Investigation of the AcrySof® IQ PanOptix* Presbyopia Correcting IOL Model TFNT00

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The objective of this investigation is to describe visual outcomes and assess the safety at 12 months (330 - 420 days) post bilateral implantation of the AcrySof® IQ PanOptix* Presbyopia correcting IOL Model TFNT00.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON44109

Source
ToetsingOnline

Brief title
Investigation of the AcrySof® IQ PanOptix* IOL Model TFNT00

Condition

- Vision disorders

Synonym
Presbyopia

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories
Source(s) of monetary or material Support: Alcon Research Ltd.

Intervention

Keyword: IOL, PanOptix, Presbyopia

Outcome measures

Primary outcome

To assess the visual outcomes and safety over a period of 12 months (330 - 420

days)

Secondary outcome

Not applicable

Study description

Background summary

Presbyopia is a condition in which the eye gradually loses the ability to focus on near objects, or accommodate. This condition affects almost all people aged sixty and beyond. The modern day quest for perfect vision after cataract surgery includes restoration of this accommodative capability. Several approaches for treating presbyopia through the design of IOLs exist in practice, including the use of multifocal IOLs. Multifocal IOLs offer the cataract patient an opportunity to have the effects of presbyopia corrected after cataract surgery by providing multiple focal points. The majority of commercially available multifocal IOLs provide two optical zones for distance and near vision. The ACRYSOF IQ PanOptix Presbyopia IOL Model TFNT00 uses similar technology of commercially available multifocal IOLs to create an additional focal point for intermediate vision.

Study objective

The objective of this investigation is to describe visual outcomes and assess the safety at 12 months (330 - 420 days) post bilateral implantation of the AcrySof® IQ PanOptix* Presbyopia correcting IOL Model TFNT00.

Study design

This is a prospective, multicenter study requiring implantation of the AcrySof® IQ PanOptix* Presbyopia correcting IOL Model TFNT00 in both eyes. The

study will take about 12 months (330 - 420 days).

Intervention

Eye surgery with removal of the original lens and replacement by an ibntraocular lens.

Study burden and risks

The patients will be asked to visit the hospital 10 times in 12 months. Each visit will take in between 20 minutes and 3 hours. Exceptionally a visit can take longer. None of the tests are experimental. There some risks associated with routine cataract surgery. These risks include bleeding, infection, inflammation, detachment of the retina, increased eye pressure, and swelling under the retina. There is a small chance that vision could actually be made worse by the surgical procedure. If the lens is not in the correct position, the vision may also be affected and the normal flow of fluid within the eye may be blocked. The patient may require additional surgery to treat these side effects and improve surgery results.

Multifocal lenses are significantly different than standard monofocal lenses. Although the multifocal lens is designed to provide near and intermediate vision in addition to distance vision, it is possible that the patient's near vision may not be asclear or as sharp in low light as with a monofocal lens implant when used with glasses. Even with a ultifocal lens, the patient may also need to wear reading glasses to see up close under dim lighting conditions.

The potential vision problems listed above may trouble the patient enough to require removal of the intraocular lens that was implanted. If there is a reduction in the vision (near or far) or if the patient has visual symptoms that cannot be tolerated, the doctor may need to perform a second surgery to reposition, remove or replace the intraocular lens.

During the study, at different visits, the patient may have eye drops used for pupil dilation which may cause temporary sensitivityto light and blurred vision. Sunglasses should be worn in bright light. Driving a car or performing any hazardous activity should not be done until the effects of the medication are gone and normal vision returns.

Eye pressure may be tested during the study. The eye pressure test involves the placement of eye drops containing a small amount of a numbing drop into the eye. It is important that the patient does not rub your eyes for at least 15 minutes after the drops are put into the eye, since small particles or dust in the eye might scratch the cornea and the numbing drop would make the patient temporarily unable to feel the pain. Minor scratching of the corneal surface may rarely occur when the pressure in the eye is measured.

I addition there is always the risk that uncommon or previously unknown side effects may occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adults, 22 years of age or older at the time of surgery, of either gender or any race, diagnosed with bilateral cataracts with planned cataract removal by phacoemulsification with a clear cornea incision;;2. Able to comprehend and willing to sign informed consent and complete all required postoperative follow-up procedures;;3. Calculated lens power within the available range;;4. Preoperative BCDVA worse than 0.20 logMAR (ie, 0.22 logMAR or worse) in both eyes;;5. Potential postoperative BCDVA of 0.20 logMAR or better in both eyes based on Investigator expert medical opinion. (NOTE: Subjects with any pathology that could reduce visual potential should not be enrolled in this trial);;6. Preoperative regular corneal

astigmatism of < 1.00 D, in both eyes;;7. Clear intraocular media other than cataract in both eyes.

Exclusion criteria

Prior operation;1. Clinically significant corneal abnormalities including corneal dystrophy (eg, epithelial,stromal, or endothelial dystrophy), inflammation or edema per the Investigator*s expert medical opinion.
Note: conditions including, but not limited to: keratitis, keratoconjunctivitis, keratouveitis, keratopathy, or keratectasia should be excluded;;2. Previous corneal transplant;;3. Ocular trauma, previous refractive surgery or refractive surgery procedures throughout the entire duration of the subjects* participation in the clinical study (including, but not limited to LASIK, astigmatic keratotomy and limbal relaxing incisions);;4. History of or current retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or presence of diabetic retinopathy that the Investigator judges could confound outcomes (NOTE: Including but not limited to background diabetic retinopathy, diabetic macular edema or proliferative diabetic retinopathy, macular degeneration);;5. Ambylopia;;6. Rubella, congenital, traumatic, or complicated cataracts;;7. Extremely shallow anterior chamber (* 2.5 mm), not due to swollen cataract;;8. Any current anterior or posterior segment inflammation of any etiology, and /or history of any disease producing an intraocular inflammatory reaction;;9. Iris neovascularization;;10. Glaucoma (uncontrolled or controlled with medication) or ocular hypertension;;11. Optic nerve atrophy;;12. Subjects with diagnosed degenerative eye disorders;;13. Known color vision deficiencies;;14. Pregnancy or lactation;;15. Any subject currently participating in another investigational drug or device study that may confound the results of this investigation;;16. Subjects who may reasonably be expected to require an ocular surgical treatment at any time during the study (other than YAG capsulotomy);;17. Situations where the need for a large capsulotomy can be anticipated (eg, diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.);;18. Subjects who are expected to require retinal laser treatment.;During Surgery;1. Any other additional procedures during the phacoemulsification and IOL implant due to intraoperative complications that require further intervention (including but not limited to posterior capture rupture, vitreous loss, zonular dehiscence that may make the IOL implant less stable, etc.);;2. Zonular or Capsule rupture;;3. Excessive iris mobility;;4. Mechanical or surgical manipulation required to enlarge the pupil prior to or at IOL implantation (pupil size must be at least 4.5 mm or larger just prior to implantation);;5. Significant anterior chamber bleeding;;6. Uncontrolled intraocular pressure;;7. Unrecognized (pre-existing but discovered during surgery ocular conditions or complications in which the IOL stability could be compromised, including zonular weakness;;8. Any incision site other than temporal;;9. Bag-sulcus, sulcus-sulcus or unknown placement of the haptics;;10. Capsulorhexis tears or any areas of *can-opener* capsulotomy.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	AcrySof® IQ PanOptix Presbyopia correcting IOL Model TFNT00
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-03-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02529488
CCMO	NL55425.068.15