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Deep Anterior Lamellar Keratoplasty Versus Penetrating Keratoplasty for Macular Corneal Dystrophy

Submission date	Recruitment status	[_] Prospectively registered
03/02/2013	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
12/02/2013	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
03/02/2014	Eye Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Macular corneal dystrophy (MCD) is characterized by multiple, grayish-white stromal opacities with indistinct and hazy borders that extend from limbus to limbus (limbus is the part between the cornea and the white of the eye). As corneal opacity slowly increases and involves the visual axis, loss of functional visual acuity occurs. A transplantation of corneal material called keratoplasty eventually becomes necessary for the restoration of vision and the recovery of corneal transparency. Penetrating keratoplasty (PK) is the traditional treatment for a variety of corneal pathologies including corneal stromal dystrophies. However, deep anterior lamellar keratoplasty (DALK) is currently considered to be the first-choice surgical procedure in patients with corneal disease not involving the endothelium, such as keratoconus, stromal scars and stromal dystrophies. The main advantage of DALK is that the patients own endothelium is retained, which eliminates the risk of endothelial graft rejection and preserves endothelial cell density. The aim of the study was to compare which of deep anterior lamellar keratoplasty (DALK) or penetrating keratoplasty (PK) worked better for macular corneal dystrophy (MCD).

Who can participate?
Patients (Turkish and aged between 16 to 67 years) requiring keratoplasty for the treatment of macular corneal dystrophy without endothelial involvement were enrolled.

What does the study involve?
Patients underwent two different keratoplasty techniques. All eyes were randomly allocated to a number on a surgical chart (even numbers received DALK, odd numbers received PK).

What are the possible benefits and risks of participating.
Benefits: patients treated with keratoplasty for the restoration of vision and the recovery of corneal transparency.
Risks: possibility of complications such as loss of endothelial cell density, graft rejection, recurrence of the disease.

Where is the study run from?
The study ran from one single centre at the Kartal Training and Research Hospital (Turkey).

When is study starting and how long is it expected to run for?
The study ran between January 2006 and June 2010.

Who is funding the study?
No government or non-governmental financial support.
Dr Esin Sogutlu Sarý based at Kartal Training and Research Hospital, Akdeniz University Scientific Research Projects Unit (Turkey)

Who is the main contact
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Kartal Training and Research Hospital 102

Study information

Scientific Title
Deep Anterior Lamellar Keratoplasty Versus Penetrating Keratoplasty for Macular Corneal Dystrophy: a randomised controlled trial

Study objectives
Deep anterior lamellar keratoplasty eliminates the risk of endothelial graft rejection and preserves endothelial cell density compared to penetrating keratoplasty in macular corneal dystrophy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee (ref:102)

Study design
Randomised interventional case series

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Macular corneal dystrophy

Interventions
Two different keratoplasty technique: Deep anterior lamellar keratopalsty vs Penetrating keratoplasty.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
A complete ophthalmologic examination was performed before the operation and postoperative visit in both groups. The examination included logMAR uncorrected visual acuity (UCVA), logMAR best-corrected visual acuity (BCVA), manifest refraction, slit lamp biomicroscopy, and corneal topographic analysis with the CSO topography system (Costruzione Strumenti Oftalmici, Firenze, Italy). Contrast sensitivity measurements and corneal aberrometric analysis were also performed postoperatively after all sutures were finally removed. The CSV-1OOOE chart (VectorVision, Greenville, Ohio, USA) was used for the assessment of contrast sensitivity. This test consists of four rows of sinewave gratings (3, 6, 12, 18 cycles/degree) that had to be observed by the patient with full correction in place at a distance of 2.5 m. After an initial demonstration, the contrast threshold was measured for each spatial frequency. All patients were tested under both mesopic and photopic conditions and the results were expressed in log units of contrast sensitivity. Corneal aberrometry was recorded and analyzed with the CSO topography system whose software automatically converts the corneal elevation profile into corneal wavefront data using Zernike polynomials with an expansion up to the 7th order. The corneal aberration coefficients and root mean square (RMS) values were calculated for a 6.0 mm pupil.
ECD of donor corneas were assessed by a specular microscope before storage in Optisol medium. The endothelium was photographed and evaluated using a Topcon SP 2000p noncontact specular microscope (Topcon Corp., Tokyo, Japan). Images of the central corneal window were reviewed by the same observer (E. S.) and manual correction of the cell borders was performed before final analysis of the endothelium. Twenty endothelial cells were marked for each analysis. For each examination, three measurements of ECD were averaged.

Key secondary outcome(s))
Surgical complications

Completion date
01/06/2010

Eligibility

Key inclusion criteria
Male and female patients aged between 16 and 67 requiring keratoplasty for the treatment of macular corneal dystrophy without endothelial involvement were included.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients who were lost to follow-up, had previous eye surgery or who underwent additional surgery combined with keratoplasty were excluded from the data analysis.

Date of first enrolment
01/01/2006

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Türkiye

Study participating centre
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Sponsor information

Organisation

Kartal Training and Research Hospital (Turkey)

ROR
https://ror.org/01c2wzp81

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Kartal Training and Research Hospital, Akdeniz University Scientific Research Projects Unit (Turkey)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

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