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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

Registration date
17/05/2021

Overall study status
Completed

Last Edited
12/09/2022

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
http://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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact detail below to request a patient information sheet.

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 ophtalmometer
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 (Mydriasert) 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 measure
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 Jeager 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

Secondary outcome measures
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 sugery
2. Spectacle dependence rate at far, intermediate and near visual distances was assessed with specifict questionnaires with scores from 0 (total independence) to 5 (for maximal dependence) at 1 month, 3 months and 6 months after sugery
3. Global visual satisfaction was assessed with specifict questionnaires with scores from 0 (absolutely not satisfied) and 10 (fully satisfied) at 1 month, 3 months and 6 months after sugery
4. Difficulties in everyday activities was assessed with specifict questionnaires with scores from 0 (total ease) to 5 (maximal difficulty) at 1 month, 3 months and 6 months after sugery

Overall study start date
01/09/2017

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 ≤1 mm

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

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 ≤ 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

Sponsor details
Department of Ophtalmology
Department of Surgical Sciences
Via Cherasco 23
10126 Turin (TO)
Italy
Turin
Italy
10126
+39 (0)116336922
roberto.vitali@unito.it

Sponsor type
University/education

Website
http://en.unito.it/

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/07/2021

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