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Small incision corneal lenticule extraction for myopia and myopic anisometropia

Submission date	Recruitment status	[ ] Prospectively registered
14/12/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/01/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/12/2023	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Myopic anisometropia is a condition where you have one normal eye and one nearsighted (or myopic) eye. The aim of this study is to assess the effect of small incision lenticule extraction (SMILE), a type of laser eye surgery, on patients with myopic anisometropia.

Who can participate?
Patients aged 18 to 30 years with myopic anisometropia treated with small incision lenticule extraction (SMILE)

What does the study involve?
All participants receive the same treatment with SMILE and undergo eye tests before surgery and at 1 week and 1, 3 and 6 months after surgery,

What are the possible benefits and risks of participating?
Participants receive free eye tests. There are no expected side effects of the treatment.

Where is the study run from?
State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Centre, Sun Yat-sen University (China)

When is the study starting and how long is it expected to run for?
January 2015 to July 2016

Who is funding the study?
The Science and Technology Program of Guangzhou (China)

Who is the main contact?
Dr Shengbei Weng, 1023816828@qq.com

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of visual outcomes and binocular vision functions following small incision corneal lenticule extraction for myopia and myopic anisometropia

Study objectives
Small incision corneal lenticule extraction (SMILE) is a predictable, effective, and safe method for correcting myopic anisometropia in adults without amblyopia.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/02/2015, Ethics Committee of Zhongshan Ophthalmic Center at the Sun Yat-sen University (State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Centre, Sun Yat-sen University, Guangzhou, 510060, China; +86 (0)13711552618; zocdpo@gzzoc.com), ref: 2013MEKY036

Study design
Single-centre observational longitudinal case-control study

Primary study design
Observational

Study type(s)
Other, Safety, Efficacy

Health condition(s) or problem(s) studied
Myopic anisometropia

Interventions
The ocular parameters used for characterizing binocular functions include: divergence and convergence amplitudes (near and distance), stereoacuity (near and distance), and near and distance horizontal phorias. The Risley rotary prisms are used to evaluate the horizontal vergence ranges. A gradually increasing horizontal Risley prism is placed in both eyes while the patient fixated on a line of Snellen optotype E. Equal amounts of rotatory prism are slowly added in front of each eye (base-in and base-out prism for divergence and convergence, respectively) at a constant velocity (approximately 2 Δ/s) until the subject first reported horizontal diplopia (break value). The distance stereoacuity is tested using the stereotest booklet (Distance Randot Stereotest, Stereo Opticals Co., Inc., range: 400-60 arcsec) at 3 meters (m) in a standard illuminated room with polarizing glasses. Near stereoacuity is measured at 40 centimeters (cm) using the Randot circles test (Stereo Randot Test 2 for Adults, Stereo Optical, ranged: 400-12.5arcsec); the graded circles are used to quantify stereopsis. Heterophoria measurements are obtained using the von Graefe technique: a 6 Δ base-up dissociating prism is placed in front of the right eye, and horizontal oculomotor deviation neutralized with a Risley rotary prism in front of the left eye.

Intervention Type
Other

Primary outcome(s)
1. Divergence and convergence amplitudes (near and distance) are measured using Risley rotary prisms preoperatively and at 1 week, 1, 3 and 6 months after surgery
2. Distance stereoacuity is measured using the stereotest booklet (Distance Randot Stereotest, Stereo Opticals Co., Inc., range: 400-60 arcsec) preoperatively and at 1 week, 1, 3 and 6 months after surgery
3. Near stereoacuity is measured using the Randot circles test (Stereo Randot Test 2 for Adults, Stereo Optical, ranged: 400-12.5arcsec) preoperatively and at 1 week, 1, 3 and 6 months after surgery
4. Heterophoria measurements are measured using Risley rotary prism preoperatively and at 1 week, 1, 3 and 6 months after surgery

Key secondary outcome(s))
Monocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) are measured using Snellen charts preoperatively and at 1 week,1,3 and 6 months after surgery

Completion date
27/07/2016

Eligibility

Key inclusion criteria
1. Aged 18 to 30 years, stable myopia for ≥1 year
2. Corrected distance visual acuity (CDVA) of 20/20 or better
3. SE of -1.00 to -10.00 diopters (D) with or without myopic astigmatism (< -1.5D)
4. Qualified for laser refractive surgery for myopia (normal ocular anterior segment examination except for refractive error)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
All

Total final enrolment
49

Key exclusion criteria
1. Patients with any ocular surface diseases
2. History of corneal or intraocular surgery, ocular trauma, keratoconus, cataract, vascular, or autoimmune diseases

Date of first enrolment
01/09/2015

Date of final enrolment
27/01/2016

Locations

Countries of recruitment
China

Study participating centre
State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University
No.54 Xianlie South Road, Yuexiu District
Guangzhou.

China
510060

Sponsor information

Organisation
State Key Laboratory of Ophthalmology

Funder(s)

Funder type
Government

Funder Name
The Science and Technology Program of Guangzhou, China (2023A04J1891)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Shengbei Weng (1023816828@qq.com). The data will be shared in Excel form from 15/12/2024.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes