

Clinical Outcomes of the Gore Synthetic Cornea Device

NCT06174376

Status	RECRUITING
Phase	Not Applicable
Sponsor	W.L.Gore & Associates
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (11)

- Patients must meet all of the following criteria to be eligible to be consented for this study.
 - Patient must be able to comprehend the study requirements and provide written informed consent. Patients must be willing to follow study instructions, agree to comply with all study procedures, and able to return for all scheduled follow-up examinations for 12 months postoperatively (the study duration). The follow-up exams may be extended up to 60 months post operatively if the patient consents to the extension.
 - Male or female patients \geq 18 years old at the time of consent
 - Physical condition suitable for undergoing surgery, as evidenced by medical history and physical examination provided by a licensed medical provider (primary care physician, nurse practitioner, internal medicine physician etc.)
 - Currently with an opaque cornea (as determined by the investigator) with or without a prior history of failed donor corneal transplantation [penetrating keratoplasty (PK) or endothelial keratoplasty (EK)] and loss of corneal clarity
- ... and 6 more (see full listing online)

Exclusion (45)

- Inability to provide written informed consent and comply with study assessments for the full duration of the study.
 - Age: $<$ 18 years
 - Patients who are pregnant/nursing or planning to become pregnant during the study.
 - Note: For women of child-bearing potential, confirmation of pregnancy status must be documented per site standard.
 - Corneal thickness measurement (epithelium to endothelium; central and mid-peripheral/ 3 to 5mm away from center at superior, inferior, nasal and temporal quadrants) in the study eye with any measurement less than 700um or more than 900um measured using US pachymetry. If one or more measurements cannot be obtained using US pachymetry, measurements using anterior segment OCT may be used
- ... and 40 more (see full listing online)

Locations (2 total)

Asociación para Evitar la Ceguera en México, I.A.P, Mexico City, Mexico
Instituto de Oftalmología Fundación de Asistencia Privada Conde Valenciana I.A. P., Mexico City, Mexico

<https://clinicaltrials.gov/study/NCT06174376>

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