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Comparing two vision corrective laser eye surgery techniques

Submission date
10/10/2022

Recruitment status
No longer recruiting

Registration date
20/10/2022

Overall study status
Completed

Last Edited
29/12/2023

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study was performed for spectacle-wearing patients who want refractive surgery (laser surgery) to correct their nearsightedness (myopia). The purpose of the study was to evaluate the differences in two techniques used for corneal epithelial remodeling and their relationship with high-order aberrations of the corneal surface.

Who can participate?
Adults aged between 20 and 35 years old with myopia

What does the study involve?
The study looks at healing after two techniques using the same laser that corrects myopia with or without astigmatism. Participants will receive topoguided Femtolasik (contoura) in one eye and customized by asphericity (custom Q) in the contralateral eye.

What are the possible benefits and risks of participating?
The benefits of participation in the study include receiving corneal refractive surgery with one of the most modern techniques available. The risks are inherent in the procedure, such as infection, for example. But corneal refractive surgery is one of the most performed and safe medical procedures in the world.

Where is the study run from?
Oftalmax – Benfica (Brazil)

When is the study starting and how long is it expected to run for?
December 2018 to January 2022

Who is funding the study?
Investigator initiated and funded (Brazil)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Epithelial remodeling in Femtolasik Topoguided and customized asphericity in the contralateral eye: a randomized double-blind prospective study

Study objectives
The aim of this study is to assess whether there is a difference in corneal epithelial remodeling comparing two corneal refractive surgery techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/04/2019, Comitê de Ética em Pesquisa - the Federal University of São Paulo (UNIFESP) (Rua Botucatu, 740. Vila Clementino, São Paulo, SP. CEP: 04023-900, Brazil; +55 (11) 5571-1062/ +55 (11) 5539-7162; cep@unifesp.br), ref: 3.245.443

Study design
Single-center interventional double-blind randomized prospective study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Myopia with or without astigmatism

Interventions
A randomized double trial: Topoguided femtolasik (contoura) will be performed in one eye and customized by asphericity (Custom-Q) in the contralateral eye.

In January 2019, the design of the research study began. After the approval of the ethics committee, the study started the screening of patients who would receive refractive surgery. On the day of the surgery, patients were randomized using a randomization program to choose the surgical technique that would be performed in the patient's right eye and the other technique in the contralateral eye. All patients performed a complete ophthalmological examination, including complementary exams. Both groups received the same treatment drops. Both techniques provide excellent results. The difference would be the form of laser ablation.

Patients underwent ophthalmological examinations and complementary imaging exams on day 1, week 1, and months 1 and 3, and 1 year after the surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Visual acuity (logMAR chart) measured using a digital projector with and without correction at 1 day, 1 month, and 3 months post-operatively

Secondary outcome measures
1. Ephthelial remodeling in microns measured using an OCT Avanti that evaluates the epithelial thickness map generated by an automatic algorithm and divided into a total of 17 sectors (central, paracentral and mid-periphery) preoperatively and at 3 months

2. Cornea total root mean square (RMS) (total high order aberrations on Cornea surface) measured using corneal tomography with the Galilei G6 using the Zernike map preoperatively and at 3 months postoperatively

Overall study start date
31/12/2018

Completion date
01/01/2022

Eligibility

Key inclusion criteria
1. Myopic patients with or without astigmatism
2. Aged between 20-35 years old
3. Spherical degree up to 8 and cylinder up to 3

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Keratoconus or predisposing topographic changes
2. Pachymetry below 500
3. PTA above 40
4. Previous eye surgery
5. Glaucoma
6. Dry eye
7. Cataract
8. Systemic diseases

Date of first enrolment
30/04/2019

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
Brazil

Study participating centre
Oftalmax
Bua Benfica, 411
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
20/12/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2023	29/12/2023	Yes	No