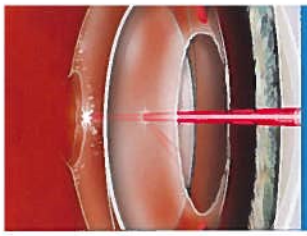

Closed Claim Study

Lack of Informed Consent and Failure to Review Topographies

By Ryan Bucsi, OMIC Senior Litigation Analyst

ALLEGATION

PRK contraindicated by keratoconus.

DISPOSITION

Case was settled for $850,000.

Case Summary

During the plaintiff's first exam, the OMIC insured informed him that he was a good candidate for LASIK. Pachymetry revealed a corneal thickness of 545 OD and 499 OS, and topography was performed. Months later, the patient returned and repeat pachymetry revealed corneal thickness of 475 OD and 443 OS. Topography was also repeated. Uncorrected visual acuity was 20/400 OD and 20/200 OS. The patient signed a LASIK consent form and was warned of the risks of operating on both eyes on the same date; however, after considering the options, he decided to proceed with bilateral same day sequential surgery. After initially confirming that the patient was a candidate for bilateral LASIK, the insured telephoned the patient to inform him that he had a thin cornea in the left eye and that he intended to perform PRK OS and LASIK OD. However, when the patient presented for surgery, the insured informed him that PRK would be performed OU since he was not a good candidate for LASIK surgery in either eye. Bilateral PRK was performed.

The patient did well during the initial postoperative period with uncorrected vision ranging from 20/50 to 20/100 OU. However, within a week, his uncorrected vision declined to 20/200 OU with corneal haze greater OD than OS. His condition did not improve and, less than one month following the bilateral PRK, the insured provided the patient's disability carrier with a letter stating that the patient was completely disabled due to corneal ectasia. The patient was subsequently fitted with custom contact lenses to help decrease the distortion resulting from the weakened corneas, but he could not tolerate the lenses, which only corrected to 20/200 OU.

Analysis

According to the plaintiff expert, the patient suffered from keratoconus OS based on a preoperative topography that revealed central corneal steepness greater than 50 diopters and corneal thickness of 440 microns. There were also preoperative clinical signs of keratoconus, including an unstable prescription, a best correctible visual acuity of less than 20/20, and increasing irregular astigmatism. Plaintiff expert stated that the patient suffered from forme fruste keratoconus in the right eye as the topographic data revealed inferior steepening and a thin cornea and should have been better counseled on his condition and not allowed to have bilateral PRK performed on the same day. Plaintiff testified that he initially presented to the OMIC insured, not for refractive surgery, but to have his glasses prescription changed. He also alleged that he was never told that the condition of his corneas increased the risk that he might suffer complications.

Unfortunately, there was no evidence in the insured's records that he had reviewed the topographies that were taken on two separate occasions. The insured clearly did not suspect that the patient was suffering from either keratoconus or forme fruste keratoconus and did not warn the patient of the increased risk of ectasia. Further complicating the defense was the fact that the patient had not signed a consent form specific to PRK.

Defense experts were unable to support the insured's care and focused instead on evaluating the plaintiff's claimed damages. Faced with the probability of a plaintiff verdict exceeding his $1 million policy limits, the insured consented to a settlement and the case was resolved.

Risk Management Principles

Diagnostic tools such as topographies are only useful if they are accurately reviewed and considered in tandem with the clinical picture. No matter how similar the risks and complications, specific informed consent must be obtained for each procedure. This includes a discussion with the patient of the procedure-specific risks, potential complications, and benefits and requires that the patient sign each consent form. If a different procedure is substituted for the original planned procedure, the consent process should begin anew, including obtaining the patient's signature on a procedure-specific consent form. To avoid an allegation of performing a contraindicated procedure, ophthalmologists should ensure that their preoperative assessment is thorough and well documented in the medical record. See the **Hotline** article.