European multicenter study with the ARTIFLEX Toric PIOL for the correction of astigmatism in phakic eyes

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Primary objectives:A. To determine the ability of the Toric ARTIFLEX PIOL to reduce astigmatism (performance); B. To establish the mechanical properties of the lens in the anterior chamber in terms of rotational stability of the lens, tilting of the...

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

Summary

ID

NL-OMON31010

Source
ToetsingOnline

Brief title
ARTIFLEX Toric

Condition

- Vision disorders

Synonym
Myopic astigmatism, nearsightedness with a cylinder

Research involving
Human

Sponsors and support

Primary sponsor: OPHTEC BV
Source(s) of monetary or material Support: OPHTEC financiert kosten van lenzen en instrumentarium

Intervention

Keyword: ARTIFLEX Toric, Astigmatism, Myopia

Outcome measures

Primary outcome

1. Reduction of cylinder

a. Magnitude of reduction (diopters);

b. % of eyes within 0.5 and 1.0 from intended correction;

2. Lens axis misalignment (compared to intended position);

3. Mechanical stability (tilting, distortion, fixation of the lens).

Secondary outcome

1. Manifest Refraction Spherical Equivalent (MRSE);

2. Best spectacle corrected and uncorrected distant visual acuity;

3. Safety (adverse events, ECC, IOP)

Study description

Background summary

Phakic PIOL implantation is one of the techniques for correcting refractive errors. Since the development of the ARTISAN Aphakia and its first use in cataract surgery in 1978, OPHTEC has introduced a range of products in the PIOL category, each recognizable by the unique *iris claw* fixation principle on which the design is based. This fixation principle is extremely versatile, allowing the lenses to be positioned in any meridian and centred on the pupil. Once fixated, the lens can not rotate or decenter.

In 1999, the European Multicenter Study with the Toric ARTISAN PIOL for the correction of myopia and hyperopia in combination with astigmatism was started. The results demonstrated that implantation of the Toric ARTISAN PIOL is a safe, predictable and effective way to reduce ametropia and astigmatism with one procedure. The Toric ARTISAN was introduced in the market in 2001. Modern cataract surgery with phacoemulsification through a small *sutureless* wound

stimulated OPHTEC to develop a foldable PIOL. After demonstrating the safety, efficacy, predictability and stability of this lens in a European Multicenter Study, the introduction of the foldable ARTIFLEX Myopia PIOL followed in 2005.

Main advantages of the small incision size needed for the foldable ARTIFLEX lens are a fast recovery time and less surgical induced astigmatism. As a result, the ARTIFLEX lenses have excellent predictability. Continuing on this path of development, OPHTEC now introduces another foldable PIOL, the ARTIFLEX Toric. In this lens, the possibility to correct astigmatism in one procedure, as in the existing ARTISAN Toric, and the advantages of a foldable lens, as in the existing ARTIFLEX Myopia, are combined.

Study objective

Primary objectives:
A. To determine the ability of the Toric ARTIFLEX PIOL to reduce astigmatism (performance);
B. To establish the mechanical properties of the lens in the anterior chamber in terms of rotational stability of the lens, tilting of the lens, distortion of the lens, fixation of the lens, etc.

Secondary objectives:
A. To determine postoperative refractive results;
B. To determine postoperative distant visual acuity;
C. To evaluate unexpected or rare adverse events.

Study design

Prospective, non-randomized and open label without a control group.
125 eyes with a follow-up of 6 month.
multicenter, 5 to 8 investigators, international.

Intervention

All patients receive a phakic intraocular iris fixated anterior chamber lens (ARTIFLEX Toric PIOL) in one or both eyes in a surgical procedure. After surgery, the investigators ask the patients to comply with their standard postoperative medication regime for approximately 3 weeks (antibiotics, corticosteroids).

Study burden and risks

The burden and risks are no different from alternative treatments (implantation with another PIOL).

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

- Stable refraction (±0.5 D; ±1.0 D for high refractive errors), as expressed by manifest refraction spherical equivalent (MRSE) for a minimum of 12 months prior to surgery, verified by consecutive refractions and/or medical records or prescription history;
- Myopic astigmatism requiring correction within the range of the ARTIFLEX Toric PIOL. The investigators will receive an availability list when it becomes available. The calculated refraction can be 0.25 D lower or higher than the minimum or maximum available lens power for both the cylinder and the sphere (e.g. if the minimum cylinder will be 1.0 D, the minimum cylinder of the patient has to be 0.75 D after calculation);
- A minimum BCVA of 0.5 in each eye;
- UCVA of 0.5 or worse;
- Less than 0.75 D difference between cycloplegic and manifest refractions;
- Regular astigmatism.

Exclusion criteria

Ocular conditions
1. Preoperative ocular condition that can predispose for future complications or interfere with the ability to evaluate the safety or effectiveness of the lens;
2. Abnormal iris (e.g. bulging or volcano shaped iris; abnormality which would preclude fixation such as aniridia);
3. Abnormal cornea (i.e., keratoconus, opaque cornea, scars, or other cornea pathologies resulting in irregular astigmatism);
4. Prior intraocular or corneal surgery;
5. Monocular vision;
6. Amblyopia;
7. Insufficient space for the intended implant (ACD < 3.2 mm);
8. High preoperative intraocular pressure, > 21 mmHg;
9. Abnormal pupil or pupil in low light > 7.0 mm (scotopic light: < 0.05 lux);
10. Patients that, when examined preoperatively, are not expected to achieve a postoperative visual acuity of 20/40 or better;
11. A minimal endothelial cell density according to the subject*s age:
21 to 25 years of age 2800 cells/mm2;
26 to 30 years of age 2650 cells/mm2;
31 to 35 years of age 2400 cells/mm2;
36 to 45 years of age 2200 cells/mm2;
> 45 years of age 2000 cells/mm2;
12. Surgical difficulty at the time of surgery which might increase the potential for complications;;Non-ocular conditions
13. Aged under 18 or above 60;
14. Acute or chronic illness that would increase the operative risk or confound the outcome(s) of the study;
15. Patients who are immuno-compromised by steroids and/or antimetabolites;
16. Subject is taking systemic medications that can confound the outcome of the study or increase the risk to the subject;
17. Subject is pregnant, plans to become pregnant, or is lactating during the course of the study, or has another condition associates with the fluctuation of hormones that could lead to refractive changes;
18. Diabetic mellitus;
19. Mentally retarded;
20. Patients that are not able to meet the extensive postoperative evaluation requirements;

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2008
Enrollment:	27
Type:	Actual

Medical products/devices used

Generic name:	Phakic Intraocular Lens (PIOL)
Registration:	No

Ethics review

Approved WMO Date:	22-08-2007
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
CCMO	NL16941.068.07