450 LASIK procedures.[1]
- In 2012, Spadea et al. reported 23 cases (0.57 percent), out of 4,027 eyes.[2]
- In 2014, Moshirfar et al. reported on 1,992 LASIK cases with no identified risk factors, in which ectasia developed in a single patient (0.05 percent).[3]

1 Klein SR et al. *Cornea.* 2006;25(4):388-403.
2 Spadea L et al. *Clin Ophthalmol.* 2012;6:1801-1813.
3 Moshirfar M et al. *Clin Ophthalmol.* 2014;8:35-42.

Optimal Use of PTA

Dr. Santhiago cautioned that PTA is not a replacement for other well-established risk assessment tools, such as the ERSS. Instead, he recommends using PTA adjunctively. "The most important thing to remember is that the available tools are not mutually exclusive," he said. "Adding PTA [to your preoperative protocol] will increase the chances that you will identify the patients with normal topography who have high risk for ectasia."

For example, Dr. Santhiago's study found that PTA and younger age were the top two factors associated with ectasia development in seemingly normal corneas. Thus, if both those factors were marginal in a prospective LASIK patient, caution might be in order, Dr. Waring advised. "We don't want to oversimplify. But if a patient has two borderline findings—say a PTA of 30 percent and an age of 18—he or she would likely not be a suitable LASIK candidate. Maybe you'll do advanced surface ablation, depending on the other risk factors."

As this is a multifactorial risk-benefit analysis, Dr. Waring said, he would also ask the following questions: What does the topography look like? What does the tomography look like? Is there a family history? Is there a history of other risk factors, such as eye rubbing? What do the direct biomechanical measurements look like with the devices that are available?

What's Ahead

ERSS update. Dr. Santhiago's research group is currently working on a mathematical equation intended to screen

for ectasia by combining the PTA formula and the ERSS. Publication is expected this year.

PTA in abnormal corneas. The researchers are also investigating the possible utility of the PTA equation in corneas with suspicious topography. "It does also appear to play a role in eyes with abnormal topography," Dr. Santhiago said. However, the numerical cutoff values are significantly lower, depending on the individual eye's risk profile, he said.[4]

Beyond PTA. Despite the utility of the PTA metric, Dr. Miller predicted that it will eventually decline in importance, as U.S. ophthalmologists migrate toward procedures that preserve more of the cornea's structural integrity.

"Do I think this is going to be a big metric 10 years from now? No, because we're going to completely change things. We won't be making flaps in the future. We'll be doing our refractive corrections with something like SMILE [small-incision lenticule extraction], which will allow us to go a lot deeper and not have as much risk of ectasia" or such problems as dry eye and dislocated flaps, Dr. Miller said. ■

1 Santhiago MR et al. *Am J Ophthalmol.* 2014;158(1):87-95.

2 Santhiago MR et al. *J Cataract Refract Surg.* 2014;40(6):918-928.

3 Randleman JB et al. *Ophthalmology.* 2008; 115(1):37-50.

4 Santhiago MR et al. *J Refract Surg.* In press.

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