Clinical Results of the KeraKlear Non-Penetrating Artificial Cornea For Corneal Blindness

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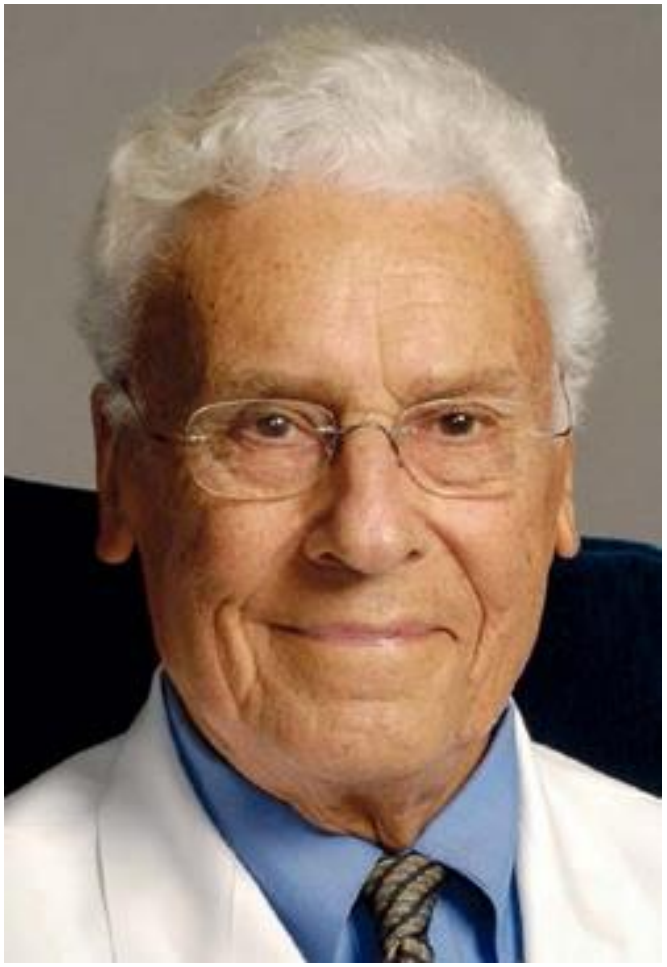
The KeraKlear Artificial Cornea has not received FDA Clearance and is limited by U.S. Law to Investigational Use Only

The KeraKlear has European CE Mark Approval

Development of the KeraKlear was Funded in Part by the US National Institutes of Health and the National Eye Institute

Why Another Artificial Cornea?



- Boston Kpro
- Miraculous outcomes
- Potential for disastrous complications
- What if we could achieve the results of Boston Kpro without the complications and avoid the need for donor tissue?

KeraKlear -1st Foldable Artificial Cornea

- Can be implanted through a micro-incision of 3.5 mm diameter into a corneal pocket made by a femtosecond laser
- Tissue sparing procedure, which requires removal of less than 5% of the patient's corneal tissue to implant.
- Has European CE Mark Approval

Indications: Non-Inflammatory Corneal Blindness

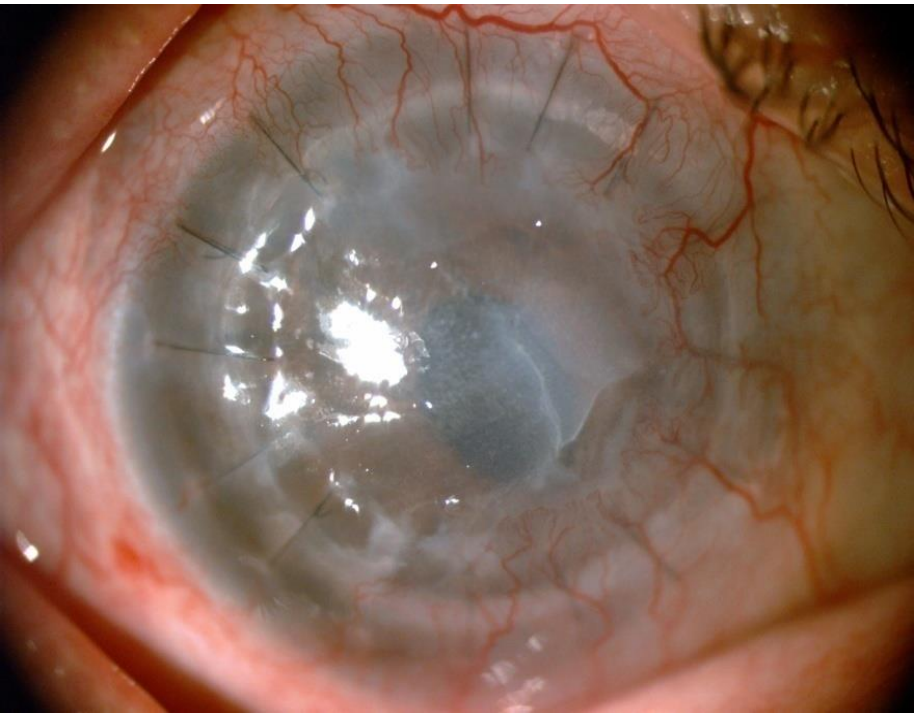
- **Indications**
  - Corneal Blindness (Snellen Acuity <20/200)
  - Failed grafts, limbal stem cell deficiency, scars, dystrophies, keratoconus

- **Contraindications**
  - Chronic Inflammation (e.g. Steven's Johnson, Ocular Cicatricial Pemphigoid, Atopic Keratoconjunctivitis)
  - Severe Dry Eyes (Schirmer Score < 3 mm after 5 min with anesthesia)
  - Full Thickness Dense Opacity

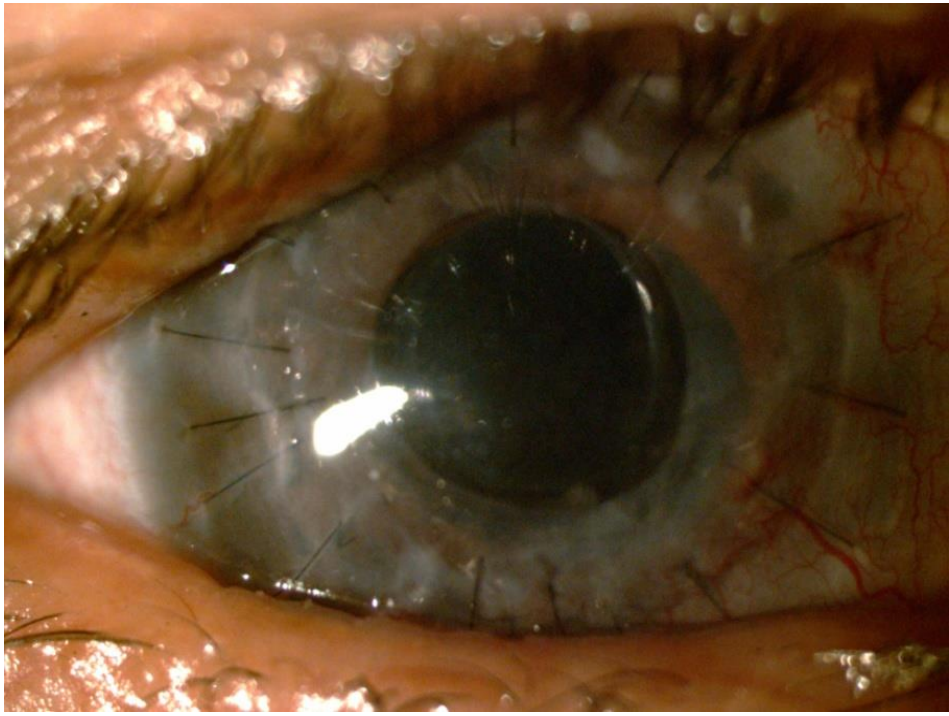
Femtosecond Implantation

Multiple Failed Corneal Transplants

Pre-op: Hand Motions

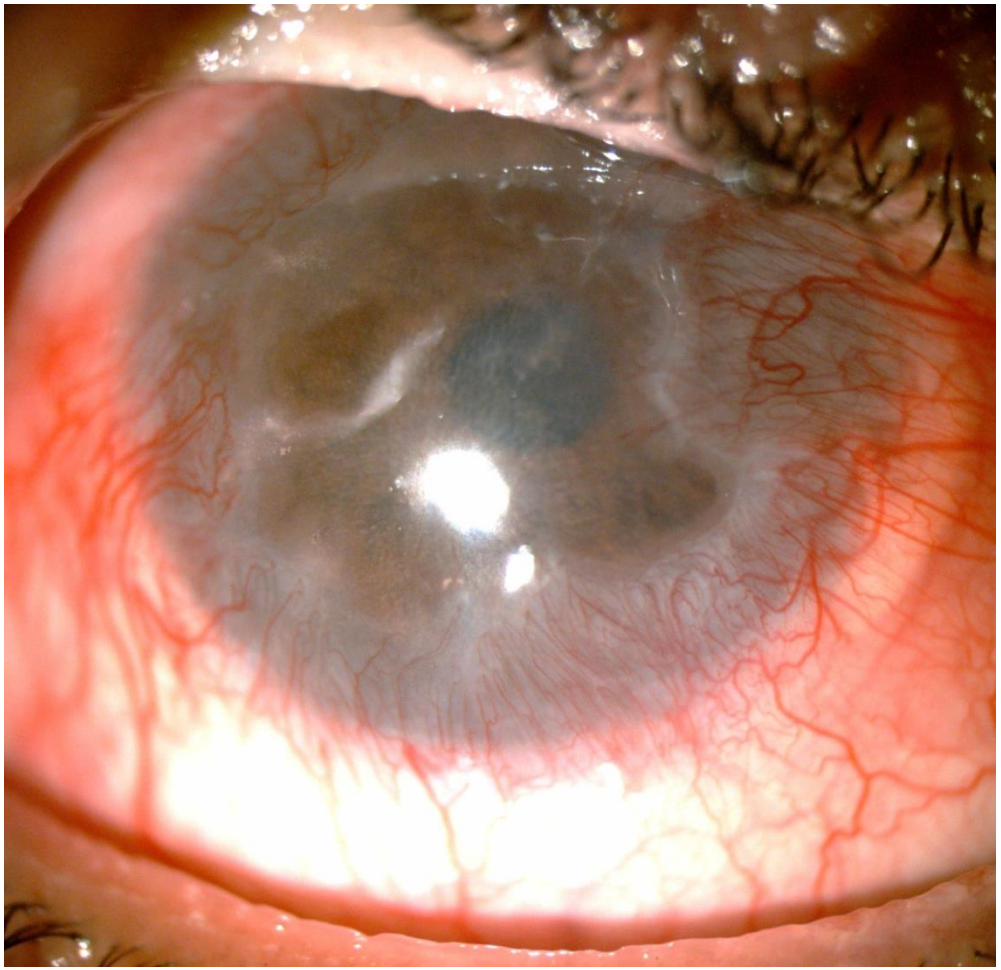


Post-op 20/60

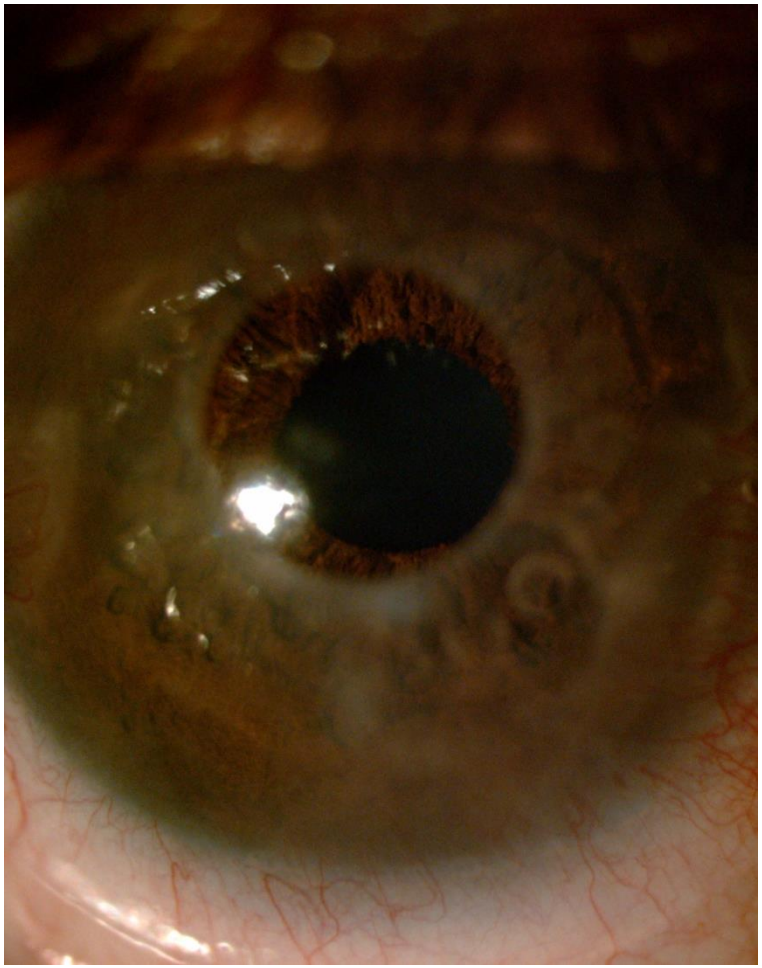


Corneal Burn with Limbal Stem Cell Deficiency

Pre-op Count Fingers Vision

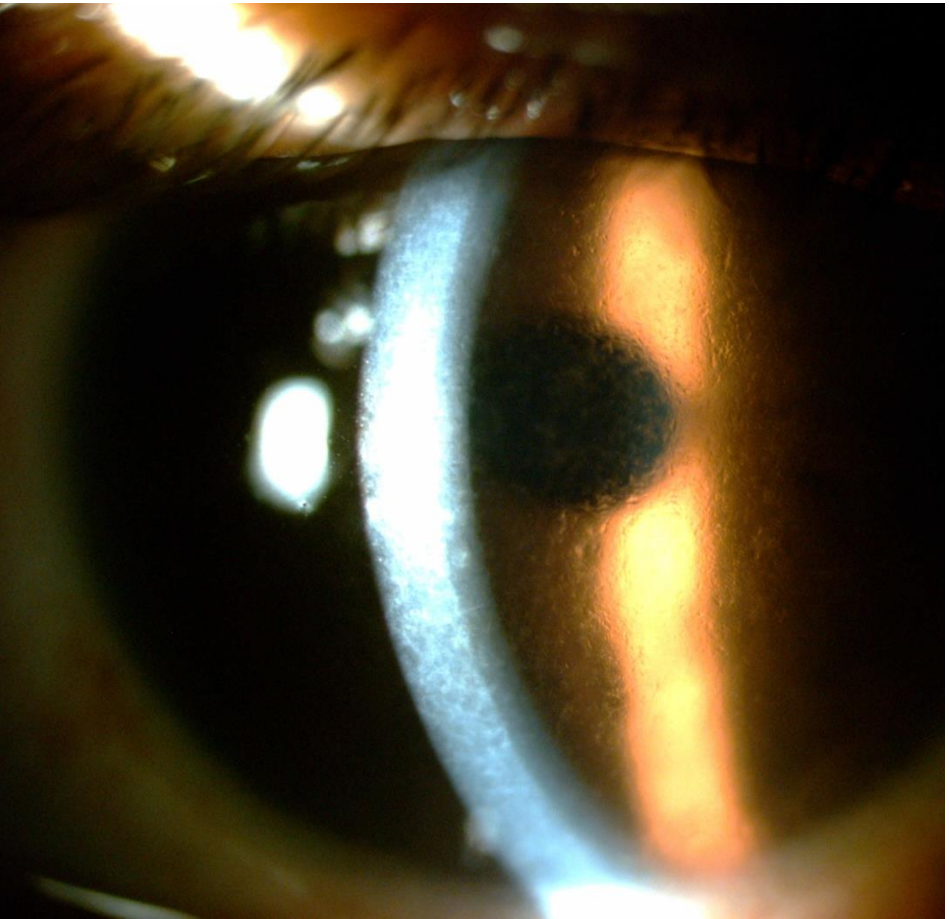


Post-op 20/20

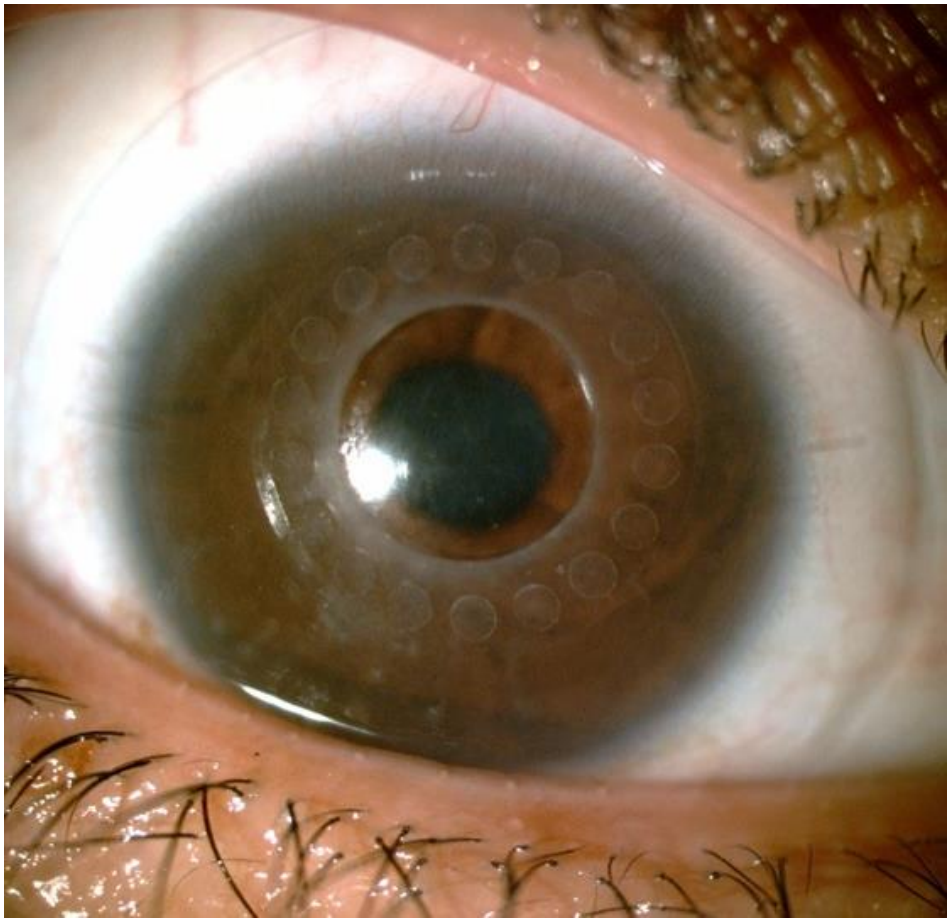


Reis Buckler Corneal Dystrophy

Pre-op 20/400

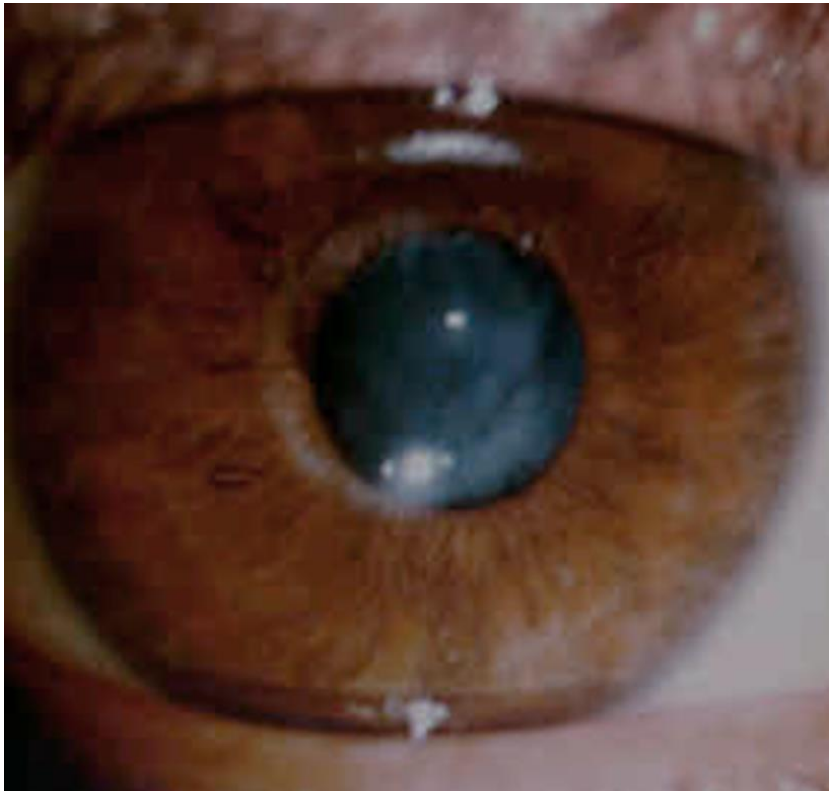


Post-op 20/40

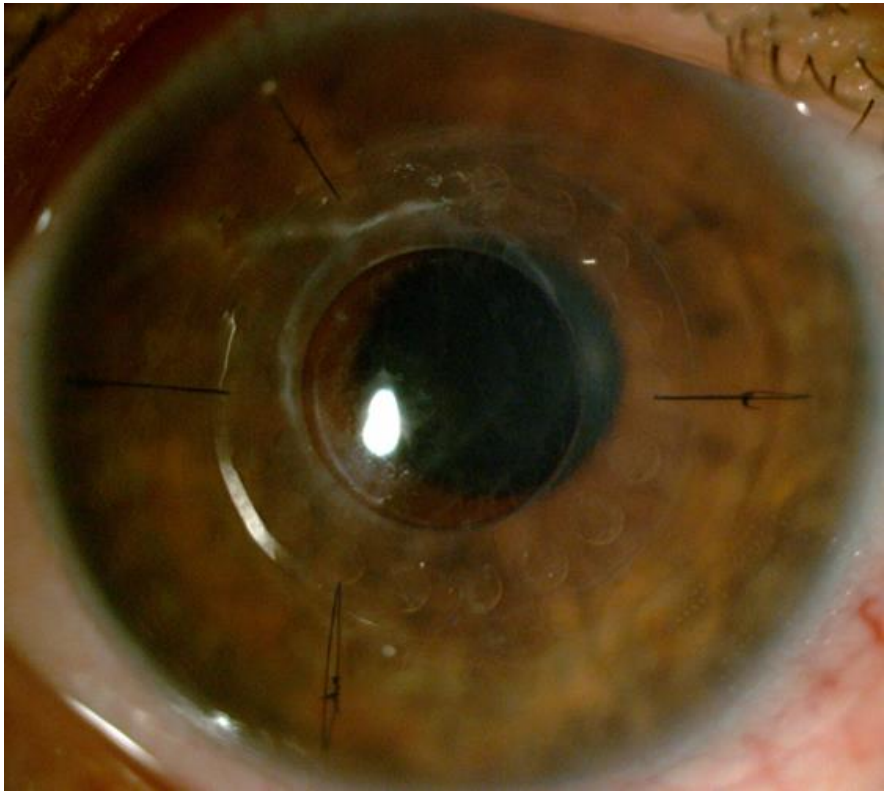


Keratoconus

Pre-op 20/400



Post-op 20/30



Clinical Data

- Pre-op Diagnoses included Failed Grafts, Burns, Corneal Dystrophies, Corneal Scars, and Keratoconus
- Average Follow-up was 50 months
- Pre-op visual acuity ranged from 20/200 to Hand Motions

Outcomes

	KeraKlear OUS N=26	Boston K-PRO (Chew) N=37	Boston K-PRO (Greiner) N=40	Alphacor (Hicks) N=322
Mean Follow-Up	50 months	16 months	41 months	15 months
Average Lines of VA Improvement	7 lines	N/A	N/A	2 lines
Eyes with VA Better than or Equal to 20/200	24 (92%)	30 (81%)	19 (48%)	133 (41.4%)
Endophthalmitis	0	4(11%)	5(13%)	2 (0.8%)
Retroprosthetic Membrane	0	24 (65%)	22 (55%)	42 (13%)
Increased intraocular pressure or glaucoma progression	0	19 (51%)	20 (67%)	N/A
Extrusion	2 (11%)	1 (3%)	6 (15%)	122 (38%)
Corneal Melting	1 (6%)	3 (8%)	6 (15%)	85 (26%)
Infection (Non-Endophthalmitis)	1 (6%)	0 (0%)	5 (13%)	1 (0.3%)

Benefits

- Only the KeraKlear is implantable without entering the anterior chamber, which adds safety by minimizing risk of intraocular infection or hemorrhage.
- Implantation with a KeraKlear keeps transplantation options open including DALK.
- Intraocular pressure remains normal after implantation and there is no need for concomitant glaucoma surgery
- Can be performed without sutures

Reasons for choosing the KeraKlear over Corneal Transplantation (PKP)

	KeraKlear	Corneal Transplant (PKP)
Avoids Rejection	✓	✗
Controls Astigmatism	✓	✗
Prescription Customizable	✓	✗
Non-Penetrating Surgery	✓	✗
Fast Recovery (days)	✓	✗
Avoids Cadaver Tissue	✓	✗
In Office Procedure	✓	✗

Conclusion

- The KeraKlear is a foldable artificial cornea which can be implanted into a corneal pocket without penetration into the anterior chamber
- Long term results show that this device can improve vision in cornea blind patients with a wide range of conditions.
- KeraKlear should be considered as a first line option before PKP, especially in countries with limited graft tissue