

## EVO PHAKIC INTRAOCULAR LENS INTRAOCULAR CONTACT LENS (ICL)

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

*Please Initial One*

\_\_\_\_\_ I have watched the  
video on my email.

\_\_\_\_\_ I have watched the  
video on the website

1. I am contemplating undergoing the phakic intraocular lens (PIOL) procedure, also known as the intraocular contact lens (ICL), because I am either too nearsighted to safely undergo LASIK or PRK, and/or my cornea is too thin, or the corneal configuration is not safe for one of the laser procedures. The PIOL has its own specific set of risks and complications different from the laser procedures. I have reviewed the section of the Video/web presentation on LASIK and I understand that the realistic expectations, limitations, side effects, and *some* of the risks and complications are similar to LASIK.

2. I understand that in order to place the PIOL, a small incision is made in my eye and the lens is permanently inserted into my eye. By definition, this is a more invasive procedure than any of the laser procedures because it involves surgery inside the eye. Accordingly, the risks and complications associated with this procedure are related to the possibility of complications occurring either during the surgery inside my eye, or as a result of having a permanent foreign body inside my eye.

3. The realistic expectation for results with the PIOL are similar to LASIK, in that following the implantation of these lenses, there is the possibility of overcorrection, undercorrection, or the induction of astigmatism where no astigmatism existed before. Accordingly, I understand that, if I have a normal cornea, I may desire a LASIK or PRK to fine tune the vision a few months following implantation of the lens. However, I also understand that if my corneal configuration is significantly abnormal, or my cornea is too thin, I may not be able to undergo a laser touch-up procedure and that in order to achieve my best possible vision, glasses or contact lenses will be necessary.

4. Some of the side effects of the PIOL are similar to LASIK. These include the potential need for enhancements using LASIK or PRK, the possibility of glare, halos, or decreased contrast sensitivity, the potential need for post-operative glasses or contact lenses (especially for driving at night), and the absolute need for reading glasses for those in their mid-40s or older (unless blended vision is performed). However, many of the complications of the PIOL are quite distinct from the LASIK and are listed below.

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5. The PIOL may need to be repositioned, or removed and replaced with another lens if the lens does not fit properly. Additionally, but rarely, as a result of chronic low grade inflammation, intermittent bleeding, if there is severe glare or halos, or increased pressure inside the eye, the implant may need to be removed and not replaced. Occasionally, one may need to use drops either to control chronic low grade increased pressure or, inflammation inside the eye, or to control pupillary dilation to diminish glare and halos at night.

6. Serious complications which can result in permanent decrease in vision or even loss of the eye relate to the possibility of severe infection introduced either at the time of surgery or in the post-operative period, retinal detachment, or severe bleeding in the back of the eye. Fortunately, these complications are exceedingly rare.

7. The development of a cataract, which is a clouding of the natural lens inside the eye, is possible following the lens implant procedure. If a cataract develops, it can either develop in the early post-operative period within the first year, or many years following the implantation of the PIOL. If a cataract develops and significantly affects the vision, then the procedure is to remove the PIOL, remove the cataract, and then place a new lens implant in the eye so as to restore vision. If it is necessary to remove the PIOL and the cataract, and to implant a new IOL, this is a very safe procedure, but the eye is again subjected to the possibility of infection, bleeding, retinal detachment, or swelling of the retina or cornea such that the vision could be poor after the cataract operation, or even result in permanent vision loss.

8. Rarely the pressure in the eye can go up to very high levels following the implantation of these lenses. This may require an application of the YAG laser in order to create small openings in the colored part of the eye (iris) called the iridectomies or may require removal of the implant. If the pressure increases significantly in the eye after PIOL surgery, this can damage the optic nerve in the back of the eye, the cornea in the front of the eye, create a cataract, or result in permanent dilation of the pupil each of which can cause disturbing glare or loss of vision.

**I have watched Dr. Mandel's Video/web presentation which reviews the realistic expectations, limitations, side effects and the risks and complications of LASIK and of the phakic intraocular lens/ intraocular contact lens procedures. I have reviewed this outline along with the Video/web presentation. I was given a copy of this outline and the LASIK outline to study before my surgery and keep for my records.**

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PATIENT SIGNATURE

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DATE

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