

Phakic Intraocular Lens (PIOLs)

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Phakic Intraocular Lens (PIOLs)

Agenda

- Safety Initiatives: Kesia Alexander, Ph.D.
- ANSI/ISO Standards: Don Calogero, MS

Safety Initiatives

Panel Input on:

- Patient Labeling
- PIOL website
- PIOL Standards: ANSI Z80.13 and ISO 11979-10
- SightNet

Safety Initiatives

Topics

- Approved PIOLs
- Patient Labeling
- PIOL website

Approved PLOs

P030028: Ophtec's Artisan/Advanced Medical Optics' Verisyse

- Panel Meeting: 02/05/04
- Approved: 09/10/04
- Post Approval study (PAS): ongoing

P030016: STAAR's Visian Implantable Collamer Lens

- Panel Meeting: 10/03/03
- Approved: 12/22/05
- Post Approval Study (PAS): on going

Safety Initiatives

Patient labeling:

- » How the device works
- » Risks/benefits
- » Alternative treatments
- » **Contraindications, warnings, precautions**
- » Are you a good candidate?
- » What to expect regarding surgery?
- » Questions to ask your doctor
- » Patient assistance information

Patient Labeling

Contraindications

- Who are less than 21 years old
- Who has an anterior chamber depth (ACD) outside of the approved range
- With an abnormal Iris (e.g., peaked pupil or elevated iris margin)
- Who are pregnant and nursing
- Who do not meet the minimum endothelial cell density (ECD)

Patient Labeling

Warnings

- **Long-term rate of cataract formation secondary to implantation, removal and/or replacement is unknown**
- **The occurrence of lens opacities in the future is unknown**
- **The long-term effects on the corneal endothelium have not been established. Patients should be advised about potential risk of corneal edema (swelling), possibly requiring corneal transplantation**
- **The potential of the lens to alter intraocular pressure and long-term risk of glaucoma, peripheral anterior synechiae and pigment dispersion are unknown.**

Patient Labeling

Precautions

- Abnormality of the iris
- Recurrent ocular inflammation
- History of ocular diseases
- Congenital bilateral
- Glaucoma
- Diabetic retinopathy

Panel Question

Please discuss any recommendations you may have for modifications to patient labeling of phakic intraocular lens.

Safety Initiatives

We currently have a website (<http://www.fda.gov/cdrh/phakic/>) available to address the following:

- » What are phakic lenses?
- » Are phakic lenses right for you?
- » What are the risks?
- » What you should know and do before during & after surgery
- » Questions for your doctor before undergoing phakic lens implantation
- » FDA approved lenses
- » Glossary of terms related to phakic lenses
- » Other resources

Are Phakic Lenses Right For You?

You are probably NOT a good candidate for phakic lenses if:

- You have large pupils, a shallow anterior chamber, an abnormal iris, had uveitis, had problems with the posterior part of your eye.
- You are not an adult. There are no phakic lenses approved by the FDA for persons under the age of 21.
- You have a disease or are on medications that may affect wound healing.
- You have a low endothelial cell count or abnormal endothelial cells.
- You actively participate in sports with a high risk of eye trauma.
- You only have one eye with potentially good vision.

What Are the Risks?

- You may lose vision.
- You may develop debilitating visual symptoms.
- You may need additional eye surgery to reposition, replace or remove the phakic lens implant.
- You may be under treated or over treated.
- You may develop increased intraocular pressure.
- Your cornea may become cloudy.
- You may develop a cataract.
- You may develop a retinal detachment.
- You may experience infection, bleeding, or severe inflammation (pain, redness, and decreased vision).
- Long-term data is not available.

What you should know and do Before, During and After Surgery

Before Surgery:

- You will need an initial examination to make sure your eye is healthy and suitable for surgery.
- You will sign an informed consent document (a form giving permission to your doctor to operate on your eye).
- You should tell your doctor if you take any medications, vitamins and other supplements, have any allergies, have undergone any previous eye surgery or have had any medical conditions.

What you should know and do Before, During and After Surgery

During Surgery:

- The lens is generally inserted into the anterior chamber (behind the cornea and in front of the iris) through an incision made in your cornea, sclera, or limbus.
- Your doctor will place some eye drops or ointment in your eye and cover your eye with a patch and/or a shield.
- The surgery will probably take around 30 minutes.

What you should know and do Before, During and After Surgery

Immediately After Surgery:

- Your doctor may prescribe pain medication to make you more comfortable during the first few days after the surgery.
- You may be sensitive to light and have a feeling that something is in your eye and you may experience minor discomfort.
- You should contact your eye doctor immediately if you have severe pain.

What you should know and do Before, During and After Surgery

Immediately After Surgery (cont'):

- Your vision will probably be somewhat hazy or blurry but it should start to improve after the first several days.
- You may experience sensitivity to light, glare, starbursts or halos around lights, or the whites of your eye may look red or bloodshot. These symptoms should decrease as your eye recovers over the next several weeks.
- Do NOT rub your eyes, especially for the first 3 to 5 days.

Questions For Your Doctor before undergoing Phakic Lens Implantation

- Do I have any conditions that would increase my risks?
- Are the size of my pupils under low lighting conditions bigger than the size of the lens? Is my anterior chamber shallow? If so, what are my additional risks?
- What are the benefits of the phakic lens for my amount of nearsightedness?
- What are the risks of having the phakic lens implanted?
- What is my risk of needing a corneal transplant in the future, if I have the phakic lens implanted, based on my age and my endothelial cell count?
- What quality of vision can I expect in the first week, first few months, and a year after surgery?

Panel Question

Please discuss any recommendations you may have for modifications to FDA's PIOL website.

Phakic Intraocular Lens (PIOLs)

THANK YOU!

OPHTHALMIC STANDARDS for Phakic IOLs

Don Calogero, MS
Senior Biomedical Engineer
FDA / CDRH/ ODE/ DOED

ISO Phakic IOL Standard

ISO 11979-10 (Phakic IOLs) which is recognized by FDA in its entirety with no additions.

ANSI Z80.13 (Phakic IOLs) is currently being reviewed for recognition.

ISO Phakic IOL Standard

Preclinical Requirements:

All optical, mechanical, biocompatibility, sterility, shelf-life and transport stability testing for PIOs has the same requirements as monofocal IOLs, with one exception.

ISO Phakic IOL Standard

Clearance analyses:

Analysis of the location of the PIOL surfaces with respect to ocular tissue must be conducted to establish the minimum anatomical dimensions acceptable for the PIOL design and the range of powers it will be available in.

ISO Phakic IOL Standard

Clinical Requirements:

The ISO PIOL standard contains the suggested design of a clinical investigation that will collect the data needed to determine the safety and performance of the PIOL.

ISO Phakic IOL Standard

1. Study design – non-controlled study, with a minimum study duration of three years to evaluate:
 - The maintenance of endothelial cell density
 - The rate of cataract development

ISO Phakic IOL Standard

2. Primary endpoint – Endothelial cell density (ECD).

Changes in ECD in PIOL subjects are compared to the normal rate of loss.

ISO Phakic IOL Standard

3. PIOL specific exclusion criteria

Recommends that subjects below recommended minimum ECD by age be excluded from study to minimize the possibility of corneal decompensation later in life.

ISO Phakic IOL Standard

4. Subject enrollment

Recommends that subjects be enrolled in 3 phases:

Phase 1 – 10 subjects followed for 6 months

Phase 2 – 100 additional subjects followed for 6 months.

Phase 3 – Remaining subjects

Recommended sample size is 300 – needed to detect clinically significant drop in ECD.

ISO Phakic IOL Standard

5. Recommended pre-op/post-op exams
 - Distance UCVA
 - Distance BSCVA
 - Near VA with distance spectacle correction
 - Manifest refraction
 - Cycloplegic refraction
 - Axial length
 - Anterior chamber depth
 - Intraocular pressure

ISO Phakic IOL Standard

Continued:

- Slit lamp exam
- Status of crystalline lens
- Gonioscopic exam
- Fundus exam with dilated pupil
- Mesopic pupil size
- Pachymetry of corneal thickness
- Keratometry
- Subject questionnaire
- Specular microscopy

ISO Phakic IOL Standard

Substudies:

- Contrast sensitivity – to assess contrast sensitivity losses that may be associated with the phakic IOL.
- Clinical clearance analysis – performed on all subjects in Phase 1 to determine the clearances between the Phakic IOL and the ocular tissue.

ISO Phakic IOL Standard

Some key recommended safety analyses

- Rate of endothelial cell density change
- Rate of cataract development
- Percentage of subjects that lose two or more lines of BSCVA

ISO Phakic IOL Standard

Clinical labeling requirements

- a summary of the clinical results of the investigation;
- any recommendations for periodic evaluations after implantation (based on the risk analysis and/ or any clinical investigation performed);
- Any restrictions in the indications for use if necessitated by the anatomical clearance analysis and clinical evaluation (e.g., ACD).

Panel Questions

Panel Questions

1. Please discuss any recommendations you may have for modifications to patient labeling of phakic intraocular lenses (PIOLs).

Panel Questions

2. Please discuss any recommendations you may have for modifications to FDA's PIOL website.

Panel Questions

3. Please discuss any recommendations you may have for future revisions of the ANSI and ISO PIOL standards.

Panel Questions

4. The training manual for SightNet participants currently emphasizes evaluation for and reporting of the following PIOL-related adverse events and complications.
 - » Toxic anterior segment syndrome (TASS)
 - » Endophthalmitis
 - » Explants
 - » Significant endothelial cell density (ECD) losses
 - » Corneal decompensation
 - » Significant losses of best corrected visual acuity (BCVA)

Panel Questions

Continued:

- » Retinal detachments
- » Intraocular pressure (IOP) spikes/elevations
- » Cataractogenesis
- » Device extrusions
- » Device failures/damage

Please discuss any recommendations you may have for revision of this list of adverse events and complications for which reporting is emphasized.