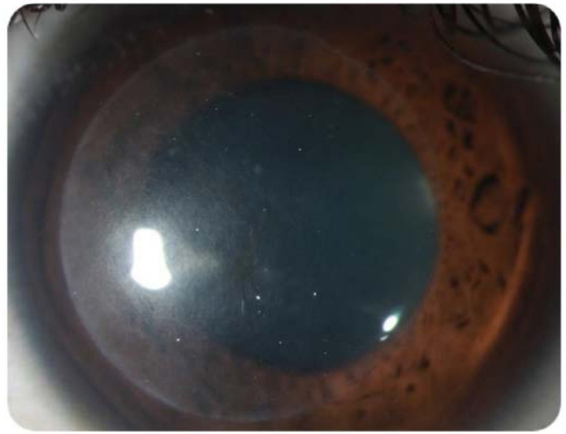
Prospective, Investigator-Initiated Study to Evaluate the Safety and Indicative Effectiveness of Xenia Custom-Made Ocular Implant in Subjects With keratoconus



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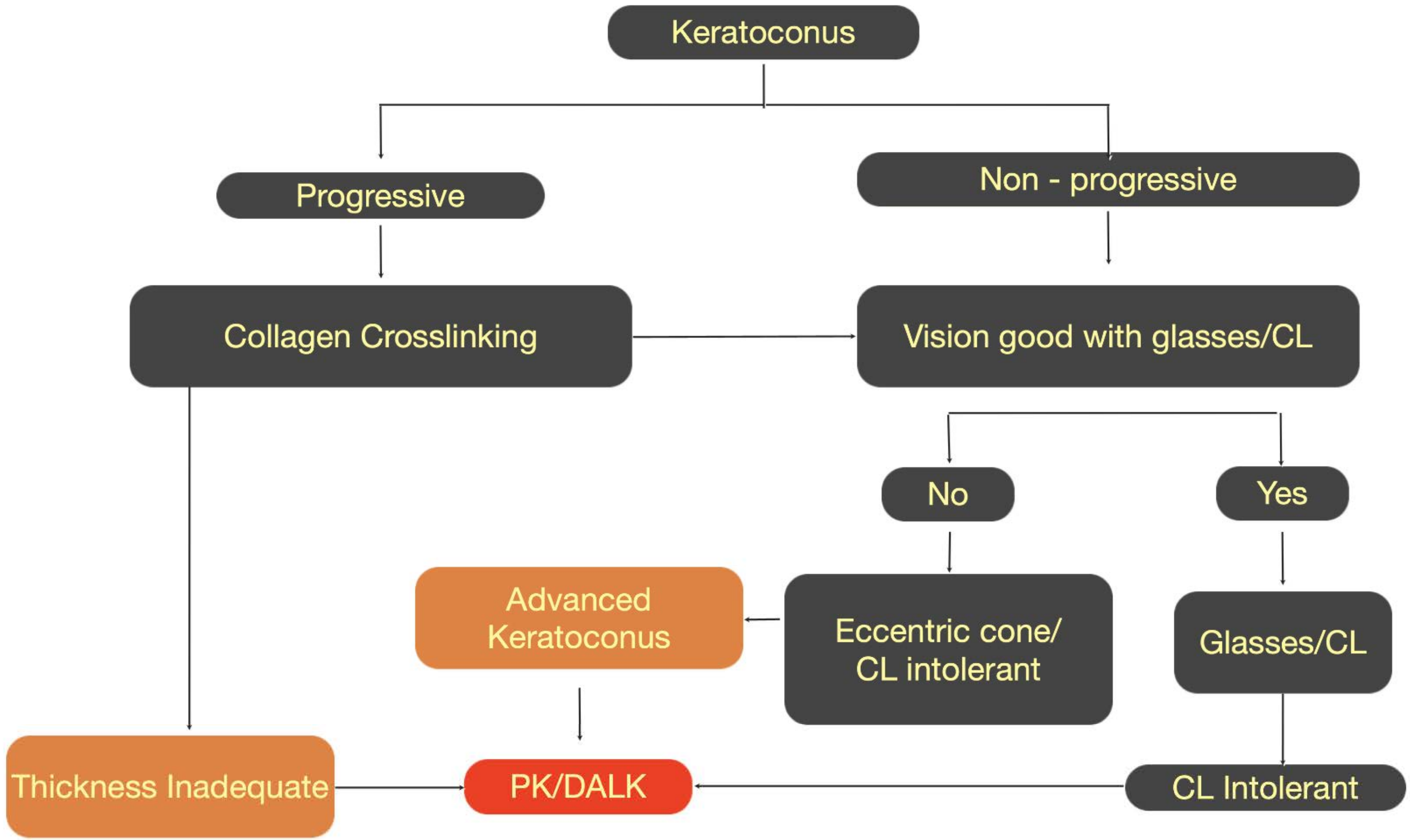
Financial Disclosure

This study was part of a clinical trial supported by Gebauer Medizintechnik GmbH, Neuhausen, Germany.

Support covered surgical and travel costs for patients and salary for one study optometrist.


Keratoconus
Progressive
Non - progressive
Collagen Crosslinking
Vision good with glasses/CL
No
Yes
Advanced Keratoconus
Eccentric cone/ CL intolerant
Glasses/CL
Thickness Inadequate
PK/DALK
CL Intolerant

Options for advanced keratoconus

Surgical Technique

Midstromal Isolated Bowman Layer Graft for Reduction of Advanced Keratoconus

A Technique to Postpone Penetrating or Deep Anterior Lamellar Keratoplasty

JAMA Ophthalmology April 2014 Volume 132, Number 4

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AMERICAN ACADEMY OF OPHTHALMOLOGY

Bowman Layer Transplantation to Reduce and Stabilize Progressive, Advanced Keratoconus

Korine van Dijk, BSc, Vasilios S. Liarakos, MD, PhD, Jack Parker, MD, Lisanne Ham, PhD, Jessica T. Lie, PhD, Esther A. Groeneveld-van Beek, MSc, Gerrit R.J. Melles, MD, PhD

Objective: To evaluate the clinical outcome of mid-stromal isolated Bowman layer transplantation, a new surgical technique to reduce and stabilize ectasia in eyes with advanced keratoconus, to postpone penetrating keratoplasty or deep anterior lamellar keratoplasty, and to enable continued daily contact lens wear.
Design: Prospective, nonrandomized cohort study at a tertiary referral center.
Participants: Twenty-two eyes of 19 patients with progressive, advanced keratoconus not eligible for ultraviolet cross-linking.
Interventions: The mid-stroma was manually dissected and an isolated donor Bowman layer was positioned within the stromal pocket.
Main Outcome Measures: Before and up to 36 months after surgery (mean follow-up, 21±7 months), best spectacle-corrected visual acuity (BSCVA), best contact lens–corrected visual acuity (BCLVA), Scheimpflug-based corneal tomography measurements, endothelial cell density, biomicroscopy, refraction, and intraoperative and postoperative complications were recorded.
Results: Two surgeries were complicated by an intraoperative perforation of Descemet membrane; no other intraoperative or postoperative complications were observed. Maximum keratometry decreased on average from 77.2±6.2 diopters (D) to 69.2±3.7 D ($P < 0.001$) at 1 month after surgery and remained stable thereafter ($P \geq 0.072$). Mean BSCVA improved from 1.27±0.44 logarithm of the minimum angle of resolution units before surgery to 0.90±0.30 logarithm of the minimum angle of resolution units 12 months after surgery ($P < 0.001$), whereas BCLVA remained stable ($P = 0.105$). Mean thinnest-point pachymetry increased from 332±59 μm before surgery to 360±50 μm at the latest follow-up ($P = 0.012$), and no change in endothelial cell density was found ($P = 0.355$).
Conclusions: With isolated Bowman layer transplantation, reduction and stabilization of corneal ectasia was achieved in eyes with progressive, advanced keratoconus. Given the low risk for complications, the procedure may be performed to postpone penetrating or deep anterior lamellar keratoplasty. *Ophthalmology 2015;122:909-917 © 2015 by the American Academy of Ophthalmology.*

Supplemental material is available at www.aaojournal.org.

OPEN

Corneal Lenticule Allotransplantation After Femtosecond Laser Small Incision Lenticule Extraction in Rabbits

Jing Zhao, MD, PhD, Yang Shen, MD, Mi Tian, MD, Ling Sun, MD, PhD, Yu Zhao, MD, PhD, Xiaoyu Zhang, MD, PhD, and Xingtao Zhou, MD, PhD

MATERIALS AND METHODS

Ethics Statement

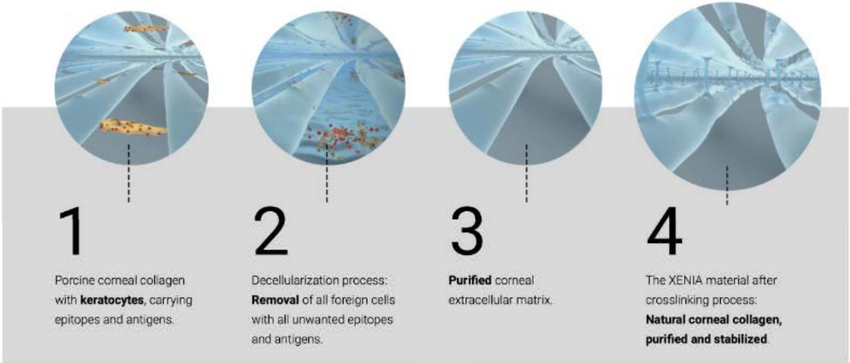
XENIA

Xenia™

- The Xenia™ Lenticule is a porcine collagen implant
- Manufactured from porcine stroma
- Isolated porcine corneas created with a nano tome followed by a liquid sterilization step
- Co-planar implant which is free of cells and their remnants.

Dimensions

- 100 to 300 microns thick
- 7 to 8 mm diameter
- Cross-linked with UV



XENIA - Study

Objectives: To evaluate the safety and indicative effectiveness of Xenia™ when implanted in subjects with keratoconus

Study Design: Prospective open-label, investigator-initiated clinical study

Number of Subjects & Enrollment: Total of 5 + 3 subjects - 12 month followup

Investigational Site: L V Prasad Eye INSTITUTE, Hyderabad

Outcome measure - Change in keratometry, Measurement Best Corrected Distance Visual Acuity

Inclusion criteria

Diagnosis of keratoconus

Visual acuity with CL - 20/40 or better

No prior surgery

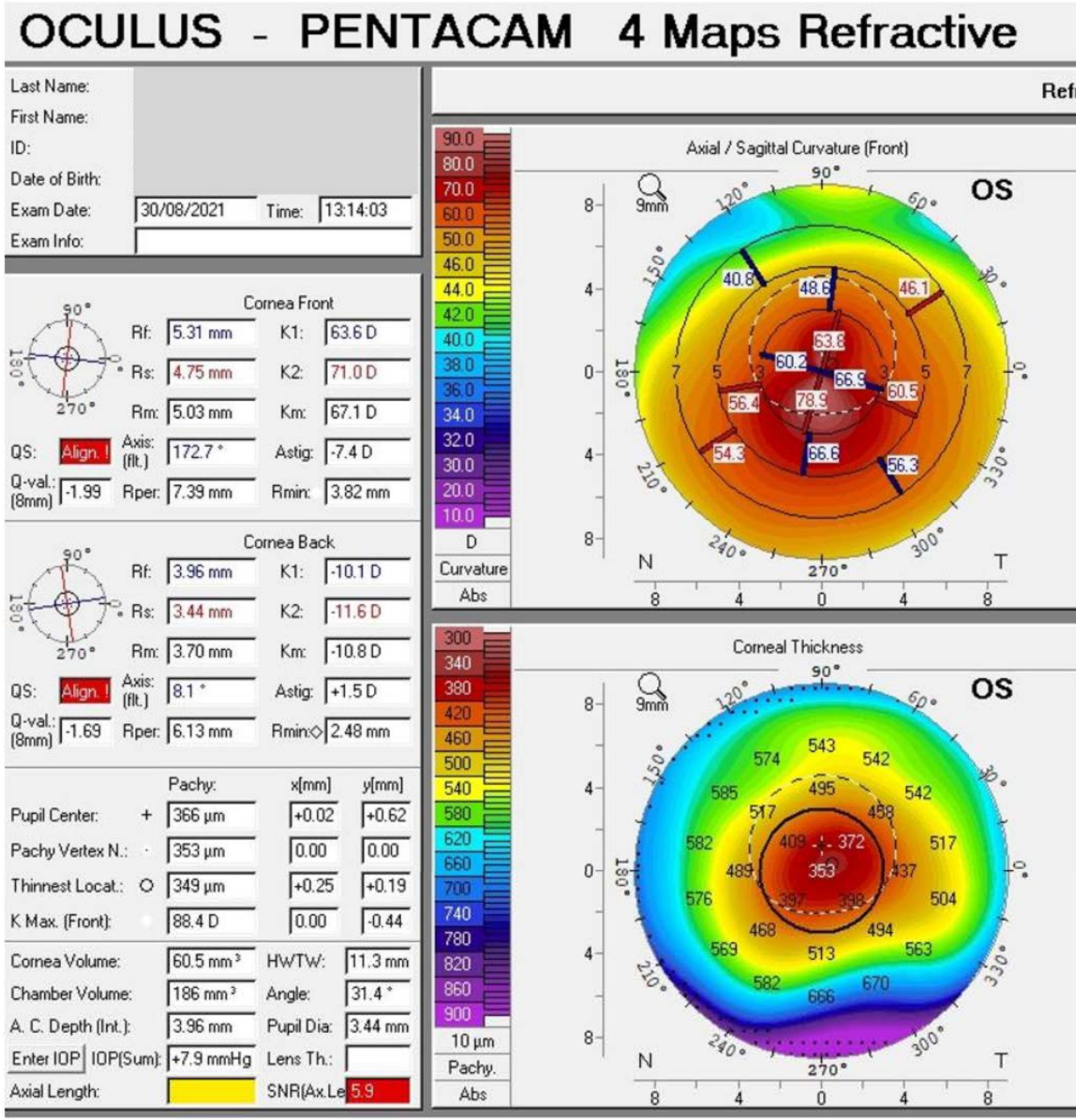
Intolerant to contact lens wear

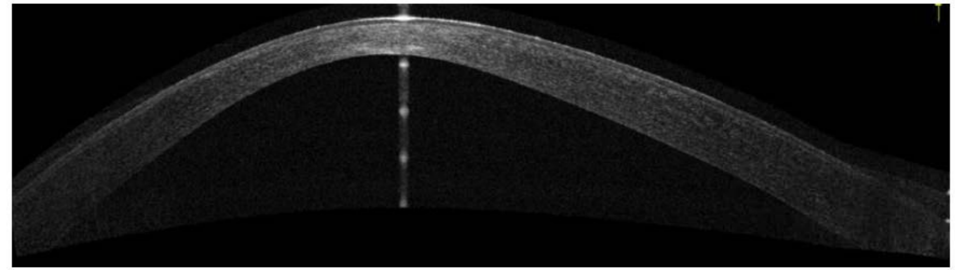
Minimal corneal thickness of 350 microns

No active ocular or systemic illness

Over 18 years of age.

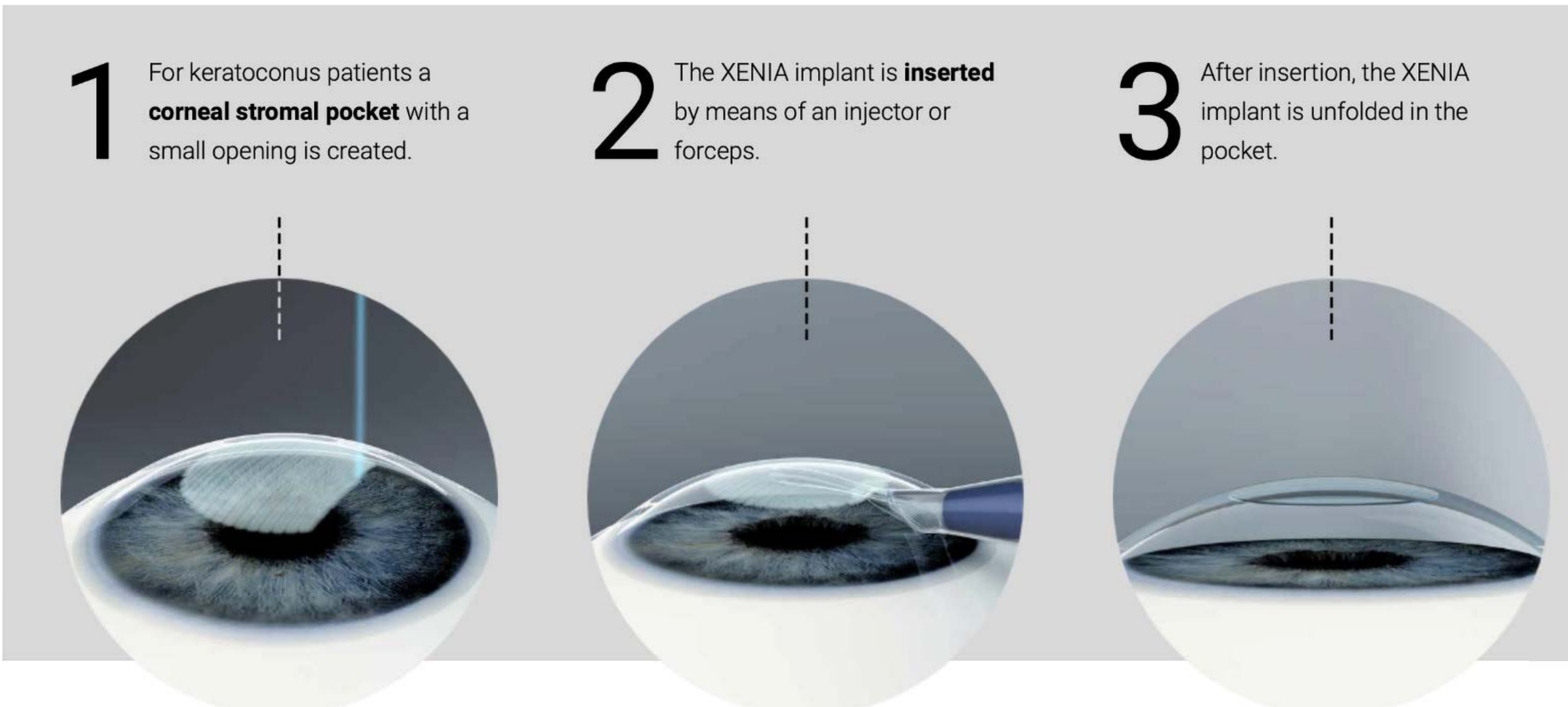
Pre op





Visual Acuity	Right Eye	Left Eye
UCVA	20/40, N6 at 30cm	CF1meter, <N36, at 30cm
Refraction	Plano/-4.00DC*45°	-11.00DS/-3.25DC*170°
BCVA	20/20P	20/200
Near vision	N6 at 30 cm	N36 at 30 cm

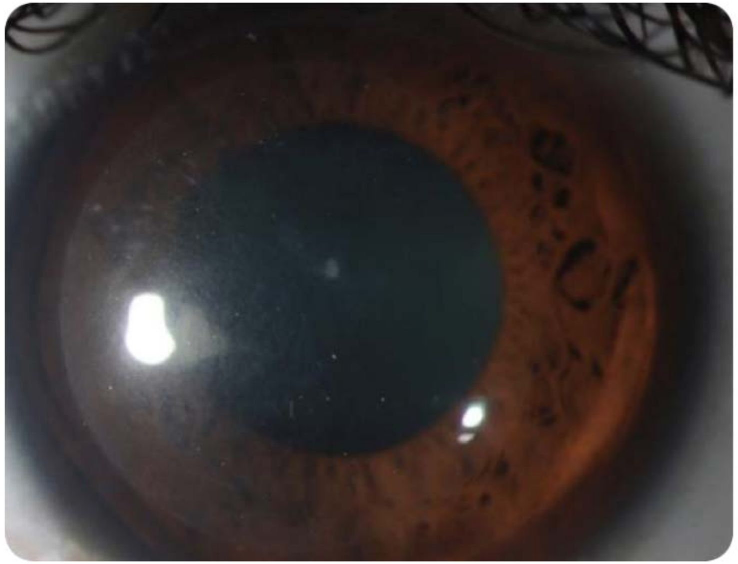
XENIA for Keratoconus



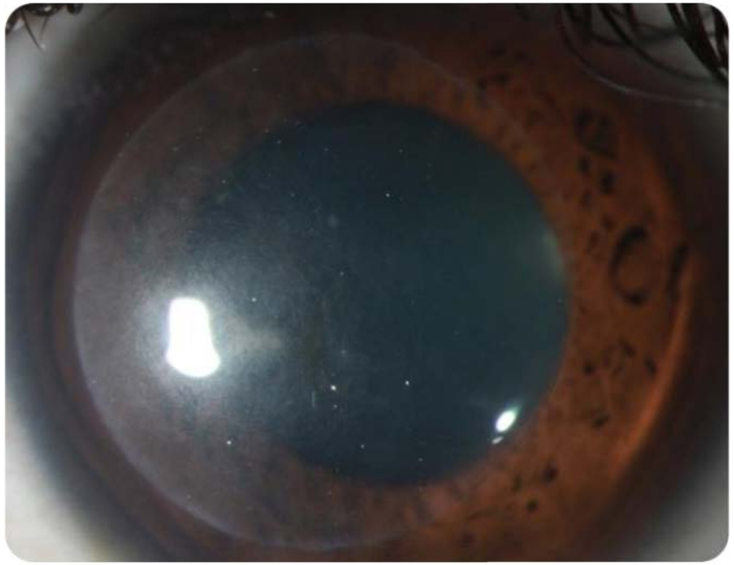
https://xenia-implant.com/the-surgical-procedure/

XENIA implant LE

Pre Op

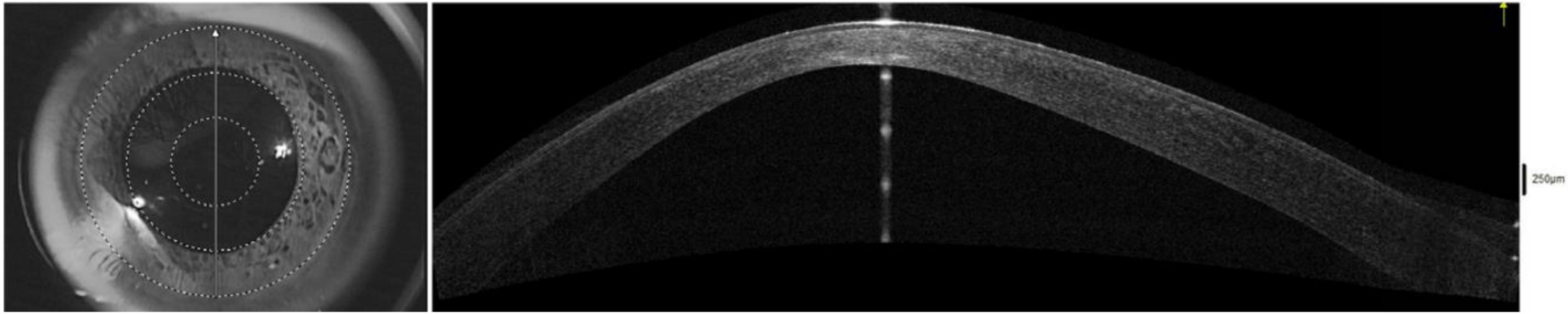


1 month post-op

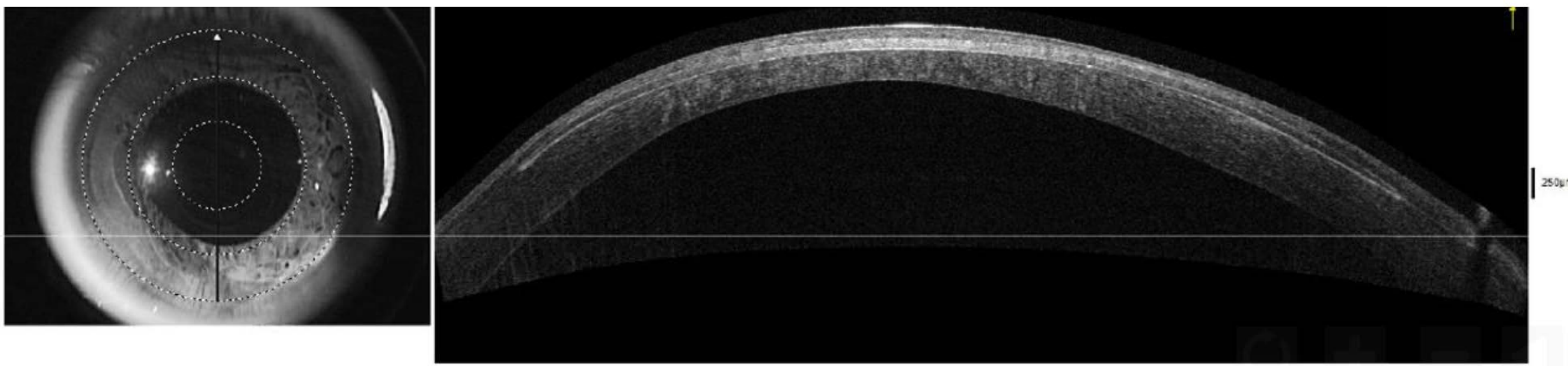


12 month post-op

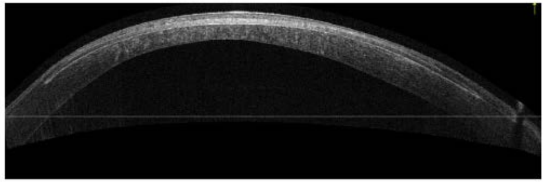
Pre op



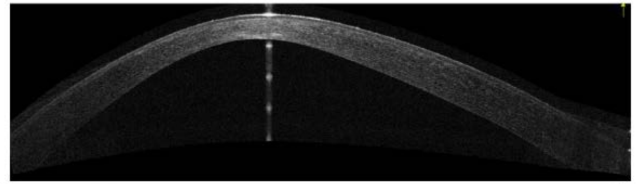
Post op

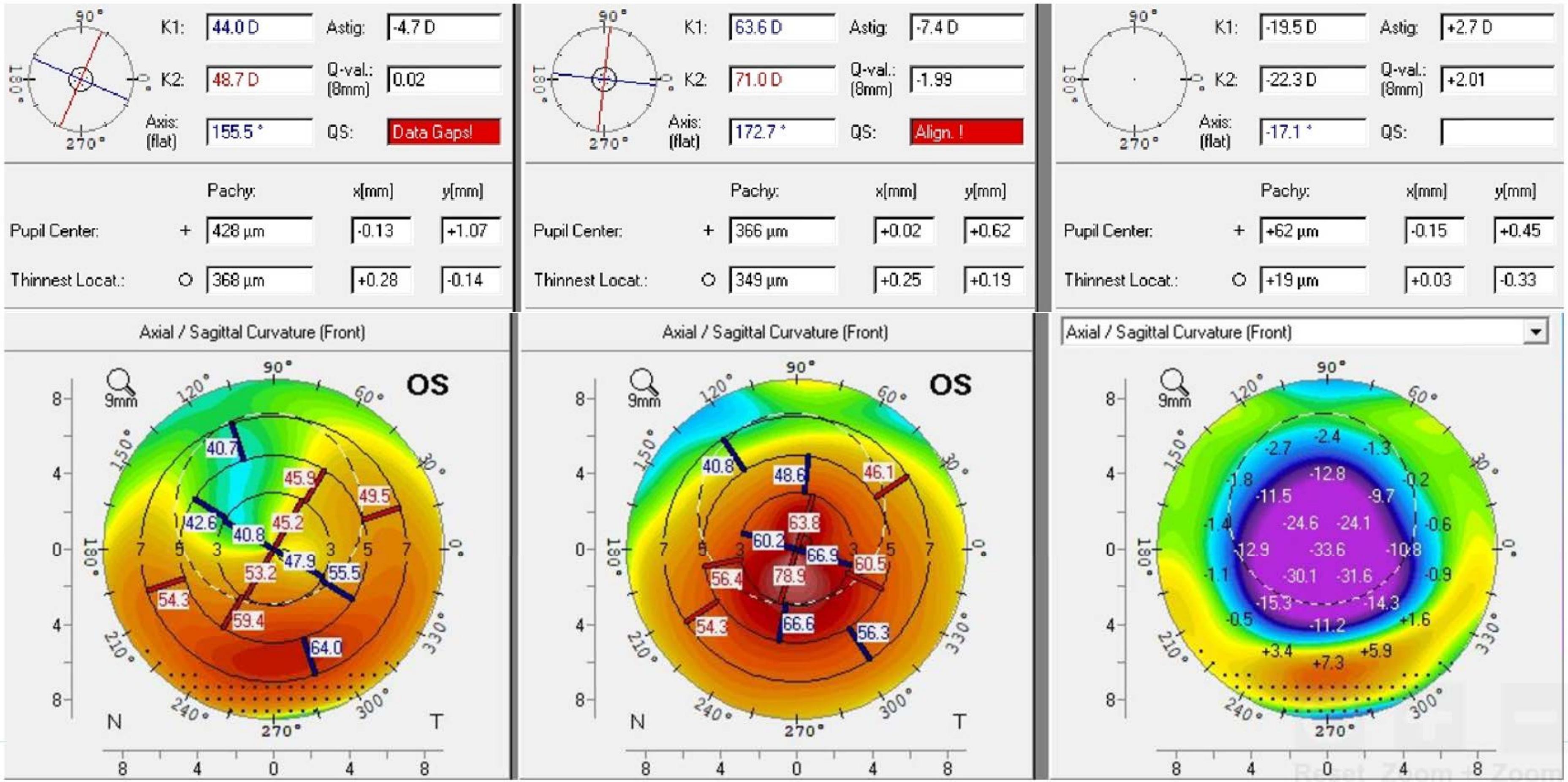


Post op x 12 months



Pre op





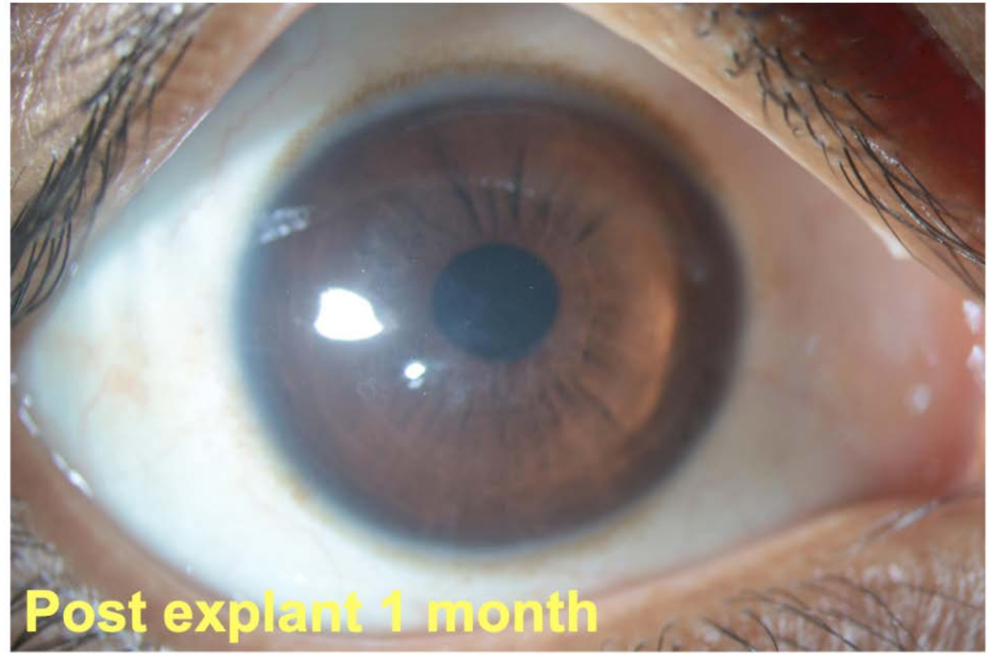
		Subject 1	Subject 2	Subject 3	Subject 4	Subject 5
Pre-op	UCVA	CF1mt	20/800	20/250	20/400	20/400
	Ref	-11/-3.00*170	-11/-7.75*70	-2.0/-6.0*140	-3.5/-3.0*150	-5.00
	BCVA	20/200, N36	20/160, N36	20/125p, N18	20/125, N10	20/250, N36
	K1,K2	63.6, 71.0	67.3, 76.2	61.6, 68.6	61.8, 65.0	56.1, 63.3
	CCT	349 µ	359 µ	370 µ	396 µ	348
POP 1m	UCVA	20/250	20/100p	20/80P	20/200	20/125
	Ref	-0.5/-5.00*120	+0.75/-1.00*5	0.0/-2.50*70	-4.0/-2.5*25	0.0/-3.0*160
	BCVA	20/125, N18	20/100, N18	20/50P, N08	20/100, N18	20/100, N24
	K1,K2	41.9, 48.2	47.4, 52.1	39.4, 42.5	54.5, 57.6	39.9, 43.7
	CCT	378 µ	386 µ	405 µ	432 µ	427
POP 3m	UCVA	20/250	20/250	20/100p	20/250	20/100p
	Ref	-2.5/-4.00*140	0.0/-3.00*50	0.0/-4.00*140	0.0/-3.50*20	+3.0/-5.0*160
	BCVA	20/80p N18	20/80, N36	20/50p, N08	20/80, N18	20/80p, N12
	K1,K2	42.7, 47.7	46.4, 51.5	38.1, 40.8	53.2, 55.7	38.4, 42.8
	CCT	383 µ	297 µ	377 µ	413 µ	416

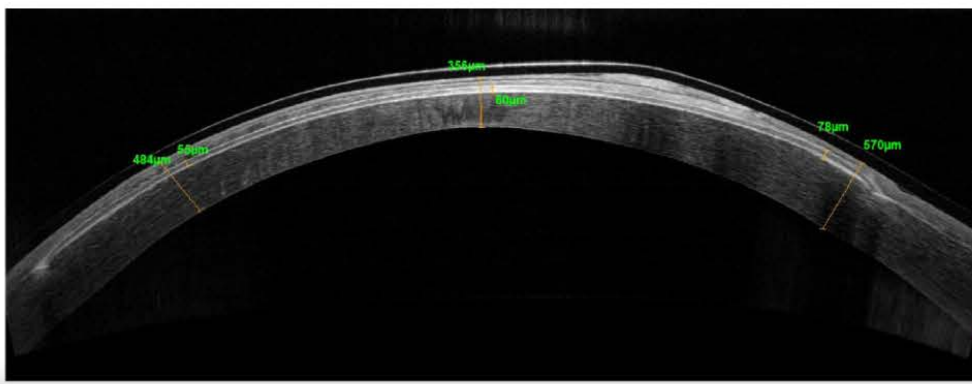
Topography

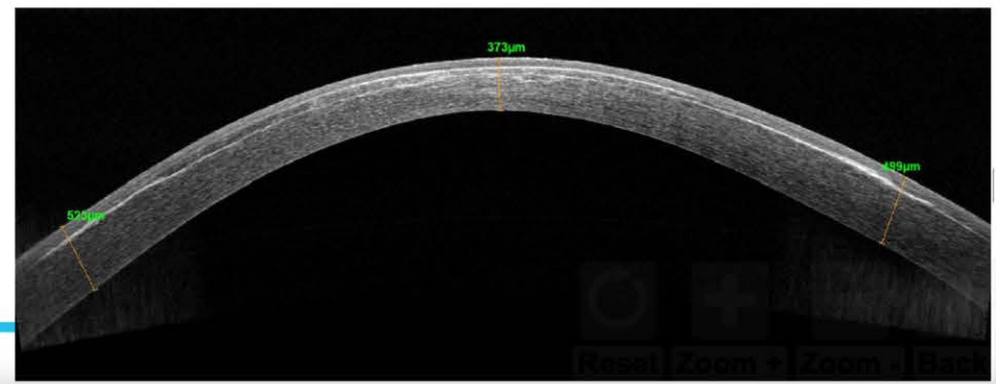
Subject	K1 Anterior					K2 Anterior					Kmax					Kmean				
	Pre-Op	1m	3m	6m	12m	Pre-Op	1m	3m	6m	12m	Pre-Op	1m	3m	6m	12m	Pre-Op	1m	3m	6m	12m
1	63.6	42	42.7	44.6	44.8	71	48.2	47.7	49.5	48.3	88.4	65.2	65.1	67.4	66.7	67.1	44.8	45.1	46.9	46.5
2	67.3	47	46.4	WD	WD	76.2	52.1	51.5	WD	WD	79.9	77.9	86.3	WD	WD	71.5	49.7	48.8	WD	WD
3	61.6	39	38.1	37.8	36.9	68.6	42.5	40.8	40.6	40.5	71.8	57.9	59.5	59	60.4	64.9	40.9	39.4	39.2	38.6
4	61.8	55	53.2	52.3	WD	65	57.6	55.7	57.7	WD	77.7	67.1	60.6	66.8	WD	63.4	56	54.4	54.9	WD
5	56.1	40	38.4	39.6	40.4	63.3	43.7	42.8	42.1	42.6	70.1	55.9	57.6	58.7	57.5	59.5	41.7	40.4	40.8	41.5
6	57.3	47	46.3	47.5	WD	65	54.3	50.4	51.1	WD	76.2	59.4	59.8	60.8	WD	60.9	50.5	48.3	49.2	WD
7	61.3	51	WD	WD	WD	67.5	53.2	WD	WD	WD	75.4	61.2	WD	WD	WD	64.2	52.1	WD	WD	WD
8	54.6	49	46.7	47.9	NA	61.1	51.5	54.3	55.7	NA	69.8	66.1	67.4	74.1	NA	57.7	50	50.3	51.5	NA

P 007

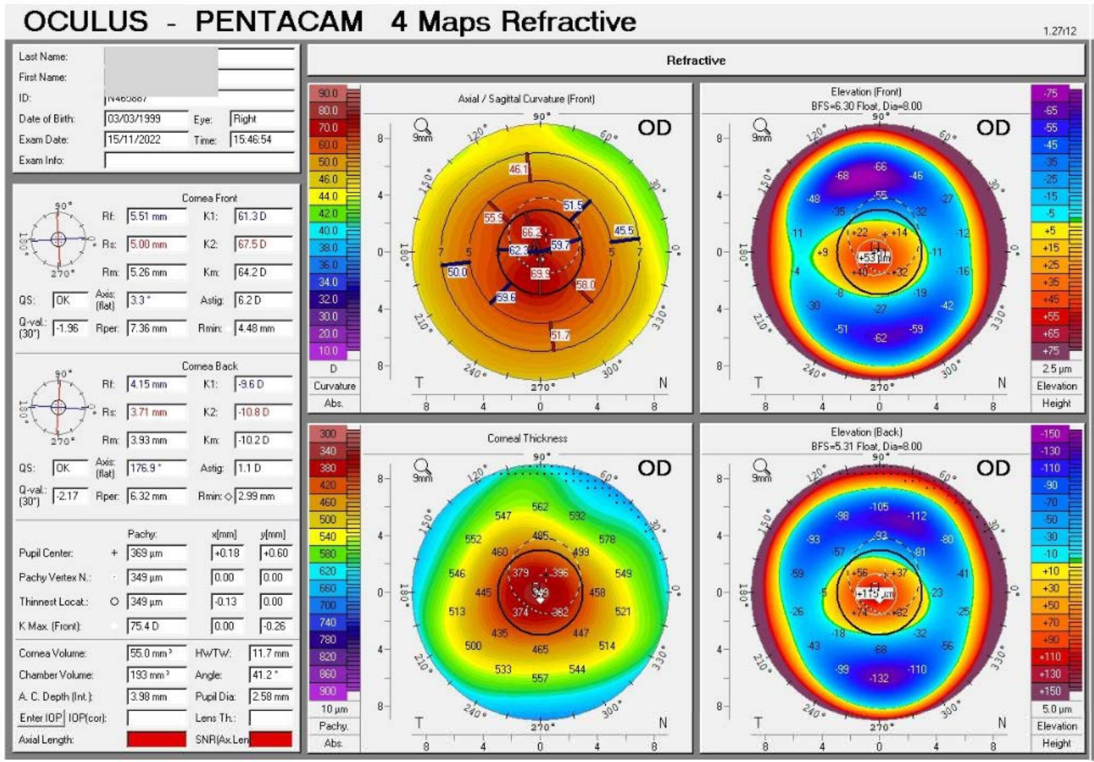

PO 3 months


Post explant 1 month

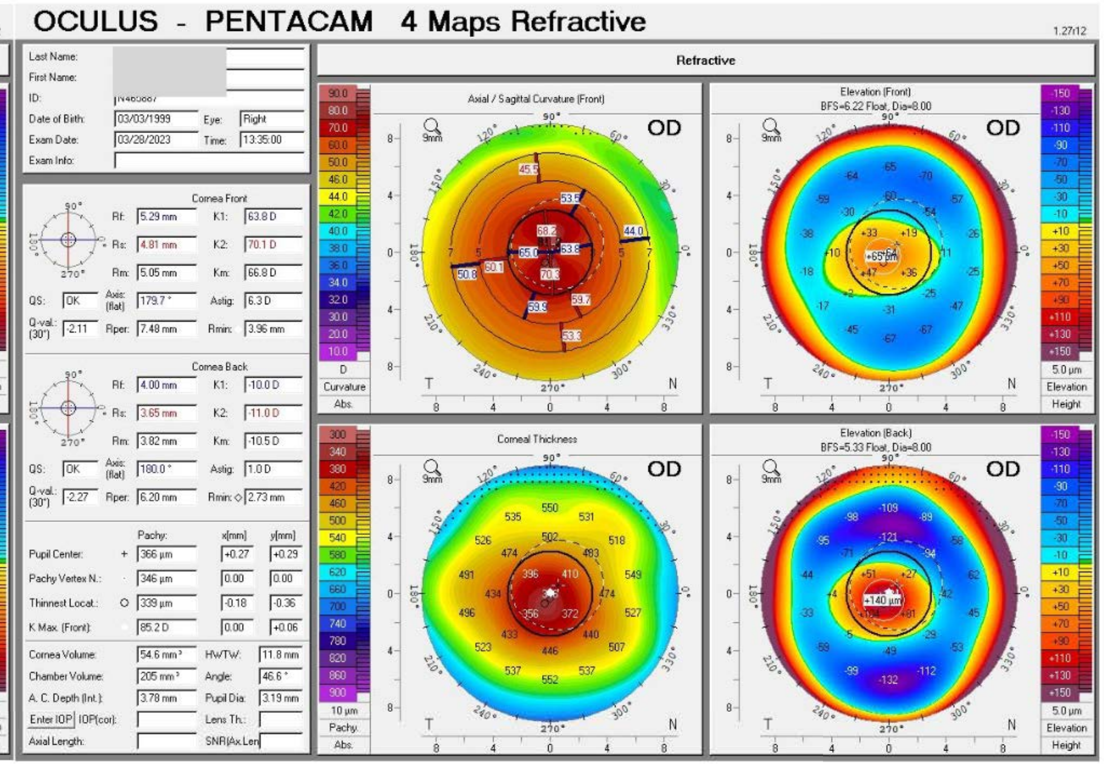

356µm
484µm
78µm
570µm


373µm

Pre Implant



Post Explant



Summary

- XENIA stromal lenticule implantation is a viable option for advanced keratoconus
- Improves corneal curvature and visual acuity and remains stable over a year
- Option for patients not suitable for collagen cross linking
- Potential to avoid need for a corneal transplant
- Stromal melt and epithelial healing issues might be sorted by deeper implants