

Informed Consent

A patient with forme fruste keratoconus seeks PRK.

BY ERIC D. DONNENFELD, MD

Informed consent is a dynamic process that demands the successful transfer of information to the patient regarding the reasonable risks and benefits of as well as alternatives to a potential treatment. The physician is responsible for this education, but it can also be provided through written material, video, and/or surrogate providers. However, the final decision to proceed with a treatment option rests in the hands of the informed patient. This article discusses the informed consent process for a patient with forme fruste keratoconus who seeks PRK.

DO OR DO NOT TREAT

Which Procedures Increase the Risk for Ectasia?

The first consideration is the basic question of why a physician would treat a patient with forme fruste keratoconus if there were an increased risk of ectasia and poor visual outcomes associated with this condition. My first response is to question the notion that PRK increases a patient's risk of ectasia. Although there is an undeniable association of LASIK and this complication, there has only been one case report of ectasia following PRK.¹ Keratoconus is an extremely common disorder with a documented prevalence of one in 2,000.² It is not unreasonable to suggest that some patients who have undergone PRK (or LASIK for that matter) would have developed ectasia with or without their surgery. However, a more conservative and perhaps reasonable statement would be that ectasia is a rare but known complication of LASIK and there is a real, but probably significantly decreased, risk of ectasia with PRK as compared to LASIK. Unfortunately, there are no data at this time that provide the known risk of ectasia after PRK.

Diagnosing an Abnormal Cornea

The first step is recognizing an unusual topography and informing the patient of your finding. I simply tell the patient that, during our preoperative examination, my colleagues and I noted that the topographic studies suggest

that the shape of his cornea is not normal. This different shape may place the patient in a higher risk category for the development of keratectasia in the future if he undergoes laser vision correction surgery. The risk of keratectasia in an eye with abnormal topography is higher with LASIK surgery, because the laser treatment is applied deeper in the cornea under a flap than during surface ablation. This technique of laser vision correction (also called PRK, LASEK, and Epi-LASIK) is thought to lessen, but not eliminate, the risk of postoperative keratectasia.

Warning Patients

Patients should be aware that ectasia is a rare but known complication characterized by irregular thinning and weakening of the cornea that can lead to a progressive change in refractive error. Ectasia may occur in completely normal eyes undergoing refractive surgery, but it is more common in individuals with high myopia, thin corneas, and irregular topography. Refractive surgery in these patients can result in a loss of UCVA and BCVA. The progressive change is similar to that associated with keratoconus.

The treatment for keratectasia and keratoconus are the same and may require soft or hard contact lenses rather than glasses to obtain satisfactory vision. In advanced stages, surgical intervention may be required to restore functional vision. Options could include corneal inlay surgery (Intacs; Addition Technology, Inc., Des Plaines, IL) or a corneal transplant. People with keratoconus develop keratectasia with or without laser refractive correction, whereas susceptible individuals may develop it after laser vision correction.

Although severe topographic irregularities are a contraindication for laser vision correction, many patients with slight abnormalities achieve excellent visual outcomes. Mild topographic changes are common, and patients who have them may or may not be at an increased risk for developing keratectasia. Currently, there is no method available for testing an individual's susceptibility to keratectasia; corneal

topography can only provide guidance. There are also no absolute criteria for identifying a patient's susceptibility to keratectasia on topography or clinical examination. Patients should sign an abnormal topography consent that includes the aforementioned information as well as a conventional PRK consent form.

Increased Risk of Ectasia and PRK

Some surgeons would argue against PRK in any patient who is at an increased risk of ectasia. I would counter that this paternalistic approach denies the patient the opportunity for improved UCVA and BCVA, increased self-esteem, safety for certain occupations, and candidacy for certain employment. The issue is one of risk and benefit that can only be decided by the patient. The alternatives to PRK such as contact lenses also have risks such as infectious keratitis, which are more common and can be much more devastating than ectasia. Nonetheless, few ophthalmologists counsel routine patients that wearing a contact lens could result in their need for a corneal transplant.

DR. DONNENFELD'S GUIDELINES

I will not perform PRK on all patients with irregular topography. I have established my own eligibility criteria, which disqualify patients with an increased risk of progression to ectasia. My standards are as follows:

- vision that can be refracted to 20/25 or better;
- keratometry of less than 50.00D;
- preoperative pachymetry of greater than 450 μ m;
- postoperative pachymetry of greater than 375 μ m;
- treatable wavefront, which allows for customized ablation;
- stable refraction for at least 1 year; and
- age over 25 years.

Although I readily admit that my guidelines are not based on scientific studies, they are a starting point for me until clinical studies provide better information. At present, I continue to perform PRK on patients with mild forme fruste keratoconus (with a thorough informed consent). My results, thus far, have been excellent, and I believe I have provided a significant service to my patients. ■

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1. Malecaze F, Couillet J, Calvas P, et al. Corneal ectasia after photorefractive keratectomy for low myopia. *Ophthalmology*. 2006;113:742-746.
2. Binder, P, Lindstrom, R, Stulling R, Donnenfeld E. Keratoconus and corneal ectasia after LASIK. *J Refract Surg*. 2005;21:749-752.