A randomized controlled trial on the visual function after bilateral implantation of two novel Extended Depth-of-Focus intraocular lenses.

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

Summary

ID

NL-OMON56071

Source
ToetsingOnline

Brief title
Vario-NL Study

Condition

- Vision disorders

Synonym
Cataract, clouding of the lens

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Teleon Surgical BV

Intervention

Keyword: Cataract, Extended Depth-of-Focus, Intraocular, Lenses, Visual acuity

Outcome measures

Primary outcome

The primary objective of this study is to compare the binocular UIVA at 66 cm under photopic conditions 3 months postoperatively, in a series of patients bilaterally implanted with the Acunex® Vario IOL versus those bilaterally implanted with the Alcon AcrySof® IQ Vivity® IOL.

Secondary outcome

- Mean mono- & binocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) at 4 mtrs 1 week, and 1 and 3 months postoperatively

- Mean binocular distance-corrected intermediate visual acuity ((DCIVA) at 66 cm at 1 and 3 months postoperatively

- Mean binocular uncorrected near visual acuity (UNVA) and distance corrected near visual acuity (DCNVA) at 40 cm at 1 and 3 months postoperatively

- Binocular defocus curves under photopic conditions at 3 months postoperatively

- Mean contrast sensitivity binocular at photopic and mesopic conditions at 3 months postoperatively

- Tilt and decentration of the IOL 1 month postoperatively

- Complication profile including halos and glare (all visits) according to the Likert scale

- Questionnaires on patient satisfaction including spectacle independence

(IOLSAT) and occurrence of optical complaints (Catquest-NL and QoV-NL) at 3

months postoperatively

Study description

Background summary

Nowadays, the most common types of intraocular lenses (IOLs) to correct aphakia after cataract surgery consist of monofocal, multifocal or extended depth of focus (EDOF) IOLs. Current monofocal IOLs provide one focal point which will provide the patient with unaided vision at only one distance, which necessitate the need of glasses to correct vision at all other distances. Multifocal IOLs (mIOLs) provide patients with unaided vision at more than one distance, causing less spectacle-dependency after cataract surgery. Although mIOLs offer better unaided near vision and less spectacle dependency in comparison to monofocal IOLs, a well-known drawback of mIOLs is the occurrence of halos and glare and the inherent loss of contrast sensitivity because of their optical design. EDOF IOLs offer an extended range of focus and enable the patient to have a wider range of unaided vision in comparison to monofocal IOLs, especially from intermediate (66 cm) to far, while mIOLs have shown better near vision in comparison to EDOF IOLs. The intermediate vision is becoming increasingly important in our day-to-day tasks (with computer or smartphone use).
The two EDOF-IOLs, which will be compared in this study are the Acunex® Vario IOL and the AcrySof® IQ Vivity® IOL. So far, there are no published studies comparing these IOLs that offer an extended range of vision at far and intermediate distances. It is expected that bilateral implantation with the Acunex® Vario IOL is non-inferior when compared to bilateral implantation with the Alcon AcrySof® IQ Vivity® IOL, with regards to binocular uncorrected intermediate visual acuity (UIVA) at 66 cm.

Study objective

The primary objective of this study is to compare the binocular uncorrected intermediate visual acuity (UIVA) at 66 cm under photopic conditions 3 months postoperatively, in a series of patients bilaterally implanted with the Acunex® Vario IOL versus those bilaterally implanted with the Alcon AcrySof® IQ Vivity® IOL.

Study design

The study design is a prospective monocenter randomized, double masked controlled clinical trial.

Intervention

All patients will recieve a standard cataract surgery on both eyes with the phacoemulsification technique. One group receives bilateral implantation with the Acunex® Vario IOL and the other group receives bilateral implantation with the AcrySof® IQ Vivity® IOL. A total of 32 patients will be randomized into either the Vario-group or the Vivity-group at a 1:1 ratio.

Study burden and risks

In this study, all participants will receive their cataract surgery according to standard procedures. As with any type of intraocular surgery, there is a possibility of complications due to anesthesia, drug reactions, and surgical problems.
Both Alcon AcrySof® IQ Vivity® IOL or the Acunex® Vario IOLused in this study, are CE-marked and commercially available in the countries in which the study will be conducted.
Postoperatively, there will be one extra postoperative visit, compared to standard cataract surgery follow-up. During the 1 month postoperative visit, there will be two additional, short and non-contact scans performed, using the IOLMaster and the Casia 2. All additional measurements are non-invasive. The participants will preoperatively and 13 weeks post-operatively be asked to fill in questionnaires (QoV-NL, Catquest-NL and the IOLSAT).
Postoperatively there may still occur residual refractive errors leading to a suboptimal patient satisfaction. Laser-treatment or spectacles may be needed to correct these errors. It is expected that the majority of participants will be spectacle-indepenent after implantation of the IOL.
Photopic phenomena (e.g. halo's and glare) can occur postoperatively, but usually these become less apparent after neuroadaptation has taken place. Compared to multifocal IOLs, these photopic phenomena as side effects are expected to occur at a lower rate and intensity in the EDOF IOLs, similar to monofocal IOLs.
Both spectacle-independency and reduced rate of photopic phenomena could significantly increase quality of life and vision-related quality of life.
Enrolled patients will receive a travel compensation (¤0,19 per km) during the last postoperative visit. If the participant travels by public transport, he/she will get a full refund for these costs.

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 18 years of age
- Bilateral cataract
- Bilateral implantation of either Acunex® Vario IOL or the Alcon AcrySof® IQ Vivity® IOL
- Expected postoperative astigmatism <= 1.00 D (use of femtosecond laser assisted cataract surgery (FLACS) astigmatic keratotomies (AKs) tolerated up to 1.5 D of corneal astigmatism preoperative)
- Bilateral implantation of a non-toric Acunex® Vario IOL or a non-toric Alcon AcrySof® IQ Vivity® IOL
- IOL power calculation between +10.00 D and +30.0 D
- Expected postoperative best-corrected visual acuity of logMAR +0.3 or better
- Availability to undergo second eye surgery on the same day or else 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
- Corneal pathology (i.e., fuchs endothelial dystrophy (FED), irregular astigmatism, herpes simplex virus (HSV) keratitis
- Extensive age-related macular degeneration (atrophic or exudative age-related macular degeneration or numerous soft drusen) and post-intravitreal injection (IVI)
- Extensive visual field loss (eg. glaucoma, cerebral vascular accident (CVA), hemianopsia, etc.)
- Extensive diabetic retinopathy
- Amblyopia, strabismus, diplopia
- Pseudo exfoliation 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)
- Cognitive cerebral or concentration disorders (e.g., dementia, Parkinson, stroke, etc.)
- Suturing of incision required at time of surgery
- Complications during surgery of the first eye.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2022
Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	Intraocular lens (EDOF IO; Acunex Vario IOL)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-03-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-04-2022
Application type:	Amendment
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	NL79042.068.21