



Innovators General Session

*A Novel Non-Penetrating
Keratoprosthesis as a Solution
for Global Corneal Blindness*

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The development of the KeraKlear Artificial Cornea was sponsored in part by grants from the National Institutes of Health.

The Presenter is the inventor of the KeraKlear Artificial Cornea and has a Financial Interest

A Few of the Things Prof. Dohlman Taught Me



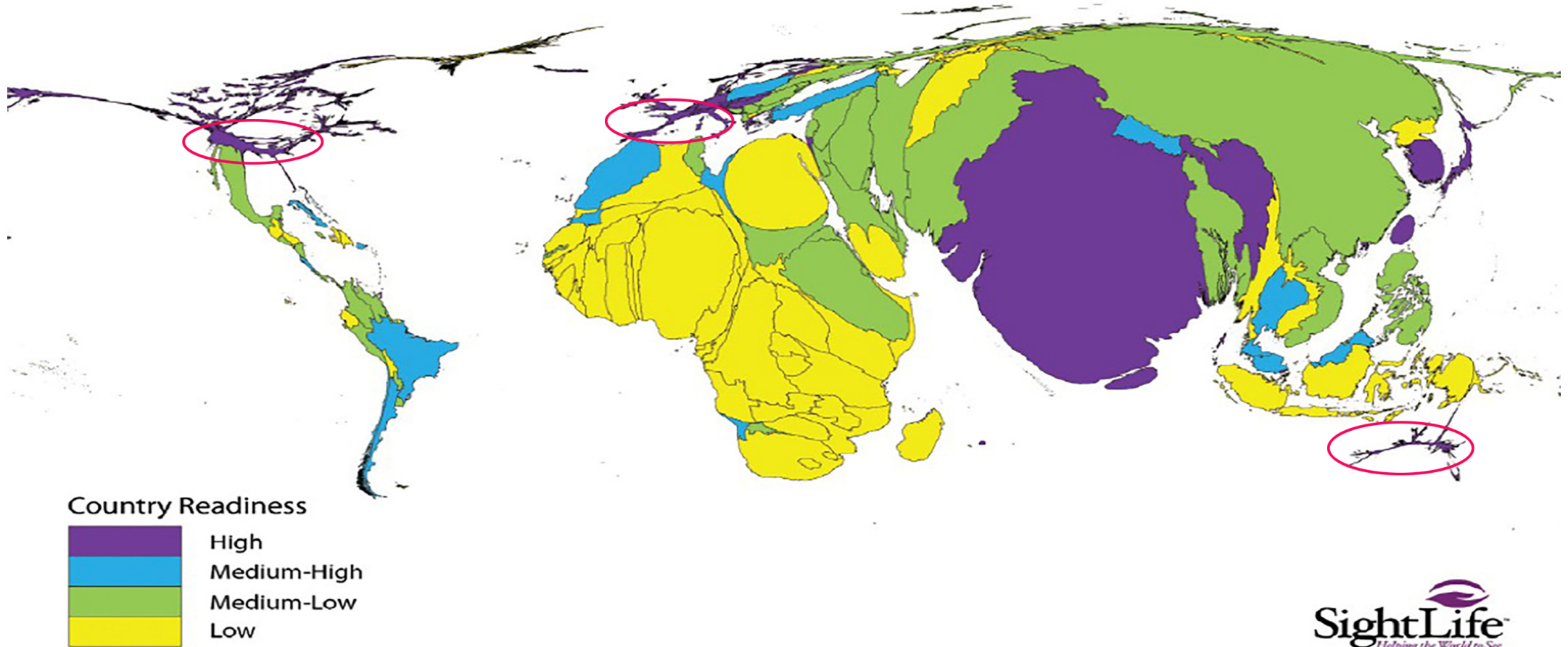
- Corneal transplantation is not for every cornea blind patient
- Boston Kpro first used in 1965
- Miraculous outcomes
- Potential for serious complications
- What if we could achieve the results of Boston Kpro without the complications and avoid the need for donor tissue?

The Worldwide Problem



- Bilateral corneal blindness affects approximately 10 million people and is the third leading cause of blindness worldwide
- 29 million people with one eye blinded by cornea disease
- 53% of world cornea blind have no access to corneal transplantation
- 12.7 million people are on corneal transplant waiting lists worldwide
- Less than 200,000 grafts are available worldwide annually
- This means that only 2% of the bilaterally corneal blind are treated each year and less than 1% of the unilaterally corneal blind

The Burden of Cornea Blindness Worldwide



What Limits Our Ability to Treat World Corneal Blindness?

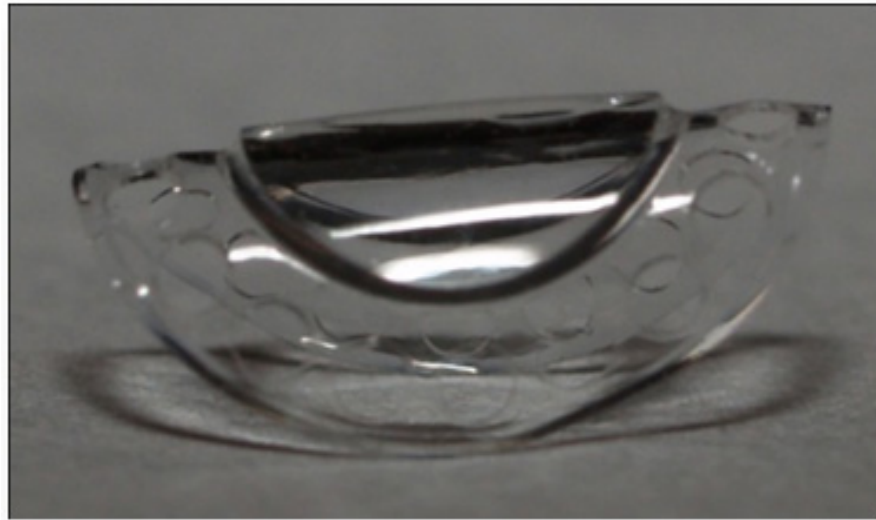


- Lack of Tissue
- Lack of Trained Cornea Transplant Surgeons
- Lack of Sterile Operating Rooms
- Risk of Severe Complications (rejection, endophthalmitis, expulsive, hemorrhage)

KeraKlear - 1st Commercially Available Non-Penetrating Artificial Cornea



- Can be implanted through a micro-incision of 3.5 mm diameter into a uniform 8 mm corneal pocket made by a femtosecond laser (Intralase iFS being used in U.S. trial)
- Non-penetrating procedure, which requires removal of less than 10% of the patient's corneal tissue to implant.
- Can replace 200-700 microns of diseased corneal tissue



KeraKlear - 1st Commercially Available Non-Penetrating Artificial Cornea

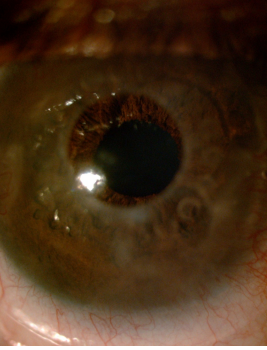


- In office surgery, performed in a clean environment
- Short learning curve
- No need to perform combined glaucoma surgery, which is often needed for penetrating artificial corneas



Femtosecond Implantation

<https://www.youtube.com/watch?v=vGZ5a4yAfME>



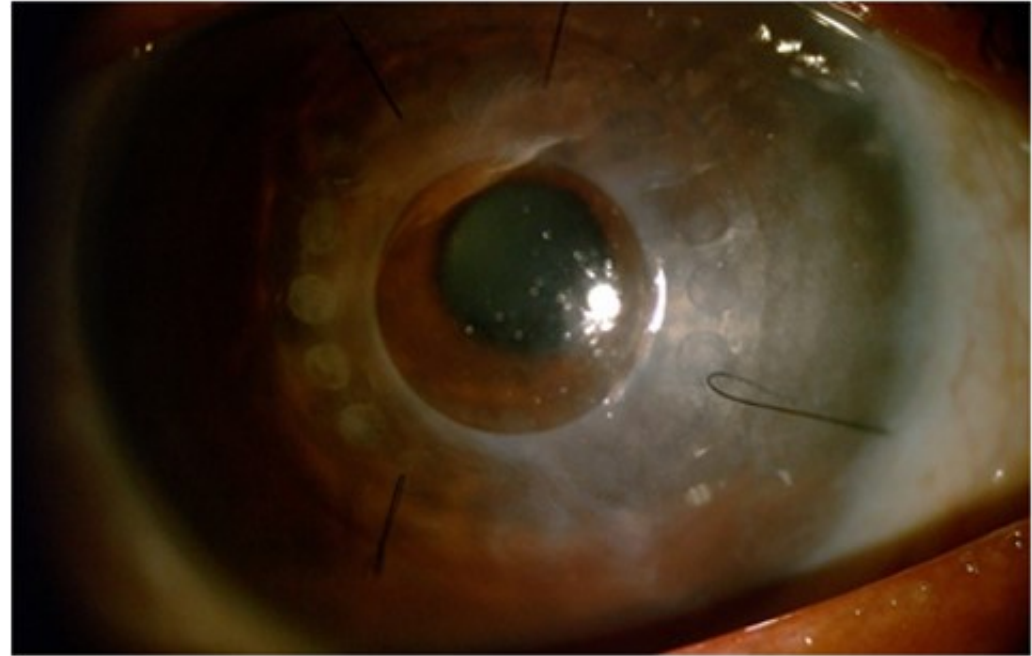
Corneal Scar



Pre-op CF



Post-op 20/40



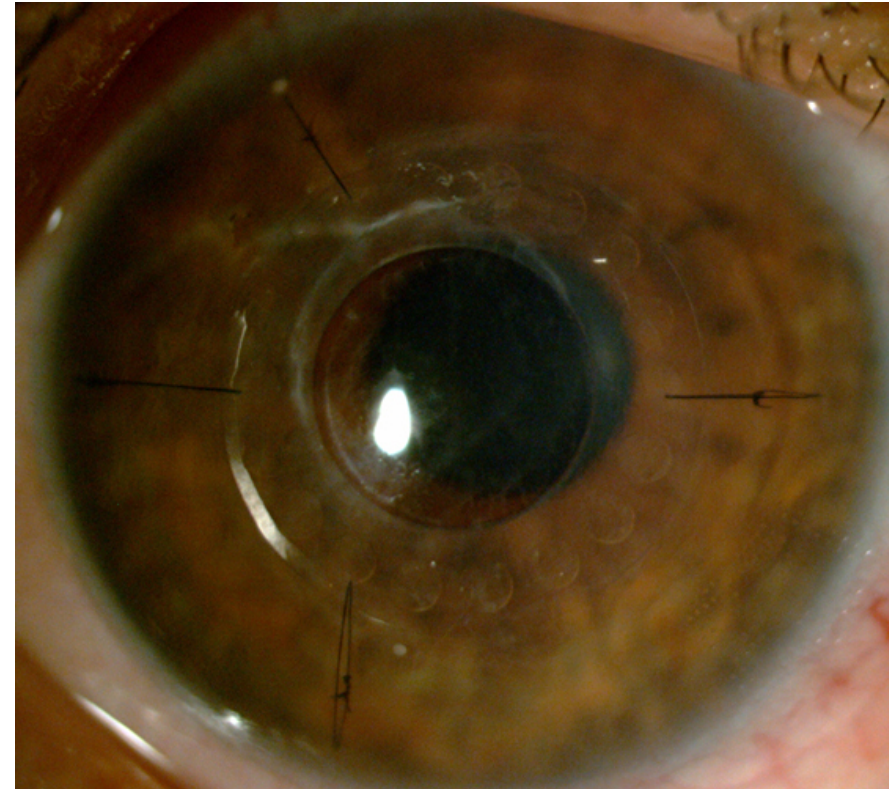
Keratoconus



Pre-op 20/400



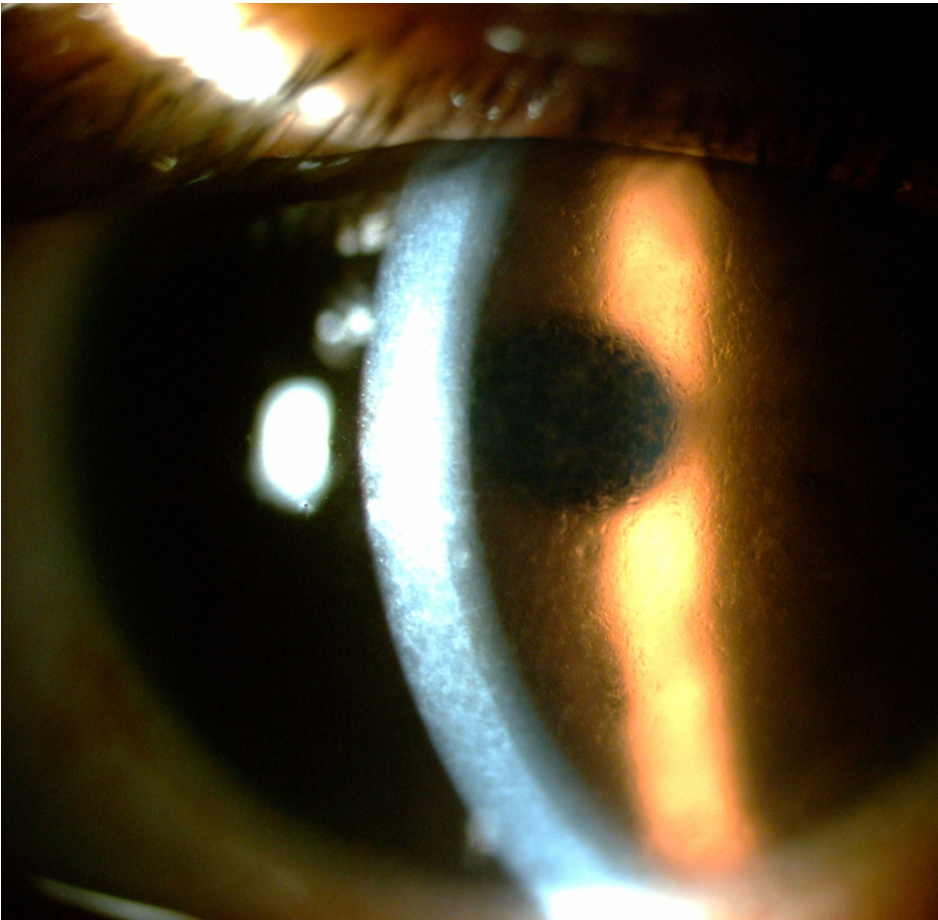
Post-op 20/30



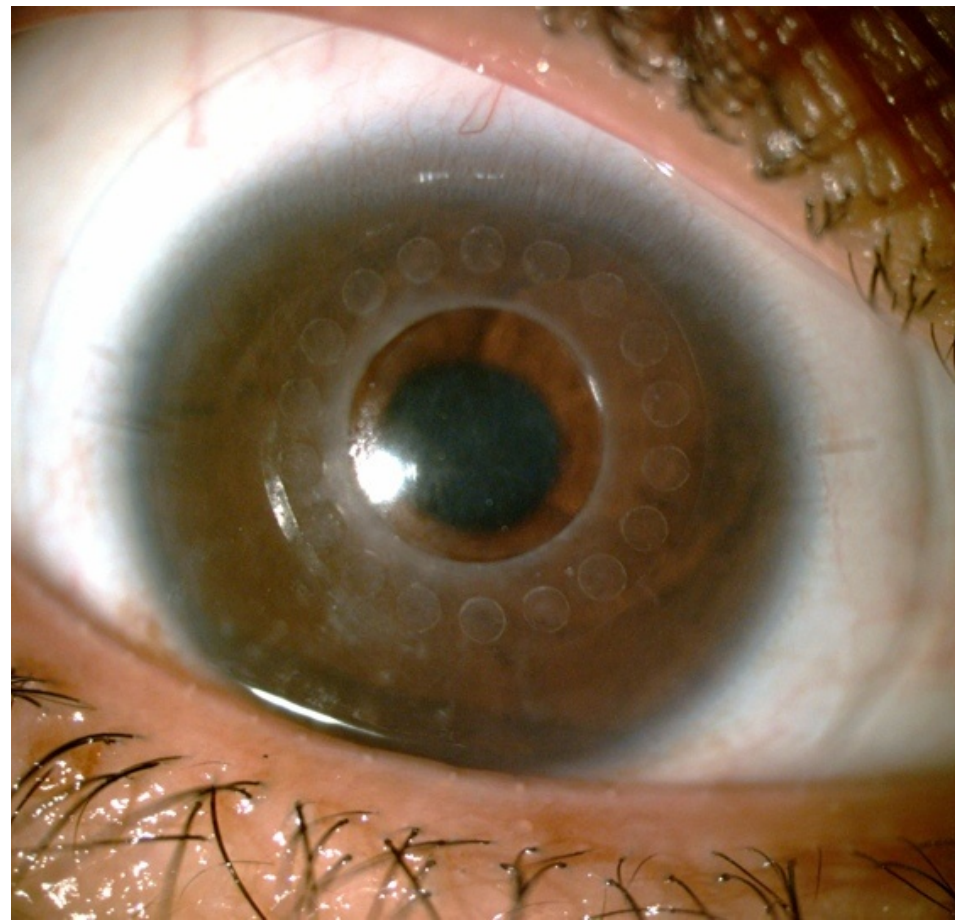
Corneal Dystrophy



Pre-op 20/400



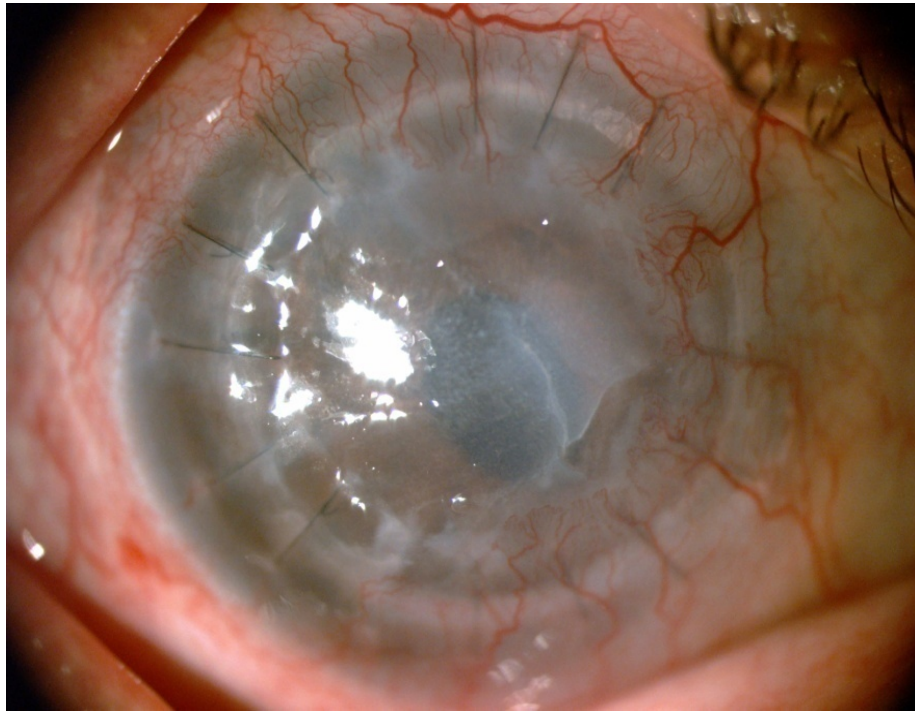
Post-op 20/40



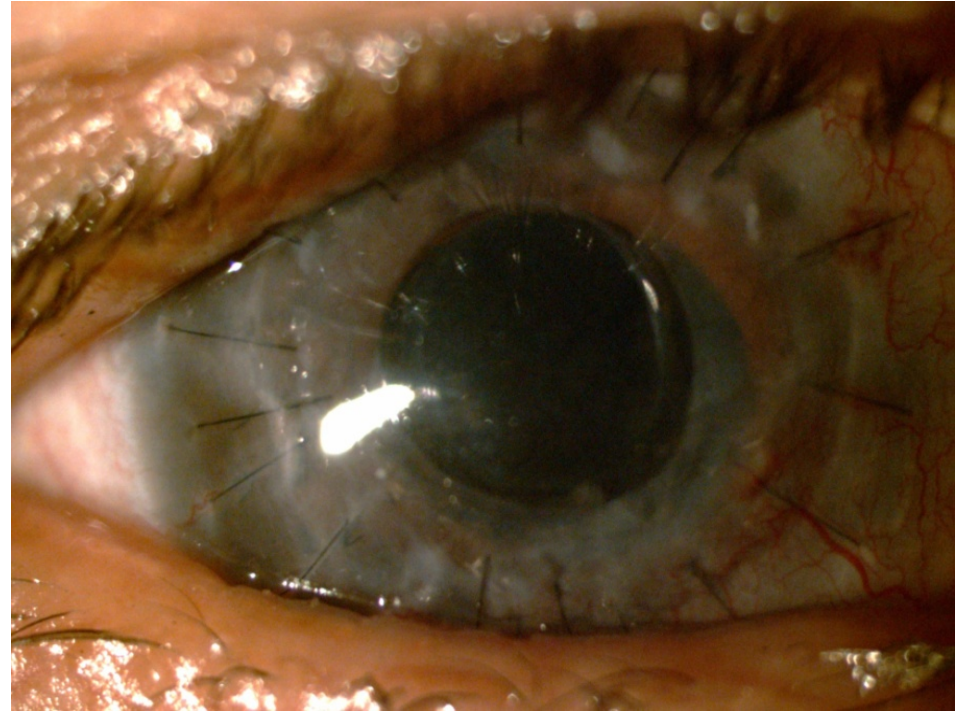
Failed Corneal Transplant



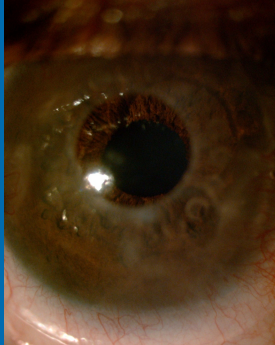
Pre-op: Hand Motions



Post-op 20/60



Outcomes



	KERALEAR OUS N=26	BOSTON K-PRO (GREINER) N=40	PK (TAN, STEWART, AL-FAWAZ)
Mean Follow-Up	50 months	41 months	36 months
Eyes with VA Better than or Equal to 20/200	24 (92%)	19 (48%)	56-100%
Endophthalmitis	0	5(13%)	.1-.77%
Retroprosthetic Membrane	0	22 (55%)	0
Increased intraocular pressure or glaucoma progression	0	20 (67%)	17-35%
Extrusion or Graft Failure	2 (11%)	6 (15%)	17-28%
Corneal Melting	1 (6%)	6 (15%)	n/a
Infection (Non-Endophthalmitis)	1 (6%)	5 (13%)	n/a

International Experience



“the new KeraKlear Kpro is a noninvasive, viable alternative to corneal transplantation with potential advantages like decreased risk of endophthalmitis, expulsive haemorrhage and worsening glaucoma. In our small series of 15 patients, none of these three complications occurred”

-Jorge Alio, MD Alicante, Spain BJO 2015

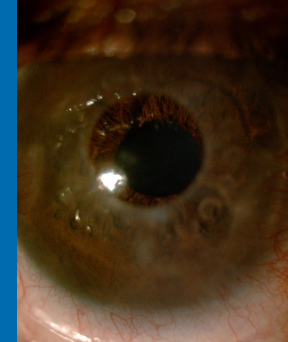
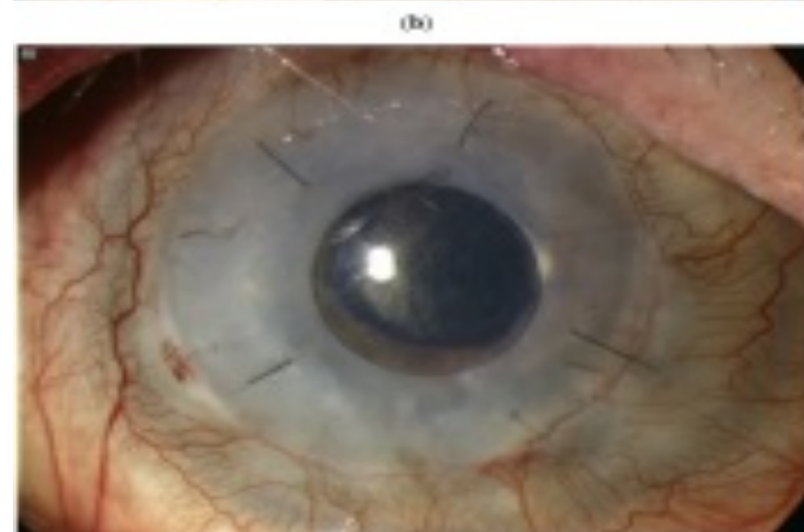
Benefits of the KeraKlear



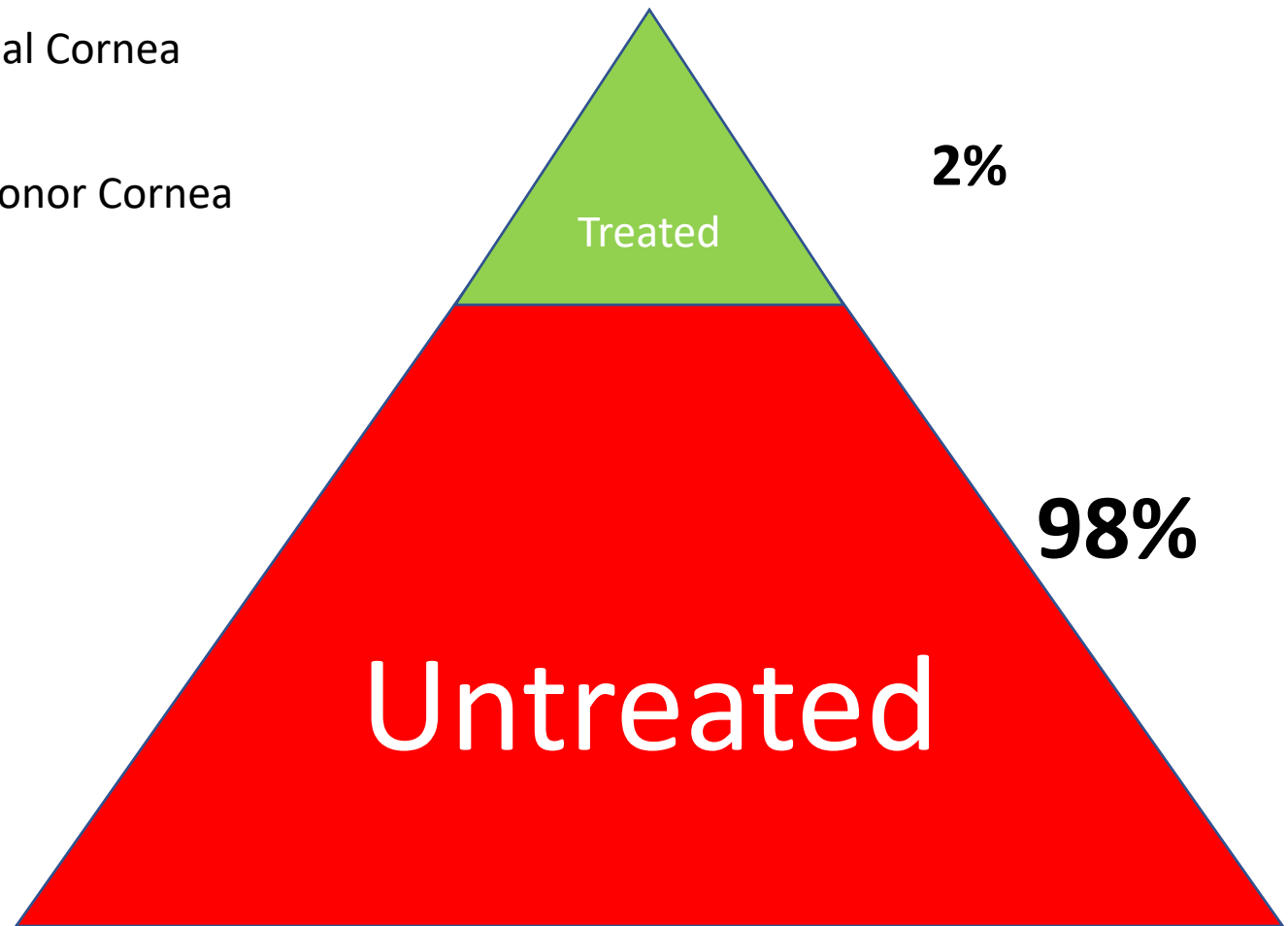
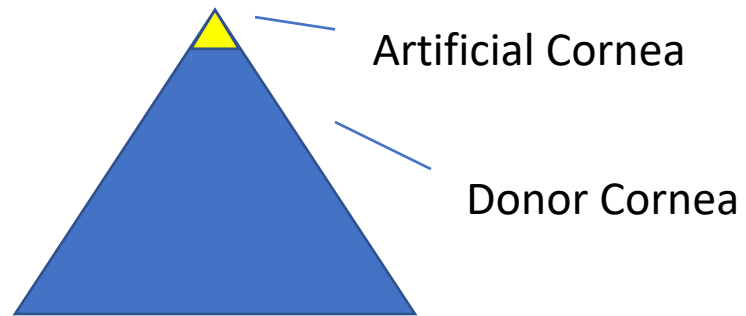
- No tissue needed
- Immediate improvement in vision after surgery
- Stability in vision within 1 to 2 months
- Prescription customizable like an IOL
- No reported cases of endophthalmitis, glaucoma or retroprosthetic membrane
- Low complication rate
- Short learning curve for the surgeon

Alternatives to Femtosecond Laser

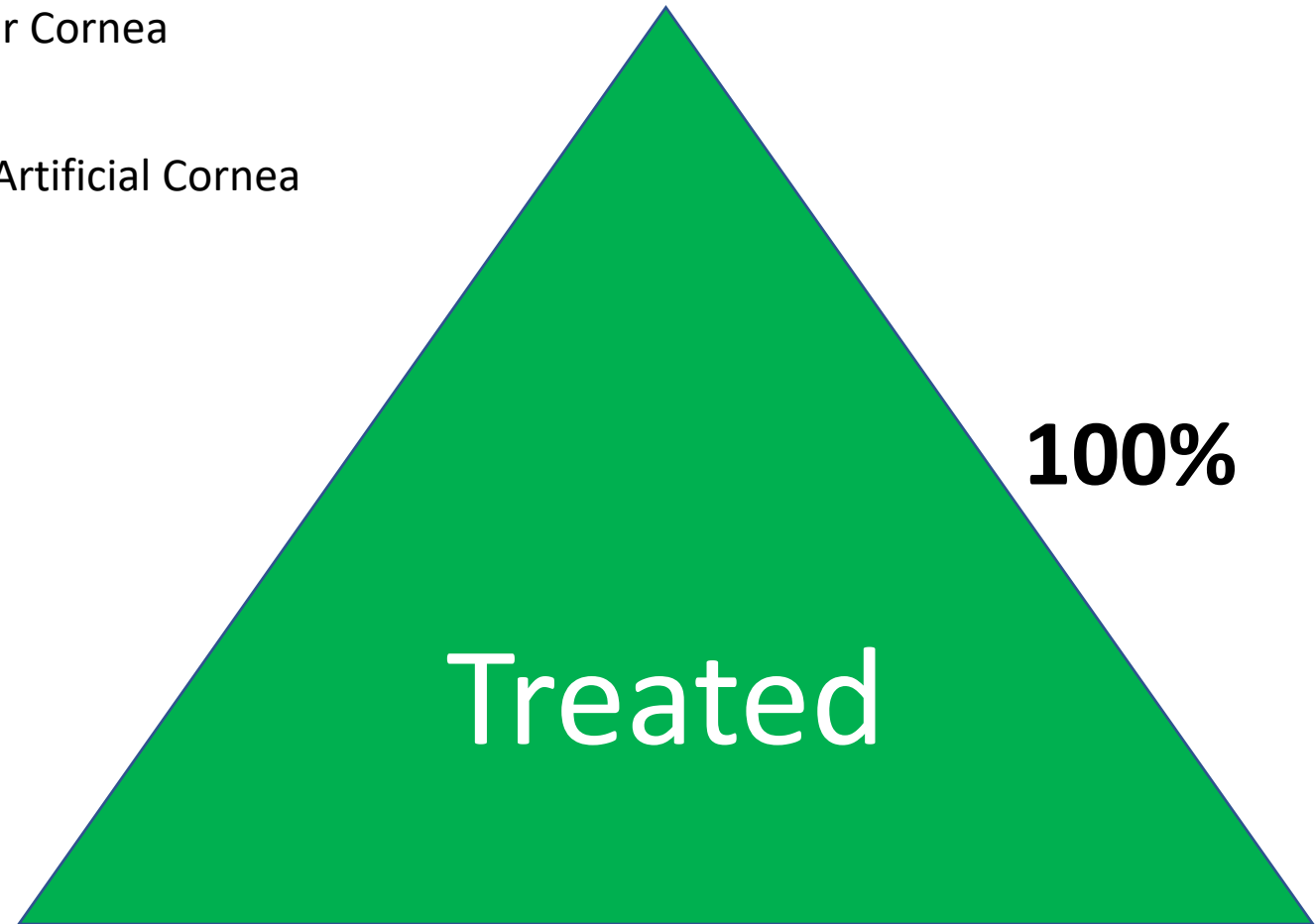
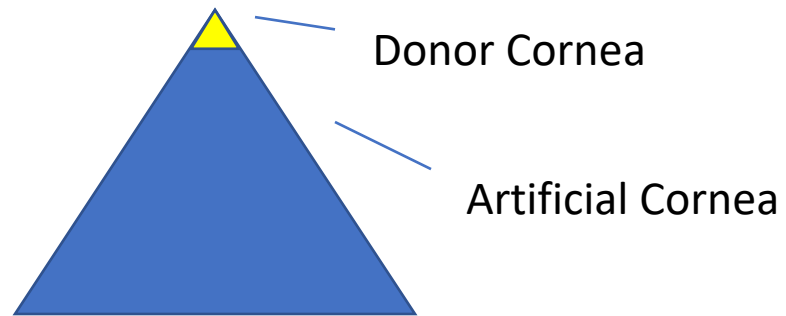
Pavel Studeny et al
Open Ophthalmol J. 2015; 9: 126–130
Czech Republic



Mismatch



Mismatch Fixed



Conclusion



- The KeraKlear Artificial Cornea is a promising alternative to penetrating keratoplasty
- It is my sincere hope that this and other technologies will finally be able to rid the world of the scourge of corneal blindness

Thank You!

