

Comparing two vision corrective laser eye surgery techniques

Submission date 10/10/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/10/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/12/2023	Condition category Eye Diseases	<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Epithelial 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 years

Upper age limit

35 years

Sex

All

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

Madalena

Recife

Brazil

50720-001

Sponsor information

Organisation

Oftalmax – Benfica

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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

[Results article](#)

Details

Date created

01/11/2023

Date added

29/12/2023

Peer reviewed?

Yes

Patient-facing?

No