A randomised, subject-masked evaluation of introcular lens stability after implantation of two different lens models: FEMTIS-study

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Primary Objective: The primary objective of this study is to compare postoperative decentration of the FEMTIS-IOL versus a standard monofocal IOL (Acrysof monofocal IOL)Secondary Objective(s): The secondary objectives of this study are to compare:-...

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

Summary

ID

NL-OMON42905

Source
ToetsingOnline

Brief title
FEMTIS-study

Condition

- Eye disorders

Synonym
Cataract, clouding of the lens in the eye

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Oculentis GmbH;Berlin;Germany

Intervention

Keyword: Cataract, Intraocular lenses, Stability

Outcome measures

Primary outcome

Mean postoperative decentration at 13 weeks postoperatively

Secondary outcome

- Mean rotation at 13 weeks postoperatively

- Mean tilt 13 weeks postoperatively

- Mean subjective refraction 13 weeks postoperatively

- Mean uncorrected distance visual acuity (UDVA) 13 weeks postoperatively

- Mean best corrected distance visual acuity (BCVA) 13 weeks postoperatively

- Complication profile 13 weeks postoperatively

Study description

Background summary

Cataract is a clouding of the crystalline lens which causes vision loss and blindness if untreated. Cataract surgery is the most frequently performed surgical intervention in medicine with an incidence of 880 surgeries per 100.000 population in 2010 amounting to a total number of over 160.000 surgeries per year in the Netherlands.1,3 The number of individuals with cataracts is predicted to reach 30 million by the year 2020.2 Due to aging of the general population this number of cataracts will only grow in the future. For the last decade conventional phacoemulsification cataract surgery (CPCS) is the dominant form of cataract surgery in developed countries, accounting for over 90 percent of these procedures.4 The basic phacoemulsification procedure has remained largely unchanged over the past 20 years, including a series of steps: creating corneal incision, capsulorhexis and lensfragmentation.4 Although highly successful, each of the steps mentioned above are created manually which affects the safety and effectiveness of the

procedure.
Since the first human eye was treated by femtosecond laser cataract surgery in 2008, the femtosecond-laser assisted cataract surgery (FLACS) became an innovative growing new technology in the world of cataract surgery.4-7 Femtosecond-lasers are capable of performing some of the most delicate and essential key steps during cataract surgery: capsulotomy, lens fragmentation, and corneal incisions. *Automating* these steps and performing them with increased precision could lead to an improved quality of capsulotomy, easier lens fragmentation, and more precisely positioned corneal incisions, which in turn, lead to improved visual and refractive outcomes, a decrease in intra- and postoperative complication rates, and increased quality of life.
In order to remove the crystallized human lens, a circular opening in the capsular lens bag, capsulotomy, needs to be created. After removing the lens an intraocular lens (IOL) can be inserted in the empty capsule bag. However, one of the factors affecting postoperative achieved visual acuity and refraction, is the behaviour of this IOL in the capsular bag. Preoperative measurements need to be obtained in order to calculate the required IOL. One of the challenges of these IOL calculations is determining exactly where in the eye the IOL will end up, the effective lens position (ELP). The position of the IOL is crucial for the IOL*s general performance because it influences the postoperative IOL tilt, decentration, and posterior capsule opacification (PCO). Considering the anatomical variety between patients, the predictability of an individual*s ELP remains an educated guess.
The ELP, and therefore the amount of IOL tilt, decentration and PCO, of an IOL is mainly influenced by the interaction between the IOL and the lens capsule, especially during the time of capsule shrinkage. Theoretically, the positive optical effect of an IOL is lost when there is more than 7 degrees of tilt or more than 0.4 mm of decentration.8 Furthermore, many studies have shown the effect of axial displacement of an IOL on refractive error. There is approximately 1.25 D change per millimetre of the IOL*s longitudinal displacement.9 This reflects the importance of a stable and predictable ELP.
As mentioned above, the anatomy of an individual*s eye is unique and therefore, each ELP will be different when placing the IOL in the capsular bag. Therefore, a new lens type has been developed: the FEMTIS® FB-313 laser lens (FEMTIS-IOL, Oculentis). This IOL has a special haptic system and is designed to be clasped in the capsular bag opening and therefore, the ELP of this IOL is theoretically more stable and predictable, resulting in a higher predictability of refractive and visual outcomes. However, in order to provide as much stability as possible a (nearly) perfect capsulotomy is needed. Several comparative studies have shown that femtosecond-lasers produce a more precise, circular, reproducible, and better centered capsulotomy compared to conventional manual capsulorhexis.6-7 The combination between the femtosecond-assisted capsulotomy and the implantation of a FEMTIS-IOL in the capsular opening, could definitely contribute to the search of perfection in cataract surgery.
In this study we will investigate the stability of lens position and the visual outcome after implantation of the new FEMTIS-IOL using FLACS

capsulotomy compared to conventional placement of the IOL in the capsular bag. So far, there are no published studies using the FEMTIS-IOL. Therefore, we will perform this randomized control trial

Study objective

Primary Objective:
The primary objective of this study is to compare postoperative decentration of the FEMTIS-IOL versus a standard monofocal IOL (Acrysof monofocal IOL)

Secondary Objective(s):
The secondary objectives of this study are to compare:
- Rotation-stability
- Tilt
- UDVA
- Postoperative subjective refraction
- BCVA
- Complication profile

Study design

The study design is a single-centre randomized clinical study. The study will be conducted at the Maastricht University Medical Centre (MUMC), the Netherlands.

Intervention

Cataract surgery with implantatie of either a FEMTIS-IOL or an Acrysof Monofocal IOL

Study burden and risks

The pre- and postoperatively examinations to be performed in this study are part of the regular medical treatment of patients who need cataract surgery. Postoperatively, there will be one extra postoperative visit, compared to standard cataract surgery follow-up.
Both the FEMTIS Laser Lens and Acrysof monofocal IOL are CE marked and commercially available in the countries in which the study will be conducted. The cataract surgery that will be performed in both groups is a standard femtosecond-laser assisted phacoemulsification procedure. As with any type of intraocular surgery, there is a possibility of complications due to anaesthesia, drug reactions, and surgical problems. An IOP increase may occur from the surgical procedure, residual viscoelastic in the eye, or a steroid response to post-operative medications. Raised IOP may be controlled with medication or non-intraocular treatment (e.g. pressure release at an existing wound edge).

There is no additional burden or risk for the patients compared to routine FLACS cataract surgery with implantation of a standard IOL. As mentioned above, the early results from Holland et al. show a comparable complication profile to standard IOL implantation.12
The possible benefits of FEMTIS-IOL implantation are a better refractive outcome, due to less decentration, tilt, and rotation postoperative. Furthermore, a highly predictable effective lens position provides better refractive outcome. Centering the capsulorhexis on the visual axis might decrease higher order aberrations, resulting in an increased postoperative patient satisfaction.13

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

Cataract
Minimum 40 years of age
Astigmatism <0.75 D
Signed informed consent

Exclusion criteria

Traumatic cataract
Corneal diseases/surgery
Extensive eye diseases, e.g. macular degeneration, glaucoma, diabetic macular disease
Amblyopia
Cognitive, cerebral or concentration disorders

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2017
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	FB-313 G Femtis Laser Lens (Oculentis)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-11-2016
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	NL58195.068.16

Study results

Date completed:	01-03-2019
Actual enrolment:	40