

ADVANCED SURFACE ABLATION PROCEDURES

LASEK, EPI-LASIK, PRK

Outline of the DVD/Video/Web Presentation
by Mark R. Mandel, M.D.

Please Initial One
_____ I have watched the
DVD that was provided

_____ I have watched the
video on the website

1. I understand that I am having an advanced surface procedure because either my cornea is too thin, or has an abnormal configuration as demonstrated by the topographic maps, such that it would not be safe to perform LASIK. I am aware that there are risks inherent in the advanced surface procedures and that no procedure is without risk, especially in patients with thinner or unusually shaped corneas.

2. I understand that the realistic expectations for results, as well as many of the risks and complications inherent in the advanced surface procedures are the same as in LASIK. I understand that I will potentially need post-operative glasses or contact lenses in order to “fine tune” the vision if an enhancement is not possible. I will need reading glasses if I am in my mid-40s or older and I do not elect to have monovision. I may possibly need night driving glasses if I elect to have monovision.

3. I realize that unlike the LASIK procedure, all of the advanced surface procedures do not incorporate a corneal flap. The advantage to this is that there can be no intra-operative or post-operative flap complications. However, the disadvantage of not having a flap is that it can take up to a month or more for the surface to heal and for the vision to become clear. Although it is ultimately the patient’s decision, this is why we tend to perform surgery on only one eye at a time.

4. I am aware that the advanced surface procedures entail removing the surface cells (epithelium) of my cornea, applying the laser to the surface of the cornea, and then placing a soft contact lens on the eye for about a week following the surgery. Because I do not have a flap, during the early post-operative period (the first week), I will experience discomfort in the eye in the form of a foreign body sensation and/or aching in and around the eye.

5. Like LASIK, if the eye is overcorrected, undercorrected, or astigmatism is induced where no astigmatism existed before, I understand that I may need a touch-up or enhancement procedure. In almost every case, this will entail performing an advanced surface procedure again. However, unlike LASIK which can be enhanced at 3-4 months after the initial procedure, to accurately enhance the eye following the surface procedures we generally have to wait 8-10 months. In this way, we can be assured that the eye measurements are stable enough to enhance with the maximum degree of accuracy.

6. Like LASIK, I understand that following any of the advanced surface procedures, I have the

chance of experiencing glare, halos, star bursts at night, and/or decreased ability to discern subtle shades of gray, especially at night. I understand that the probability of developing these annoying side effects is less if I have a wavefront procedure, but even with the wavefront ablation, the probability of experiencing these side effects is not zero.

7. Unlike LASIK, I understand that scarring of the surface of the cornea is possible following any of the surface procedures. This is especially true with the higher amounts of nearsightedness (-6.00 diopters and above). Accordingly, I understand that Dr. Mandel uses a medicine known as Mitomycin-C which is applied to the surface of my cornea at the time of surgery. **Although Mitomycin-C is an FDA approved drug, I understand that this is an “off label” use of Mitomycin-C - meaning it is not FDA approved for this application.** I realize that there is the potential for complications as a result of the use of Mitomycin-C, but that to date there are no known reports of complications using Mitomycin-C associated with the advanced surface procedures.

8. I understand that, like any surgical procedure, infection is possible following the advanced surface procedures. If this occurs, the infection will be treated vigorously with antibiotic drops. However, even with intense treatment, a corneal infection can result in severe corneal scarring which significantly limits vision, necessitating the use of a hard contact lens or even a corneal transplant in order to achieve acceptable vision. In some very rare cases, the infection can be so severe as to cause permanent uncorrectible loss of vision in the eye.

9. I am having the advanced surface procedure because it was determined that my cornea was either too thin or the configuration of my cornea was too abnormal to safely undergo the LASIK procedure. The reason why the LASIK procedure is unsafe in thin or abnormally configured corneas is because of the risk of developing progressive thinning and protrusion of the cornea known as ectasia or keratoconus.

I may in fact have the potential to develop ectasia or keratoconus even with no laser intervention based on the fact that my cornea is thin and/or abnormally shaped. I understand that even the advanced surface procedures may hasten the development of ectasia or even precipitate the development of ectasia. Although this is much less likely than if I were to have the LASIK procedure, the probability of developing ectasia is not zero even with the advanced surface procedures. If ectasia occurs following the advanced surface procedure, then I am aware that I will be obligated to use a hard contact lens or undergo a corneal transplant operation in order to see well.

I have watched Dr. Mandel’s DVD, web presentation, which reviews the realistic expectations, limitations, side effects and the risks and complications of advanced surface ablation procedures. I have also reviewed the LASIK section of the DVD. I have read this outline along with the DVD. I was given a copy of this outline to keep for my records. I have also read Dr. Mandel’s handout entitled “Information about Surface Procedures: LASEK/PRK/EPI-LASIK”.

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PATIENT SIGNATURE

DATE