

Evaluation of the effects of multifocal lenses on visual performance in patients affected by bilateral cataract and treated with phacoemulsification (cataract surgery)

Submission date 11/05/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/05/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/09/2022	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cataracts are when the lens, a small transparent disc inside your eye, develops cloudy patches. Over time these patches usually become bigger causing blurry, misty vision and eventually blindness.

Cataract surgery involves replacing the cloudy lens inside your eye with an artificial one.

The purpose of this study is to evaluate the visual results and patients' satisfaction of surgical treatment of phacoemulsification (cataract surgery) and implantation of the innovative intraocular multifocal lens (MFIOL) Oculentis LENTIS Mplus MF30 in patients with bilateral (in both eyes) cataract.

Who can participate?

Adult patients over 50 years old with cataract in both eyes

What does the study involve?

We recruit candidates for bilateral cataract extraction surgery. Each subject undergoes complete ophthalmologic evaluation in the 90 days before the procedure. Each patient receives a preoperative prophylactic treatment with moxifloxacin eye drops (5 mg/mL), one drop three times each day for three days before the surgical procedure. Afterwards, each patient undergoes bilateral cataract extraction surgery. Each eye is treated during a different session, one 30 days after the other.

Prof. R. Nuzzi and his team will perform all surgical procedures. After surgery, patients are kept under observation for a few hours and later discharged according to standard protocol. They are subsequently asked to show up to follow-up ophthalmologic visits after one day (t1), seven days (t2), one month (t3), three months (t4) and six months (t6).

What are the possible benefits and risks of participating?

Participants will have their cataract removed and may have their visual acuity improve. Thanks to the implantation of a multifocal intraocular lens, they may reduce their spectacle dependence in

everyday activities at different visual distances, which could not be achieved with standard mono-focal intraocular lenses. All participants are exposed to the risk of ocular surgery, which, although rare, can be severe, such as retinal detachment, ocular internal hemorrhage and infection, or less serious like corneal and/or retinal edema. Multifocal intraocular lenses may produce adverse visual effects in some patients, such as halos, glares, double vision, etc.

Where is the study run from?

Department of Ophtalmology, A. O. U. Città della Salute e della Scienza di Torino, Turin, Italy.

When is the study starting and how long is it expected to run for?

September 2017 to September 2020

Who is funding the study?

University of Turin (Italy)

Who is the main contact?

Prof. Raffaele Nuzzi, prof.Nuzzi_Raffaele@hotmail.it

Contact information

Type(s)

Public

Contact name

Prof Raffaele Nuzzi

ORCID ID

<https://orcid.org/0000-0002-9213-2718>

Contact details

University of Turin

Via Cherasco 23

Turin

Italy

10126

+39 (0)116332220

raffaele.nuzzi@unito.it

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CS2/725

Study information

Scientific Title

Evaluation of the effects of multifocal lenses on visual performance in patients affected by bilateral cataract and treated with phacoemulsification: future prospects of a surgical treatment more oriented to the real refractive needs of the patient

Study objectives

The purpose of this study was to evaluate the visual results and patients' satisfaction of surgical treatment of phacoemulsification and implantation of the innovative intraocular multifocal lens (MFIOL) Oculentis LENTIS Mplus MF30 in patients with bilateral cataract.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/05/2018, Ethics Committee of A. O. U. Città della Salute e della Scienza di Torino (University of Turin, Corso Bramante 88/90 – 10126 Torino - Italy; +39 (0)11633.4171; comitatoetico@cittadellasalute.to.it), ref: CS2/725

Study design

Single-center interventional prospective non-randomized

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cataract surgery (phacoemulsification)

Interventions

We recruit candidates for bilateral cataract extraction surgery. Each subject will undergo complete ophthalmologic evaluation in the 90 days before the procedure (as part of a standard preoperative practice), with:

collection of personal data and anamnesis

slit lamp ocular examination of the anterior segment and fundus oculi

ocular applanation tonometry with Goldman tonometer

determination of refraction and UCVA (uncorrected visual acuity) and BCVA (best-corrected visual acuity) for both eyes at 4m, 60 cm and 33 cm with ETDRS and Jaeger tables

keratometry with Javal's ophthalmometer

optical eye biometry (Topcon Aladdin®) and contact eye biometry (we observed no differences between these two procedures; $p > 0.1$)

corneal surface topography with Topcon Aladdin®

photopic and mesopic pupillometry with Topcon Aladdin®

Each patient will receive a preoperative prophylactic treatment with moxifloxacin eye drops (5 mg/mL), one drop three times each day for three days before the surgical procedure.

Afterwards, each patient underwent bilateral cataract extraction surgery. Each eye will be treated during a different session, one 30 days after the other.

Prof. R. Nuzzi and his team will perform all surgical procedures, which consisted in:

Preoperative application of local mydriatic agents (Mydriaser) 1 h before surgery.
Preoperative application of local anesthetics (Benoxinate, 0.4%).
Sterile field preparation and disinfection with povidone-iodine for 3 minutes.
Corneal tunnel incision of 2,2 mm and paracentesis followed by introducing viscoelastic fluid (Viscoat and Visthesia) in the anterior chamber.
Execution of continuous circular capsulorhexis.
Nucleus hydrodissection.
Cataract extraction with phacoemulsification technique.
MFIOL LENTIS Mplus LS-313 MF30 implantation in the capsular bag.
Removal of viscoelastic fluid in front of and behind the lens.
Hydrosuture.
Disinfection and medication.

Oculentis suggests that the Mplus Lens category performs the best if the MFIOL that provides the minimal myopic shift is selected for implantation. Nevertheless, after ocular biometry, we will choose the IOL that will provide the minimal hyperopic shift for all patients bilaterally. After surgery, patients will be kept under observation for a few hours and later discharged according to standard protocol.

They are subsequently asked to show up to follow-up ophthalmologic visits after one day (t1), seven days (t2), one month (t3), three months (t4) and six months (t6). On all those occasions, we will perform slit-lamp eye examination, ocular tonometry, refraction determination, monocular UCVA and BCVA evaluation for each eye at 4 m, 60 cm and 33 cm with ETDRS tables and Jaeger tables. We will evaluate the binocular UCVA at 4 m, 60 cm and 33 cm in the last three visits. In the same time intervals of one month, three months and six months, we will also assess patients' satisfaction, personal spectacle independence, the incidence of adverse visual effects, the treatment effect on different daily activities with specific questionnaires.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Postoperative uncorrected and best-corrected visual acuity for far distances is assessed with LogMar and ETDRS charts for each eye at 1 day, 7 days, 1 month, 3 months and 6 months
2. Postoperative uncorrected and best-corrected visual acuity for intermediate distances (60 cm) is assessed using the Jaeger eye chart for each eye at 1 day, 7 days, 1 month, 3 months and 6 months
3. Postoperative uncorrected and best-corrected visual acuity for near distances (33cm) is assessed using the Jaeger eye chart for each eye at 1 day, 7 days, 1 month, 3 months and 6 months
4. Postoperative binocular uncorrected visual acuity for far (4 m), intermediate (60 cm) and near (33 cm) distances at 1 month, 3 months and 6 months

Key secondary outcome(s)

1. Rate of visual disturbances was assessed with specific questionnaires with scores from 0 (for absence of disturbances) to 5 (for maximal difficulty) at 1 month, 3 months and 6 months after surgery
2. Spectacle dependence rate at far, intermediate and near visual distances was assessed with specific questionnaires with scores from 0 (total independence) to 5 (for maximal dependence) at 1 month, 3 months and 6 months after surgery
3. Global visual satisfaction was assessed with specific questionnaires with scores from 0

(absolutely not satisfied) and 10 (fully satisfied) at 1 month, 3 months and 6 months after surgery
4. Difficulties in everyday activities was assessed with specific questionnaires with scores from 0 (total ease) to 5 (maximal difficulty) at 1 month, 3 months and 6 months after surgery

Completion date

30/09/2020

Eligibility

Key inclusion criteria

1. Bilateral cataract
2. Age >50 years
3. Regular corneal astigmatism, <1.00 D
4. K angle \leq 1 mm

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

20

Key exclusion criteria

1. Patient with optical means opacities other from cataract
2. Age-related macular degeneration
3. Previous history of ocular surgery
4. Irregular corneal astigmatism
5. Amblyopia
6. Concurrent neurologic or neuromuscular diseases (cerebral ictus, myasthenia, etc.)
7. Uncontrolled open/close-angle glaucoma
8. Severe ocular complications related to diabetes (retinopathy, macular oedema, vitreal hemorrhage, etc.)
9. Patients with operative or postoperative complications
10. Patients with a pupil diameter of \leq 5,2 mm in mesopic lighting conditions

Date of first enrolment

30/05/2018

Date of final enrolment

01/03/2020

Locations

Countries of recruitment

Italy

Study participating centre

Ophthalmology Department of A.O.U. Città Della Scienza e Della Salute di Torino

Via Cherasco 23

Turin

Italy

10126

Sponsor information**Organisation**

University of Turin

ROR

<https://ror.org/048tbm396>

Funder(s)**Funder type**

University/education

Funder Name

Università degli Studi di Torino

Alternative Name(s)

University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Italy

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are intended to be available upon reasonable request forwarded to the Institute of Ophthalmology of University of Turin (prof.Nuzzi_Raffaele@hotmail.it).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/08/2022	12/09/2022	Yes	No