

PHAKIC INTRAOCULAR LENS INTRAOCULAR CONTACT LENS (ICL)

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

Please Check One

- I have watched the DVD
that was provided
- I have watched the video
on the website

1. I am aware that I will be undergoing the phakic intraocular lens (PIOL) procedure because I am either too nearsighted to safely undergo LASIK or one of the advanced surface procedures, and/or that my cornea is too thin or the corneal configuration is not safe for one of the laser procedures. Although the PIOL has its own specific set of risks and complications different from the laser procedures, I have reviewed the section of the DVD 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 require a LASIK or advanced surface procedure to fine tune the vision a few months following the implantation of the lens. However, I also understand that if my corneal configuration is significantly abnormal, 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 may be necessary.

4. I am aware that at least two weeks before the implant procedure two small openings must be placed in the iris (the colored part of my eye) using the YAG laser. These openings are necessary in order to normalize the pressure between the front and back chambers of my eye after the lens has been implanted. The risks and complications associated with the placement of these two iris openings are very rare and very minimal, but may include temporary bleeding inside the eye, low grade inflammation for a short period after the openings are created, and/or the very rare possibility of permanent glare and visual distortion as a result of these openings.

5. Many of the side effects of the PIOL are similar to LASIK. These include the potential need for enhancements, 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 monovision is performed). However, many of the complications of the PIOL are quite distinct from LASIK and are listed below.

6. The PIOL may need to be repositioned, or removed and replaced with another lens if the lens does not fit properly. Very rarely as a result of chronic low grade inflammation, occasional intermittent bleeding, or permanent increased pressure inside the eye, the implant may need to be removed and not replaced. Occasionally, patients may require the permanent use of anti-inflammatory drops to control low grade inflammation. One may need to use pressure lowering drops either to control chronic low grade increased pressure inside the eye, or to control pupillary dilation to diminish glare and halos at night.

7. 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.

8. 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. In the FDA trials, this was seen in about 1.6% of cases. 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 would be poor after the operation.

9. Even with the two small iris openings (iridectomies), the pressure in the eye can go up to very high levels following the implantation of these lenses. This may require another application of the YAG laser in order to increase the size of the iridectomies. If the pressure increases significantly in the eye after PIOL surgery, this can damage the optic nerve in the back of the eye or the cornea in the front of the eye such that permanent vision loss may occur.

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

PATIENT SIGNATURE

DATE

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