A randomised, subject-masked evaluation of visual function after bilateral implantation of two types of presbyopia-correcting multifocal intraocular lenses (IOLs): the Symfony-study

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Primary Objective: The primary objective of this study is to compare the postoperative visual outcomes in a series of patients bilaterally implanted with the AT LISA tri 839MP IOL versus those bilaterally implanted with the TECNIS® Symfony IOL (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anterior eye structural change, deposit and degeneration
Study type	Interventional

Summary

ID

NL-OMON42871

Source
ToetsingOnline

Brief title
Symfony-study

Condition

- Anterior eye structural change, deposit and degeneration

Synonym
presbyopia and cataract surgery; age-related long sight and removal of the natural lens of the eye and implantation of an artificial lens

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Abbott Medical Optics Inc.;Santa Ana;CA;USA

Intervention

Keyword: cataract surgery, presbopia-correcting IOLs, spectacle-independency

Outcome measures

Primary outcome

The primary endpoint is the binocular uncorrected visual acuity at 80 cm

distance under both photopic and mesopic conditions 13 weeks postoperatively.

Secondary outcome

Secondary endpoints are: binocular (un)corrected visual acuity at far (4

meters) and near (40 cm) under both photopic and mesopic conditions, reading

performance, patient satisfaction, and complication profile.

Study description

Background summary

Since the introduction of intraocular lenses (IOL) in the treatment of cataract, the postoperative accommodative loss of the human eye has been a trending topic. Numerous studies show a high rate of spectacle-independency after bilateral implantation of multifocal IOLs (MIOL). However, glare and halos under different light conditions are common complaints after MIOL implantation. Due to its unique design, the TECNIS® Symfony IOL (ZXR00) is theoretically providing a continuous range of high-quality vision for far, intermediate, and near distances with the same low incidence of halos and glare associated with monofocal IOLs.
The goal of this study is to compare the AT LISA trifocal 839MP (a commonly used multifocal IOL) versus the TECNIS® Symfony Extended Range of Vision IOL in

terms of postoperative achieved visual acuity at different distances and patient satisfaction. So far, there are no published studies comparing both IOLs. Therefore, we will perform this randomized control trial.

Study objective

Primary Objective:
The primary objective of this study is to compare the postoperative visual outcomes in a series of patients bilaterally implanted with the AT LISA tri 839MP IOL versus those bilaterally implanted with the TECNIS® Symfony IOL (ZXR00). Primary outcome measure is the mean binocular uncorrected intermediate visual acuity at 80 cm under both photopic and mesopic conditions at 13 weeks (3 months) postoperatively.

Study design

Single-centre randomised clinical trial

Intervention

Cataract surgery with bilateral implantation of either a TECNIS® Symfony Extended Range of Vision IOL (Symfony IOL, Abbott) or an AT LISA trifocal 839MP IOL (Zeiss).

Study burden and risks

The pre- and postoperatively examinations to be performed in this study are part of the regular medical treatment of patients with cataract who need cataract surgery. There are four postoperative visits, which is one more compared to standard cataract surgery. Both the TECNIS® Symfony Extended Range of Vision IOL (Symfony IOL, Abbott) and the AT LISA trifocal 839MP (Zeiss) used in this study, are CE marked and commercially available in the countries in which the study will be conducted.

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

- Minimum 21 years of age
- Bilateral cataract
- Bilateral implantation of Tecnis Symfony or AT LISA tri 839 (same lens model in both eyes)
- Expected postoperative astigmatism <= 1.00 D
- IOL power calculation between +10.00 D and 32.00 D
- Expected postoperative best-corrected visual acuity of logMAR +0.3 or better
- Availability to undergo second eye surgery within 2 weeks of the first eye surgery
- Willing and able to comply with scheduled visits and other study procedures
- Signed informed consent

Exclusion criteria

- Previous corneal surgery and/or reshaping
- Clinically significant corneal endothelial dystrophy (e.g., Fuchs* dystrophy)
- Irregular astigmatism
- History of corneal disease (e.g., herpes simplex, herpes zoster keratitis, etc.)
- Extensive age related macular degeneration (atrophic or exudative age-related macular degeneration or numerous soft drusen)
- Extensive visual field loss (e.g., glaucoma, CVA, etc.)
- Extensive diabetic macular disease
- Amblyopia, strabismus
- Keratoconus
- Pseudoexfoliation syndrome or other capsule or zonular abnormalities that could affect

postoperative centration or tilt of the IOL
- Pupil abnormalities (non-reactive, tonic pupils, abnormally shaped pupils, or pupils that do not dilate at least 3.5 mm under mesopic/scotopic conditions)
- Suturing of incision required at time of surgery
- Complications during surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	TECNIS Symfony Extended Range of Vision IOL
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-11-2016
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
Other	In behandeling
CCMO	NL56878.068.16

Study results

Date completed:	01-01-2019
Actual enrolment:	30