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Claim Abstract:

Bilateral LASIK Surgery

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Scenario

A young woman's visual acuity was corrected with glasses to 20/20 in both eyes. The ophthalmologist performed an assessment for appropriateness of LASIK surgery. Her pupil size was noted as being 6 mm., which was estimated using a muscle light and size card (as opposed to a pupillometer). The patient partook in detailed education and informed consent discussions. Following simultaneous bilateral LASIK surgery, the patient complained of inability to read and drive with associated halos, ghosting and starbursting. The physician noted that there was a slight undercorrection and planned to wait for refraction to stabilize before further treatment. The possible need for surgical enhancement was determined and subsequently performed. Post-operatively, there was some symptomatic improvement. However, in a short period of time, the inability to read, halos, and ghosting symptoms returned.

Several months later, the pupils were again measured as 6 mm. utilizing the previously described method of measurement. The physician prescribed a medication to decrease the pupil size. Still dissatisfied with the outcome of the surgery, the patient sought the opinion of a corneal specialist, whose measurement of the pupil size was 8mm., which was determined through the use of a pupillometer. Corneal topographies indicated mild, irregular astigmatism in both eyes. The patient was informed that her symptoms were due to pupils that were too large for the ablation zone and that prior to surgery she was at increased risk for developing post-LASIK complications such as those she was now experiencing.

Allegation & Outcome

The patient brought suit against the ophthalmologist for inappropriate selection of a surgical procedure resulting in complications that contributed to her inability to read, drive, and maintain employment. The inability to substantiate the method of pupil measurement as the standard of care cast

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doubt upon whether the best care was provided. The claim was settled.

Clinical Perspective

- 1. The use of a pupil card may not provide the most accurate depiction of pupil size.
- 2. Patients with large pupil size may experience greater risk of post-operative vision problems.

Defense Perspective

- There was a significant disparity between the ophthalmologist's pupil measurements and the corneal specialist's measurements, which in itself evidenced at least the existence of a margin of error in using a card to measure pupil size.
- Clinical research was taken into consideration, which questioned the correlation between pupil size and post-LASIK complications.

Patient Safety & Risk Management Perspective

- 1. The need to identify those patients with large pupils makes precise pupillometry measurements crucial.
- 2. The informed consent discussion, physician documentation and forms should specifically indicate the possibility exists that patients with large pupil size may be at increased risk for specific complications.

The *Physician Office Practice Toolkit*, found on our secure website at www.princetoninsurance.com (*registration/log-in required*), provides pertinent resources on informed consent.

Also see a sample informed consent form, which you may consider using as a guide for your informed consent discussion with patients. This form can be downloaded at www.PrincetonInsurance.com/downloads/

Risk_Review_Downloads/Spring.2010/SampleConsentForm_Lasik.pdf.

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