

Protecting LASIK Patients

A new dual DNA test can identify patients with a genetic mutation who should not have laser vision correction.

BY MITCHELL A. JACKSON, MD

Ophthalmologists use the most advanced technologies for laser vision correction (LASIK, PRK, LASEK) and achieve visual acuities of 20/20 or better in more than 90% of patients, but the risk of complications remains. Patients consider any adverse event in an elective procedure to be a bad outcome. The biggest fear LASIK surgeons have is corneal ectasia; its prevalence is about one in 2,000, comparable to that of keratoconus in the general population.¹ Advanced corneal topography systems such as the Orbscan (Bausch + Lomb), Pentacam Comprehensive Eye Scanner (Oculus Optikgeräte), Galilei (Zeimer), and Cassini Color LED Topographer (iOptics) have allowed clinicians to identify patients at increased risk of postsurgical ectasia, but even the devices' use cannot guarantee avoiding this complication.

Another potential complication of laser vision correction is the development of granular corneal dystrophy type 1 (GCD1) or type 2 (GCD2).² GCD is an autosomal-dominant condition caused by genetic mutations on the *TGFBI* gene that are associated with the wound-healing process of the cornea. Homozygous individuals start to lose visual acuity during infancy and are blind by adolescence. Patients with the heterozygous condition typically develop visual acuity loss later in life as a result of exposure to ultraviolet light and/or eye surgery that involves the cornea such as LASIK, PRK, phototherapeutic keratectomy, and/or LASEK.

Disturbingly, the global heterozygous prevalence of GCD appears to be greater than that of keratoconus, and patients undergoing laser vision correction may be at higher risk of developing GCD than corneal ectasia based on the known prevalence rates of each condition. When present, GCD causes permanent gray or white intrastromal corneal deposits that are clinically apparent as corneal haze and are only treatable by penetrating keratoplasty. A new test may facilitate GCD's detection.

GLOBAL PREVALENCE

One out of every 870 individuals studied in the Korean population is at risk of carrying the GCD2 genetic muta-

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tion.³ Although the DNA test for GCD originated in Korea, and many studies have been performed in that country and in Japan, sufficient testing has not been performed to determine the mutation's prevalence in the United States and the Western Hemisphere. GCD is found in all ethnic groups. Recent research indicates that GCD1 has a similar mechanism as GCD2 and poses similar risks for refractive surgery candidates. Another recent study suggests that Europe and the United States have proportionately higher rates of GCD1 compared with GCD2.⁴

THE TEST

To identify patients at risk of adverse outcomes after laser vision correction, Avellino Lab, a Clinical Laboratory Improvement Amendment-certified facility, developed a diagnostic test to detect GCD. The Avellino DNA Dual Test for LASIK Safety is the world's first genetic test for both GCD1 and GCD2. The company reports that it has tested over 430,000 pre-LASIK patients (primarily in Korea and Japan) and has identified 399 individuals to date as positive for the genetic mutation that causes GCD2 (a prevalence of 1:1,078). This is the only genetic test available to ophthalmologists that relates to the cornea and its response to any type of laser vision correction procedure.

The test involves a simple mouth swab to determine whether a person carries the GCD1 or GCD2 genetic mutation. Specifically, the examiner takes 10 swipes from inside each of the patient's cheeks. The sample is
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sent to Avellino Lab via a prepaid courier-tracked envelope, and within 24 hours, the test results are available to the physician via a password-protected encrypted website portal. Thanks to the rapid turnaround, there is no delay in scheduling a laser vision correction procedure within days of the preoperative evaluation.

I perform this test on every patient who is a candidate for laser vision correction, and because the results are back within 24 hours, there is no delay in performing surgery. There is an upfront fee (which may vary from practice to practice) charged to the patient that is nonrefundable but is applied as credit to the overall surgical fee if the patient has a normal test result and proceeds with the procedure.

CONCLUSION

It is surgeons' responsibility to achieve successful results for LASIK patients while avoiding potential sight-threatening complications such as corneal ectasia and/or GCD. Because GCD's prevalence may outstrip that of corneal ectasia, in my opinion, all US refractive surgeons should administer the Avellino test, as is the norm in Korea and Japan. ■

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