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Comparing the outcomes and complications of protected and unprotected penetrating keratoplasty in treating chronic pseudophakic corneal edema

Submission date
27/07/2023

Recruitment status
No longer recruiting

Registration date
02/08/2023

Overall study status
Completed

Last Edited
02/08/2023

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Penetrating keratoplasty is a surgical procedure where a damaged or diseased cornea (the clear outer layer at the front of the eye) is replaced by donated corneal tissue. This study aims to assess and compare the outcomes of patients who underwent penetrating keratoplasty following the development of chronic corneal edema (buildup of fluid) resistant to medical treatment after cataract surgery.

Who can participate?
Adult patients (aged 18 years and older) who have undergone cataract surgery and subsequently developed chronic corneal edema resistant to medical treatment in one eye

What does the study involve?
Participants are grouped according to whether they underwent protected or unprotected penetrating keratoplasty. Assessments of visual acuity, endothelial cell count, intraocular pressure, and anterior segment examination will be conducted before and after surgery. Complications will also be recorded, and participants will fill out a questionnaire about their quality of life at baseline and 1 year after the operation.

What are the possible benefits and risks of participating?
Participants may benefit from more thorough monitoring of their health status, earlier detection of any complications, and potentially improved treatment outcomes. Risks include those associated with the surgical procedures, plus the slight discomfort of additional examinations and time commitment for follow-up visits.

Where Is the study run from?
Hospital Hermanos Ameijeiras (Cuba)

When Is the study starting and how long is it expected to run for?
August 2017 to December 2021

Who is funding the study?
Hospital Hermanos Ameijeiras (Cuba)

Who is the main contact?
Dr Tian Yang, fabian.yangtian@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Tian Yang

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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
“Open sky” penetrating keratoplasty versus simultaneous penetrating and lamellar keratoplasty for pseudophakic bullous keratopathy

Study objectives
When a protected penetrating keratoplasty is performed, there is improved best-corrected visual acuity (BCVA), reduced risk of an "open sky" scenario, higher probability of preserving the

intraocular lens in the posterior chamber, and less corneal endothelial cell loss compared to traditional penetrating keratoplasty (unprotected penetrating keratoplasty).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/02/2018, Cuban Medical Ethics Committee (San Lázaro 701 between Belascoain and Marqués González, Havana, 10400, Cuba; +86 (0)537 8761210; yudith@hha.sld.cu), ref: 000

Study design
Single-center cross-sectional descriptive observational study

Primary study design
Observational

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Patients with a diagnosis of irreversible pseudophakic chronic corneal edema who required penetrating corneal transplantation due to failure to improve with other medical treatments

Interventions
Participants in this study undergo either an unprotected or protected partial penetrating keratoplasty to treat chronic pseudophakic corneal edema.

Upon enrolment, patient data is gathered from medical histories and participants are assigned to either the unprotected or protected keratoplasty groups. Preoperative and postoperative evaluations are conducted using various ophthalmic diagnostic tools and techniques, including Snellen E Optotype, Zeiss SL 20 Slit Lamp, and Topcon SP-3000P specular microscope.

The surgical procedure involves general anesthesia, insertion of a lid speculum, application of a Flieringa scleral fixation ring, corneal incisions and keratoplasty. Donor corneas processed in accordance with APABO (Pan American Association of Eye Banks) standards are used for transplantation. The storage duration of the cornea is 3 to 5 days and endothelial cell density is more than or equal to 2,500 cells/mm^2. The graft diameter is 7.5 mm for the recipient and 8.0 mm for the donor in both groups.

Postoperative care includes topical antibiotic and anti-inflammatory treatments, with varying regimens over a 6-month period. Artificial tears are also administered for 6 months.

Follow-up appointments are scheduled weekly during the first 2 months and bi-monthly until the end of 1 year when the study concludes. In these visits, transplant status, suture condition, medication tolerance, and complications are assessed. All patients also undergo a conclusive endothelial count through specular microscopy at the end of the year.

The total observation period of this study is 1 year from the surgery, and this also constitutes the duration of follow-up.

Intervention Type

Procedure/Surgery

Primary outcome(s)
1. Visual acuity assessed using the Snellen E chart at baseline (preoperative), immediately postoperative, and at the follow-up visits scheduled weekly for the first 2 months, then every 2 months until completion of 1 year.
2. Endothelial cell count of the donor pre and post transplants is measured using specular microscopy (Topcon SP-3000P) at baseline (preoperative) and 1 year postoperative.

Key secondary outcome(s))
1. Intraocular pressure is measured using a pneumatonometer preoperatively and postoperatively at each follow-up visit scheduled weekly for the first 2 months, then every 2 months until completion of 1 year.
2. Condition of the transplant, transparency, status of sutures, and tolerance to medication, evaluated by anterior segment biomicroscopy at each follow-up visit scheduled weekly for the first 2 months, then every 2 months until completion of 1 year.
3. Any intraoperative, immediate, and late complications are recorded and managed appropriately. The complications are evaluated at each follow-up visit scheduled weekly for the first 2 months, then every 2 months until completion of 1 year.
4. Postoperative medication tolerance evaluated by the patient's reported symptoms and by clinical evaluation during each follow-up visit scheduled weekly for the first 2 months, then every 2 months until the completion of 1 year.
5. Quality of life assessed using an NEI VFG-25 scale covering aspects like vision-related daily life activities, discomfort, and overall satisfaction with the treatment at baseline and at 1 year postoperative.

Completion date
28/12/2021

Eligibility

Key inclusion criteria
1. Patients operated on for cataracts who developed chronic corneal edema resistant to medical treatment in an eye with some visual possibility
2. Written informed consent to participate in the research

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Refusal of the patient to undergo another surgical treatment or not having the possibility of vision

Date of first enrolment
01/03/2018

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Cuba

Study participating centre
Hospital Clínico Quirúrgico Hermanos Ameijeiras
San Lázaro 701 between Belascoain and Marqués González
Havana
Cuba
10400

Sponsor information

Organisation
Universidad de Ciencias Médicas de la Habana

ROR
https://ror.org/04kgp9g48

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

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 Tian Yang (fabian.yangtian@gmail.com). This includes anonymised data pertaining to patient demographics, preoperative and postoperative measures of visual acuity, endothelial cell count, intraocular pressure, as well as records of complications and outcomes of quality-of-life questionnaires. The data will become available following the publication of the study's main results, and it will remain accessible for a period of five years. Access to the data will be granted for purposes of peer review, replication of analyses, meta-analyses, and for the development of further research questions and hypotheses. Data access requests will be reviewed by Dr Tian Yang, and will be granted to verified researchers, academics, and healthcare professionals, who must commit to using the data for the specified purposes only, and to maintaining the confidentiality of the data. Data sharing will be executed via a secure online data repository or through encrypted email transmission, depending on the preference and capabilities of the recipient. Participants' consent for the anonymisation and sharing of their data was obtained as part of the study's informed consent process. All data will be fully anonymised before sharing, with all direct and indirect identifiers removed to protect participants' privacy and confidentiality. There are no ethical or legal restrictions on data sharing noted. Any other comments or requests for clarification regarding the data should be directed to Dr Tian Yang at fabian.yangtian@gmail.com.

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