

10 Year Follow-up of Phase III Pivotal U.S. Trial of Corneal Crosslinking in Progressive Keratoconus and Ectasia

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Financial Disclosure

- **Steven A. Greenstein MD**

- Alcon
- Glaukos

- **Steven Huang**

- None

- **Peter S. Hersh MD**

- Alcon
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- **John D. Gelles**

- Bausch + Lomb
- BostonSight
- Essiri Labs
- EyecareLive
- Glaukos
- Mojo Vision
- SPARCA
- Synergeyes

Corneal Collagen Crosslinking

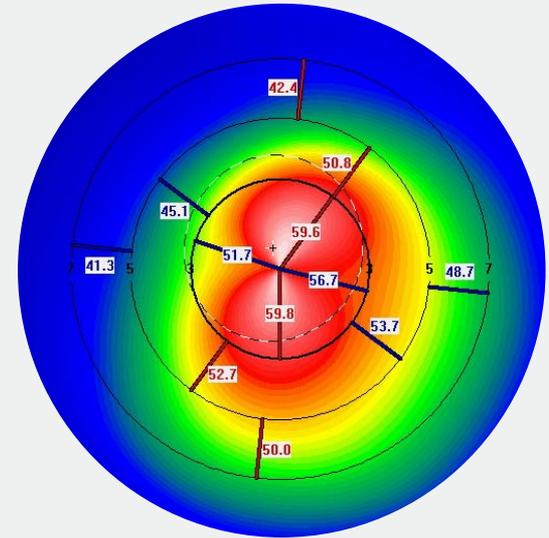
FDA trial

- **February 6, 2008: First U.S. case**
- **April 15, 2016: FDA approval**
- **Indications**
 - Corneal collagen crosslinking for the treatment of progressive keratoconus
 - Patient >14 years old
 - Corneal ectasia after refractive surgery



Purpose

- To report the long term (10-year) outcomes of patients treated as part of the US pivotal trial.



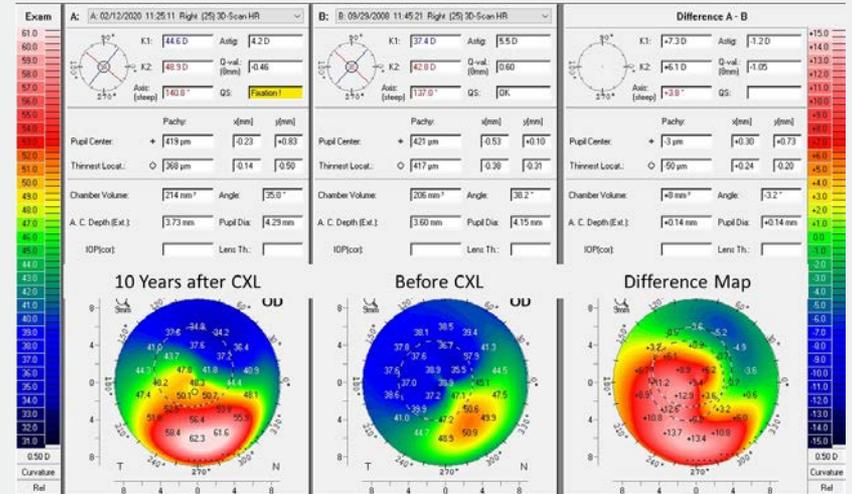
Methods

- **Single Center**
 - Participated in US multicenter pivotal clinical trials for crosslinking (Glaukos Inc)
 - 30 Eyes (16 patients)
 - 15 keratoconus
 - 15 ectasia after laser refractive surgery
 - 10 (6 KC, 4 EC) eye underwent topography altering surgery after CXL

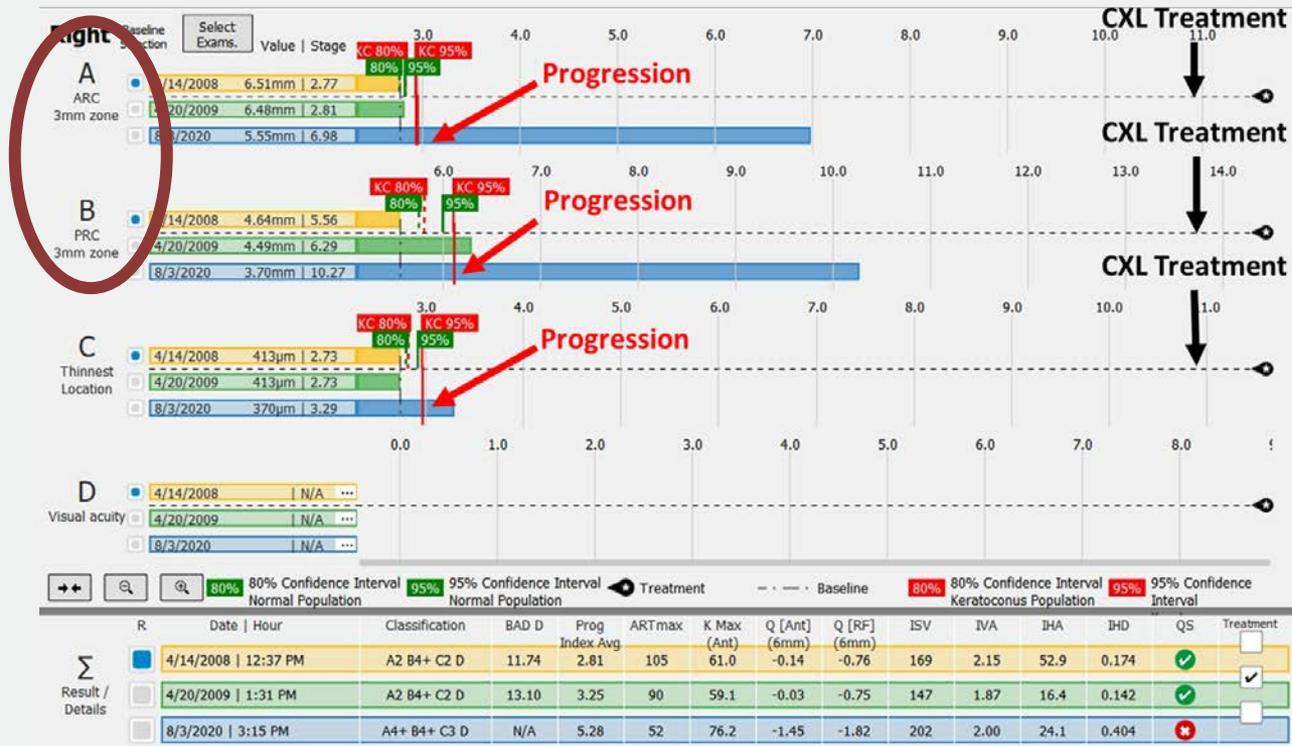
Methods

- Progression was defined

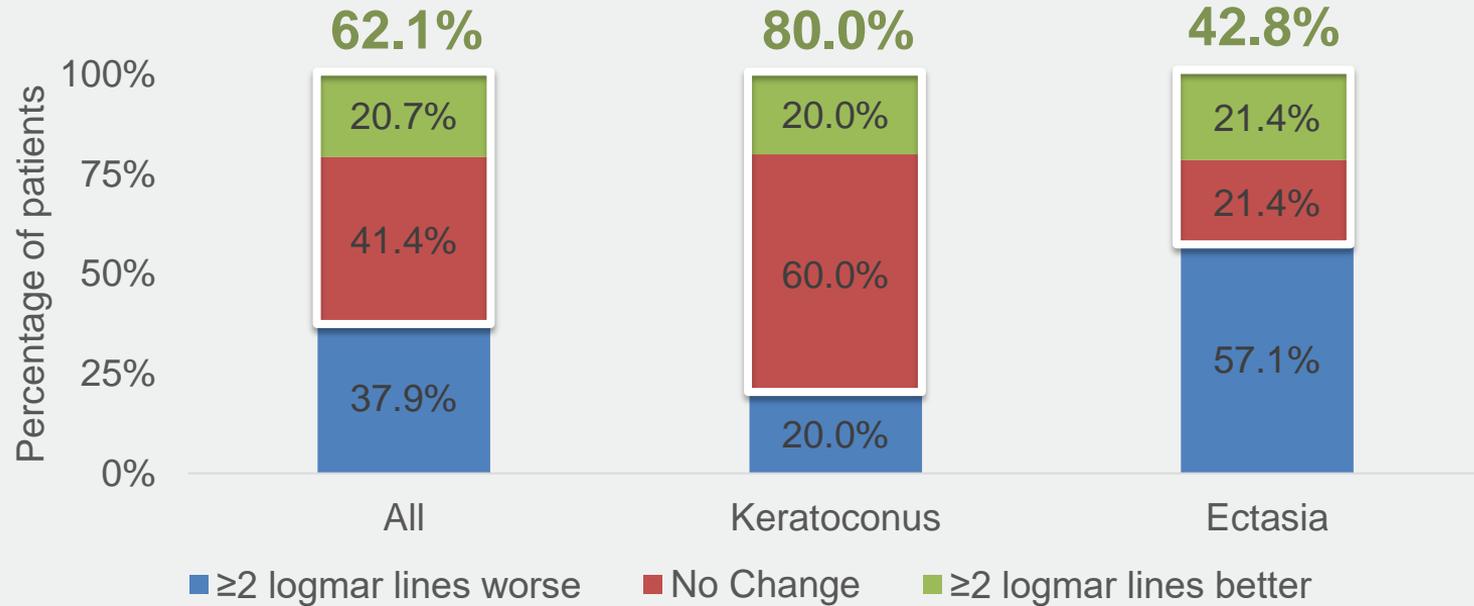
- 1) Steepening of $K_{\max} \geq 2D$
- 2) Worsening visual acuity (UCVA or BSCVA) ≥ 2 logMar lines
- 3) Belin ABCD progression display



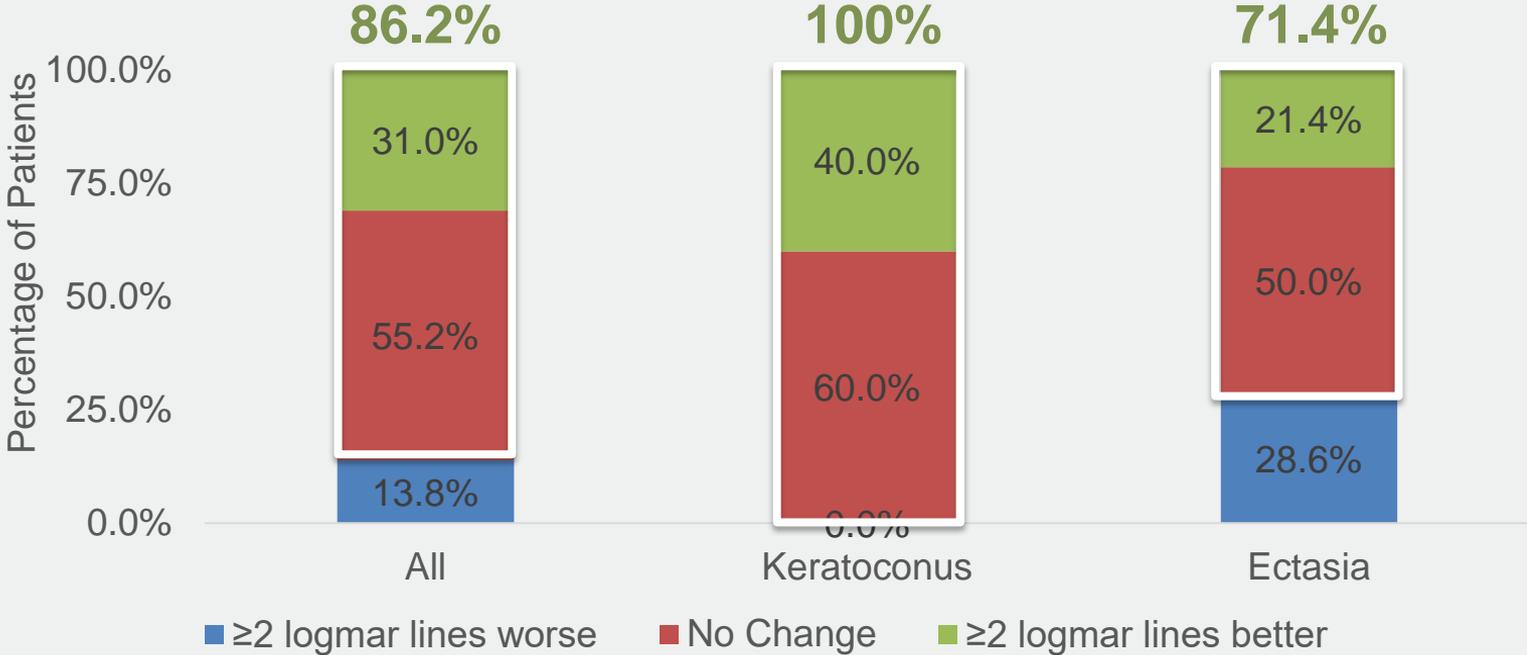
Belin ABCD Progression Display



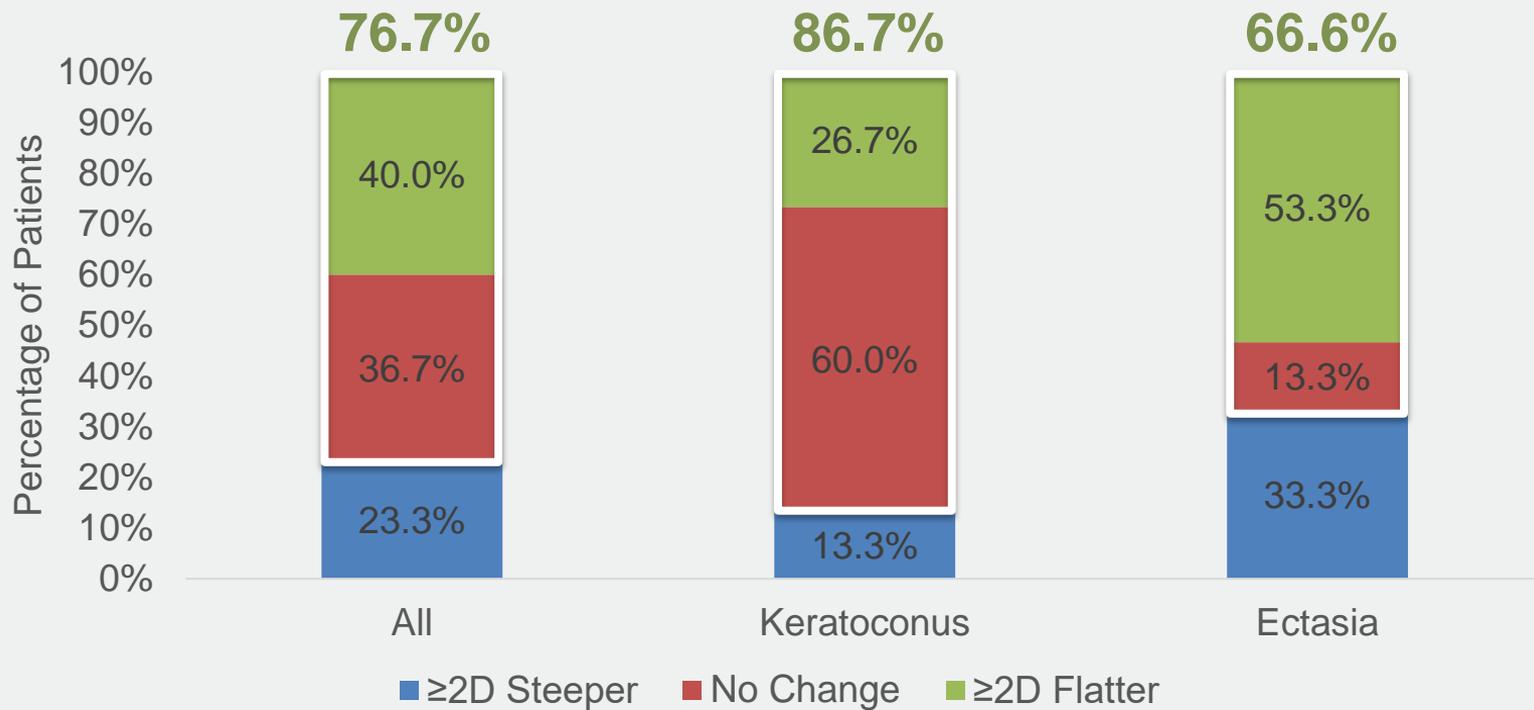
Uncorrected Visual Acuity



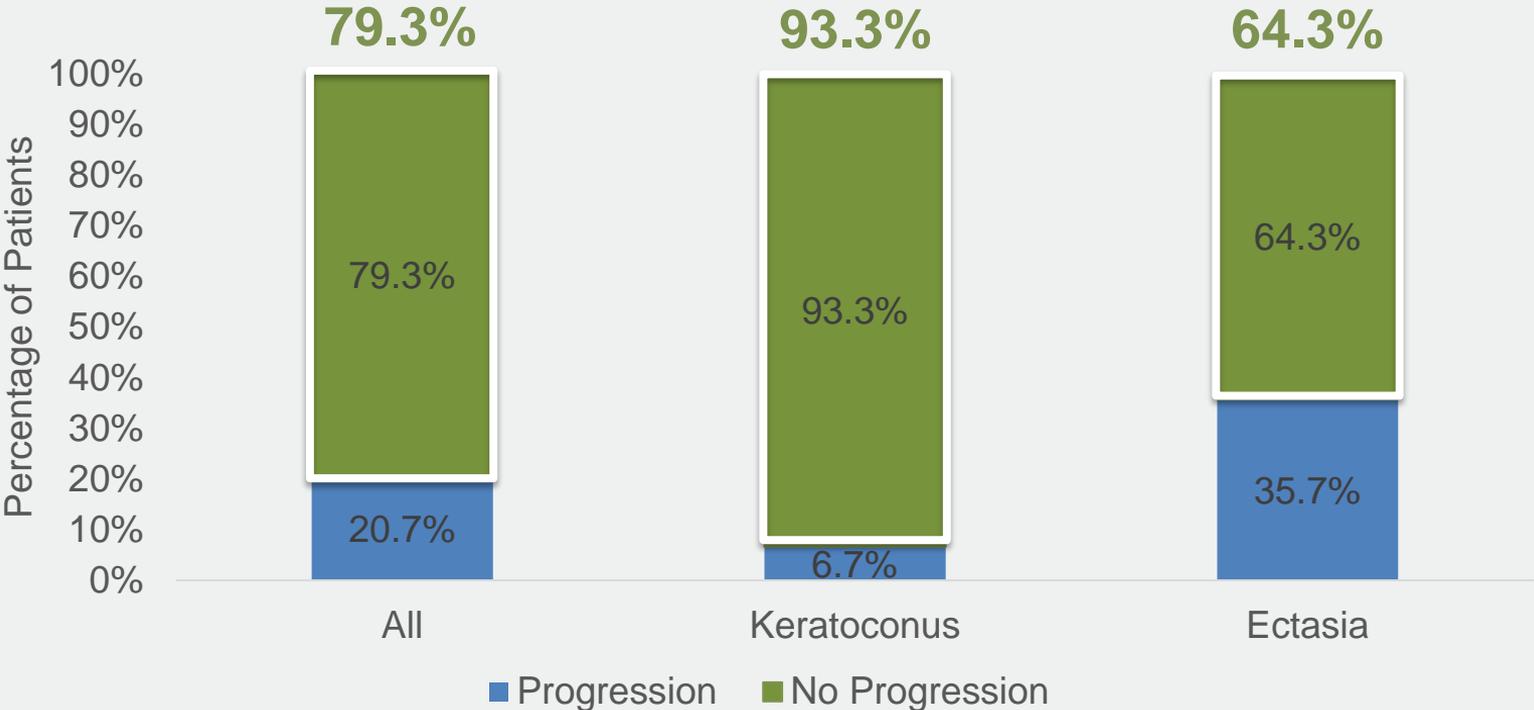
Best Spectacle Corrected Visual Acuity



Topography (K_{max})



Belin ABCD Progression Display



No Surgery

	All				No Surgery			
	Preop	1 year	10 Year	P value (between visits)	Preop	1 year	10 Year	P value (between visits)
UCVA (LL)	0.80±0.36	0.77±0.43	0.86±0.44	0.7	0.75±0.21	0.76±0.49	0.86±0.46	0.8
BSCVA (LL)	0.36±0.23	0.22±0.14	0.30±0.23	0.9	0.34±0.24	0.20±0.14*	0.32±0.34	0.9
K _{max} (D)	58.0±10.6	55.4±7.1	56.3±9.2	0.5	59.7±10.3	55.4±7.7	58.3±10.1	0.6
ARC (mm)	6.8±1.2	6.8±1.0	6.9±1.0	0.9	7.1±1.4	6.9±0.9	6.7±1.1	0.9
PRC (mm)	4.9±1.0	4.9±0.8	4.8±0.8	0.8	4.8±1.1	5.0±0.9	4.8±0.9	0.8

Conclusions

- **In general, CXL appears to remain stable 10 years after treatment**
 - Stable topography
 - 77% of the entire cohort
 - 87% of keratoconus eyes
 - 67% of ectasia eyes
 - Stable BSCVA
 - 86% of the entire cohort
 - 100% of keratoconus eyes
 - 71.4% of ectasia eyes



Thank You

The CLEI Center for Keratoconus

