Implantation of a non-diffractive extended depth-of-focus IOL and a monofocal IOL after myopic corneal laser refractive surgery: a randomized controlled trial.

Published: 24-01-2025
Last updated: 08-02-2025

The primary objective of this study is to compare the mean binocular DCIVA at 66 cm under photopic conditions 3 months after cataract surgery, in a series of patients, who previously underwent myopic laser surgery, bilaterally implanted with the non...

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

Summary

ID

NL-OMON57264

Source
ToetsingOnline

Brief title
EDOF vs monofocal IOL implantatin after myopic laser surgery

Condition

- Vision disorders

Synonym
Cataract, clouding of the lens

Research involving
Human

Sponsors and support

Primary sponsor: Universiteitskliniek voor Oogheelkunde
Source(s) of monetary or material Support: Alcon Laboratories, Inc.,Alcon Laboratories;Inc.

Intervention

Keyword: Cataract, Corneal Surgery, EDOF, Intraocular lens, Laser

Outcome measures

Primary outcome

The primary objective of this study is to compare the mean binocular DCIVA at 66 cm under photopic conditions 3 months after cataract surgery, in a series of patients, who previously underwent myopic laser surgery, bilaterally implanted with the non-diffractive advanced monofocal AcrySof® IQ Vivity® IOL (intervention-group) versus the Alcon monofocal AcrySof® IQ SN60WF IOL (control-group) both targeted for mini-monovision.

Secondary outcome

1. Visual acuity outcomes at 1 week postoperatively:

a. Monocular uncorrected distance visual acuity (UDVA) at 4m, using the ETDRS or Snellen chart

b. Monocular corrected distance visual acuity (CDVA) at 4m, using the ETDRS or Snellen chart

2. Visual acuity outcomes at 4 weeks postoperatively:

a. Monocular uncorrected distance visual acuity (UDVA) at 4m, using the ETDRS chart

b. Monocular corrected distance visual acuity (CDVA) at 4m, using the ETDRS

chart

3. Visual outcomes at 3 months postoperatively:

a. Monocular and binocular uncorrected distance visual acuity (UDVA) at 4 m, us-ing the ETDRS chart

b. Monocular and binocular corrected distance visual acuity (CDVA) at 4 m, using the ETDRS chart

c. Binocular uncorrected intermediate visual acuity (UIVA) at 66 cm, using the ETDRS chart

d. Binocular uncorrected near visual acuity (UNVA) at 40 cm, using the ETDRS chart

e. Binocular distance-corrected near visual acuity (DCNVA) at 40 cm

f. Binocular target corrected distance, intermediate, and near visual acuity (TCDVA, TCIVA, and TCNVA)

4. The percentage of eyes in which the postoperative manifest refractive spherical equiva-lent (MRSE) is within ± 0.25, 0.50, 0.75 and 1.00 D of the target refraction.

5. Uncorrected distance visual acuity distribution subset analysis based on pre-laser sur-gery refraction.

6. Binocular uncorrected defocus curve and target corrected defocus curve at 4 m (rang-ing from +1.50D to -2.50D) at 3 months postoperatively, in photopic

conditions.

7. Patient-reported outcomes, using the validated version of the Catquest-SF9 question-naire, at 3 months postoperatively.

8. Questionnaire on patient spectacle independence (IOLSAT) and occurrence of optical complaints (QoV) at 3 months postoperatively.

Study description

Background summary

In 1998 the FDA gave the first approval for LASIK (laser in situ keratomileusis) surgery, a safe procedure to adjust the refractive status of the cornea in pre-presbyopic and pre-cataract patients.(1) The population of post-LASIK patients requiring cataract surgery and seeking spectacle independence is expected to increase in the coming years. However, using presbyopia correcting multifocal intraocular lenses (mIOLs) after preceding corneal refractive surgery is controversial due to the potential side-effects of these mIOLs such as halos and glare, and less predictable postoperative refractive outcomes. This unpredictability arises from changes of the ratio between the anterior and posterior corneal curvatures, leading to inaccuracies in total corneal refractive power estimation and ineffective lens position predictions with the standard IOL calculation formulas.(2-4)

Currently, the standard care for cataract surgery after corneal laser treatment involves the implantation of the monofocal AcrySof® IQ SN60WF lens, which is widely regarded as the standard option. Patients preferring greater spectacle independence can opt for an Extended Depth of Focus (EDOF) IOL, such as the Alcon AcrySof® IQ Vivity®, if no medical contraindications exist. However, these patients must perform co-payment for this EDOF IOL.

The Alcon AcrySof® IQ Vivity® is an EDOF IOL that consists of a central 2.2 mm wavefront-shaping area with smooth continuous anterior surface transitions from the periphery to the center for providing the extended focal range. The wavefront-shaping area stretches and shifts the wavefront, which results in an extended focal range of > 1.5 diopters (D). This design provides continuous vision from distance to intermediate distances and preserves the contrast

sensitivity. Besides, this IOL has a monofocal visual disturbance profile without the halos and glare that are frequently experienced by patients after mIOL implantation.(5) For this reason, the non-diffractive IOL design could become a preferred choice for post-LASIK patients.

Despite promising outcomes for EDOF lenses in retrospective and prospective cohort studies, no robust evidence currently supports their superiority over monofocal lenses in post-corneal laser patients.(6-8) Moreover, post-LASIK patients face an increased risk of residual refractive error (target deviation) after IOL implantation, with the risk and its impact on visual acuity varying by lens design. Scientific data on the risks and visual impact of such deviations remain limited, further emphasizing the need for a comparative study. This study aims to address this knowledge gap by conducting a double-masked, randomized, prospective clinical trial comparing the visual function of bilateral non-diffractive advanced monofocal Alcon AcrySof® IQ Vivity® IOL implantation with the standard Alcon monofocal AcrySof® IQ SN60WF IOL, both targeted for mini-monovision, in patients with previous myopic laser corneal surgery. By providing insight into visual performance, this trial seeks to clarify whether the EDOF IOL offers significant advantages over the monofocal IOL in this specific patient group.

References:

1. Solomon KD, Fernández de Castro LE, Sandoval HP, Biber JM, Groat B, Neff KD, et al. LASIK world literature review: quality of life and patient satisfaction. Ophthalmology. 2009;116(4):691-701.
2. Seitz B, Langenbucher A, Nguyen NX, Kus MM, Küchle M. Underestimation of intraocular lens power for cataract surgery after myopic photorefractive keratectomy11The authors have no proprietary interest in the development or marketing of this or any competing instrument or piece of equipment. Ophthalmology. 1999;106(4):693-702.
3. Chan TC, Liu D, Yu M, Jhanji V. Longitudinal evaluation of posterior corneal elevation after laser refractive surgery using swept-source optical coherence tomography. Ophthalmology. 2015;122(4):687-92.
4. Wang L, Hill WE, Koch DD. Evaluation of intraocular lens power prediction methods using the American Society of Cataract and Refractive Surgeons Post-Keratorefractive Intraocular Lens Power Calculator. J Cataract Refract Surg. 2010;36(9):1466-73.
5. van Amelsfort T, Webers VSC, Bauer NJC, Clement LHH, van den Biggelaar F, Nuijts R. Visual outcomes of a new nondiffractive extended depth-of-focus intraocular lens targeted for minimonovision: 3-month results of a prospective cohort study. J Cataract Refract Surg. 2022;48(2):151-6.
6. Bucci FA, Jr. Patient Satisfaction, Visual Outcomes, and Regression Analysis in Post-LASIK Patients Implanted With Multifocal, EDOF, or Monofocal IOLs. Eye Contact Lens. 2023;49(4):160-7.
7. Christopher KL, Miller DC, Patnaik JL, Lynch AM, Davidson RS, Taravella MJ. Comparison of Visual Outcomes of Extended Depth of Focus Lenses in Patients

With and Without Previous Laser Refractive Surgery. J Refract Surg. 2020;36(1):28-33.
8. Ferreira TB, Pinheiro J, Zabala L, Ribeiro FJ. Comparative analysis of clinical outcomes of a monofocal and an extended-range-of-vision intraocular lens in eyes with previous myopic laser in situ keratomileusis. J Cataract Refract Surg. 2018;44(2):149-55.

Study objective

The primary objective of this study is to compare the mean binocular DCIVA at 66 cm under photopic conditions 3 months after cataract surgery, in a series of patients, who previously underwent myopic laser surgery, bilaterally implanted with the non-diffractive advanced monofocal AcrySof® IQ Vivity® IOL (intervention-group) versus the Alcon monofocal AcrySof® IQ SN60WF IOL (control-group) both targeted for mini-monovision.

Study design

The design of this study is a multicenter, double masked, prospective randomized controlled trial. Patients who previously underwent myopic corneal refractive surgery on both eyes and now suffering from cataract which requires cataract surgery on both eyes will be included in the study. This study will be conducted in 3 different centers in 2 different countries.
The study consists of two study-groups: intervention group (bilateral implantation with the non-diffractive advanced monofocal AcrySof® IQ Vivity® IOL) and the control-group (bilateral implantation with the Alcon monofocal AcrySof® IQ SN60WF IOL both targeted for mini-monovision. A total of 48 patients will be randomized into either the intervention-group or the control-group at a 1:1 ratio. Patients and study-optometrists/research assistants doing the postoperative measurements will be masked. Surgeons are impossible to mask, due to the difference in (optical) design between both IOLs. All surgeries will be performed by experienced surgeons, performing >250 cataract surgeries per year. Cataract extraction will be performed using either the conventional or Femtosecond-laser assisted cataract surgery, according to the preference of the surgeon.

The IOL power calculation will be performed according to the optical biometry assessment of the IOLMaster700 and the Barrett True K formula will be used among all participants, using the Barrett True K toric calculator. The surgeons will use their personalized lens constants for optimal results. The power calculation will be targeted on mini-monovision in all participants, for the dominant eye we choose an emmetropic target closest to zero, and the non-dominant eye a myopic target between -0.25 and -0.75D is selected. Eye dominance is determined using the Miles test (triangle test).

Patients will be examined pre-operatively and 1 week, and 1 and 3 months

postoperatively. All patients will undergo delayed sequential bilateral cataract surgery (DSBCS) with the following post-operative examinations: one week after surgery of the first operated eye, one week after surgery of the second operated eye, and 1-, and 3-months postoperative visits at which both eyes will be examined in the same visit. Both eyes are examined simultaneously at 1, and 3 months postoperatively in order to minimize the number of postoperative follow-up visits for patients. Consequently, with DSBCS, at 1 months postoperatively, the first eye will be 5 weeks after surgery and the second eye 3 weeks. At 3 months postoperatively, the first eye will be 13 weeks after surgery and the second eye 11 weeks. We assume that this time difference does not affect the results.

Intervention

All patients will receive a standard cataract surgery on both eyes with the phacoemulsification technique. One group receives bilateral implanation with the AcrySof IQ Vivity IOL (EDOF IOL - intervention-group) and the other group receives bilateral implanation with the AcrySof IQ Monofocal IOL (Monofocal IOL - controlgroup). total of 48 patients will be randomized into either the intervention-group or the control-group at a 1:1 ratio.

Study burden and risks

In this study, all participants will receive their cataract surgery according to standard procedure. As with any type of intraocular surgery, there is a possbility of complications due to anesthesia, drug reactions, and surgical problems. Both Alcon AcrySof Vivity and Monofocal IOLs, used 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 in addition to the standard cataract surgery follow-up. All additional measurements during this visit are non-invasive. And lastly, the participants will be asked to fill out questionnaires at 3 months posoperatively regarding patient satisfaction, quality of vision and spectacle independence.
Postoperatively there may still be residual refractive errors leading to a suboptimal patient satisfaction. Laser-treatment or spectacles may be needed to correct these errors. In addition, optical disturbances (halos and glare) can occur postoperatively, but usually these become less apparent after neuroadaptation has taken place. According to the literature, EDOF and monofocal IOLs carry comparable risks for these optical disturbances after surgery.
Enrolled patients will receive travel compensation during the last postoperative visit (¤0.,19 per km). If participants travel by public transport, a full refund for these costs will be offered.

Contacts

Public
Selecteer

P Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Selecteer

P Debyelaan 25
Maastricht 6229 HX
NL

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 age-related cataract
• Bilateral implantation of either the toric or non-toric Alcon AcrySof® IQ Vivity® IOL or IQ SN60WF IOL
• IOL power calculation between +10.0 D and +30.0 D
• Expected postoperative best-corrected visual acuity of logMAR +0.2 or better
• Previous refractive corneal laser surgery for correction of myopia (LASIK and PRK).
• Availability to undergo second eye surgery within 2 weeks after the first eye surgery
• Willing and able to comply with scheduled visits and other study procedures

• Signed informed consent

Exclusion criteria

• Patients with preoperative corneal astigmatism >1.50D
• Patients with a postoperative expected refractive residual astigmatism <=0.50D
• Patients with a pre-laser myopia exceeding 6.0D
• Preoperative central corneal thickness <400 micron
• Corneal total higher order aberration >0.4 micron in a 4mm pupil (measured via pre-op Pentacam)
• Corneal pathology (i.e. Fuchs endothelial dystrophy (FED), irregular astigmatism, her-pes 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 (e.g. glaucoma, cerebral vascular accident, hemianopsia)
• Extensive diabetic retinopathy

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:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	Intraocular lens (EDOF IOL; Alcon AcrySof IQ Vivity IOL)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-01-2025
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	NL87062.068.24