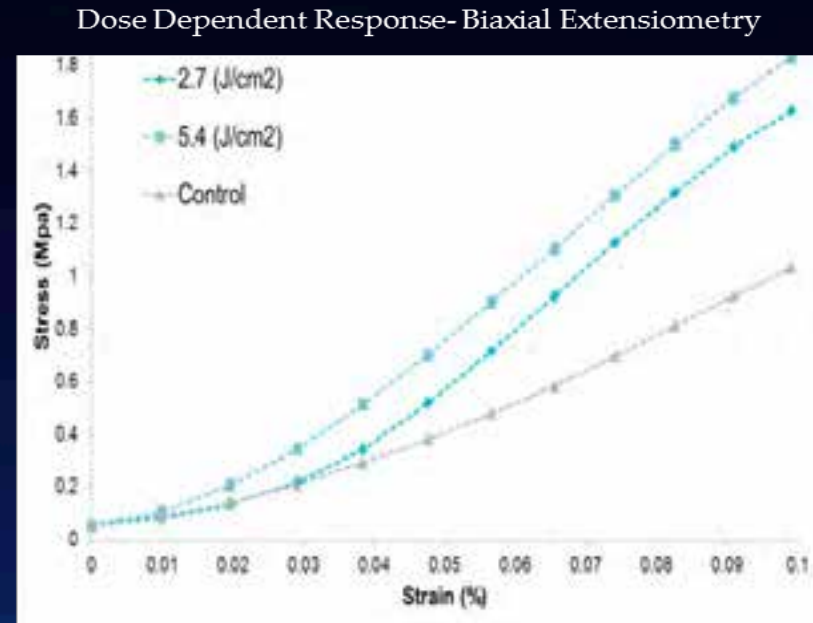
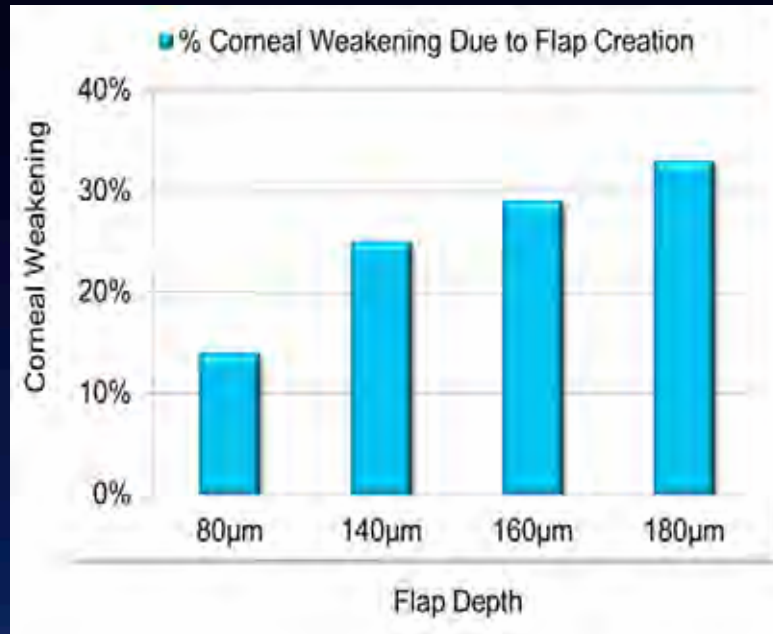




LASIK XTRA : WHAT DOES THE LITERATURE SHOW?

Lasik Xtra: Restoring corneal strength



Creation of the LASIK flap weakens the cornea by as much as 30%. Lasik Xtra treatment protocols are designed to apply sufficient stiffening to restore the cornea to its pre-LASIK level of stiffness, without excessive change

Lasik Xtra: Corneal strengthening during LASIK



The goal of Lasik Xtra is to restore biomechanical integrity to corneas that have been weakened by refractive surgery to achieve stable, predictable visual outcomes in order to:

- Reduce the risk of post- LASIK refractive regression
- Reduce the risk of post- LASIK ectasia

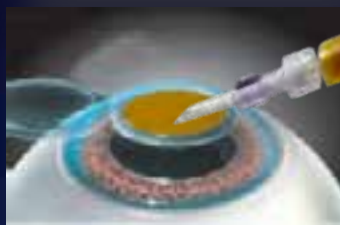


Courtesy of C. Mazzotta MD, PhD,
Siena University, Italy

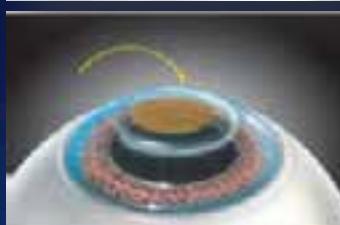
Lasik Xtra: Corneal strengthening during LASIK



The LASIK flap is left open following excimer laser ablation



Dextran free riboflavin is applied to the stromal bed immediately after ablation



Riboflavin is rinsed from the eye, and the flap is repositioned as usual

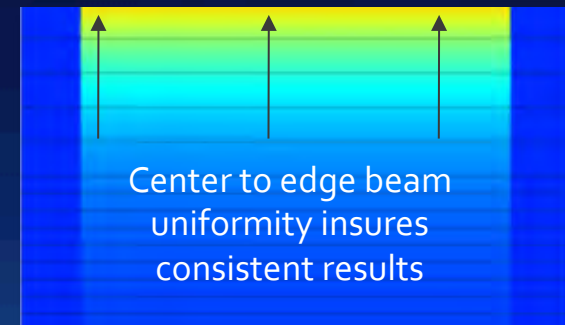


UVA illumination is applied through the closed flap for 90 seconds at 30mW/cm²

Lasik Xtra: Maintaining Predictability

Pan-corneal treatment

- KXL system with homogenous beam profile and large depth of focus is used to cross-link the entire central 9mm of the cornea
- Uniform treatment across the large treatment zone restores stability without redistributing corneal stresses (no shape change)
- This differs from treatment of keratoconus, where the cornea has a focal region of weakness

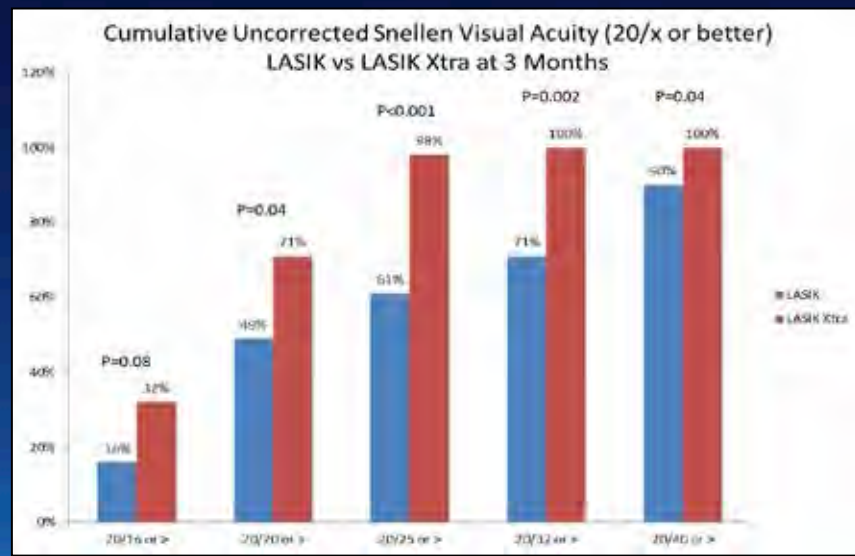
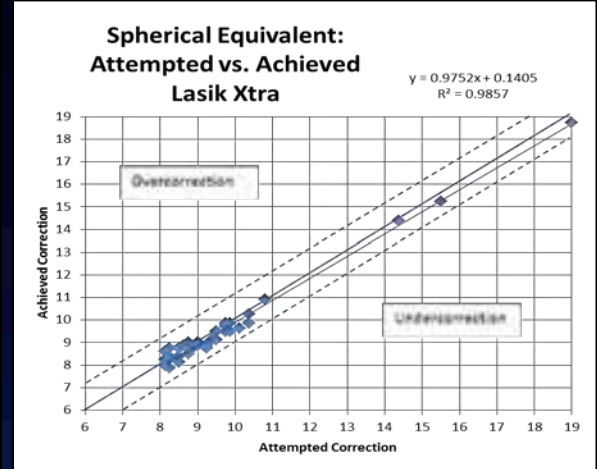
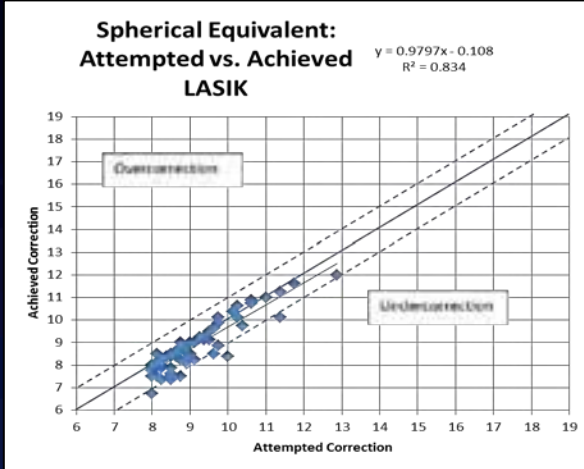


LASIK + CORNEAL CROSS-LINKING: KEY POINTS

- What do we know:
 - LASIK weakens the cornea
 - Cross-linking stiffens the cornea

- What Do We Need to Know?
 - Can we safely add cross-linking to LASIK?
 - Can we achieve predictable refractive outcomes with Lasik Xtra?
 - Can Lasik Xtra improve corneal stability?

Lasik Xtra: Clinical Results



Lasik Xtra: Safety

Published studies show no endothelial cell loss

- Celik HU, Alagöz N, Yildirim Y, et al. Accelerated corneal crosslinking concurrent with laser in situ keratomileusis. *J Cataract Refract Surg.* 2012;38(8):1424–31
- Kanellopoulos AJ. Long-term safety and efficacy follow-up of prophylactic higher fluence collagen cross-linking in high myopic laser-assisted in situ keratomileusis. *Clin Ophthalmol.* 2012;6:1125–30.
- Tomita M, Yoshida Y, Yamamoto Y, Mita M, Waring G. In vivo confocal laser microscopy of morphologic changes after simultaneous LASIK and accelerated collagen crosslinking for myopia: One-year results. *J Cataract Refract Surg.* 2014;40(6):981–90.
- Mazzotta C, Balestrazzi A, Traversi C, Caragiuli S, Caporossi A. In vivo Confocal Microscopy Report after Lasik with Sequential Accelerated Corneal Collagen Cross-Linking Treatment. *Case Rep Ophthalmol.* 2014;5(1):125–31.
- Wu Y, Tian L, Wang L, Huang Y. Efficacy and Safety of LASIK combined with Accelerated Corneal Collagen Cross-Linking for Myopia: Six Month Study. *Biomed Res Int.* 2016;5083069.

Lasik Xtra: Safety

Superficial corneal crosslinking during laser in situ keratomileusis

Theo G. Seiler, MD, Isaak Fischinger, MD, Tobias Koller, MD,
Viktor Derhartunian, MD, Theo Seiler, MD, PhD
J Cataract Refract Surg 2015; 41:2165–2170

- In a study applying 9mW/cm² CXL, a greater post-operative inflammatory response was seen in the Lasik + CXL group during the first postoperative week.
- DLK resolved in all eyes by 1 week.
- No eyes in either group lost CDVA at 1 year post-operatively.



Figure 1. Slitlamp photograph of a cornea 1 day after superficial corneal crosslinking and LASIK. The whole interface shows a distinct, confluent haze that can persist for months and must be distinguished from DLK stage 2.

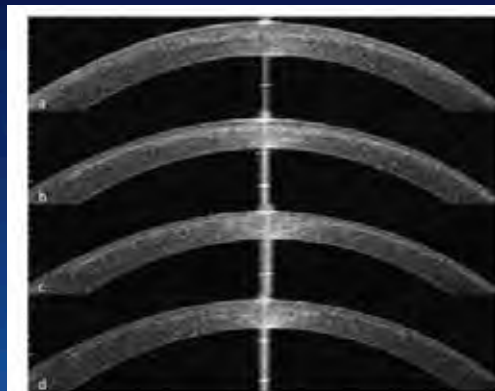


Figure 2. Temporal evolution of the OCT findings 1 day (a), 1 month (b), 4 months (c), and 12 months (d) after superficial corneal crosslinking during LASIK. The hyperreflective layer is $\pm 20 \mu\text{m}$ thick around the interface.

Lasik Xtra: Predictability

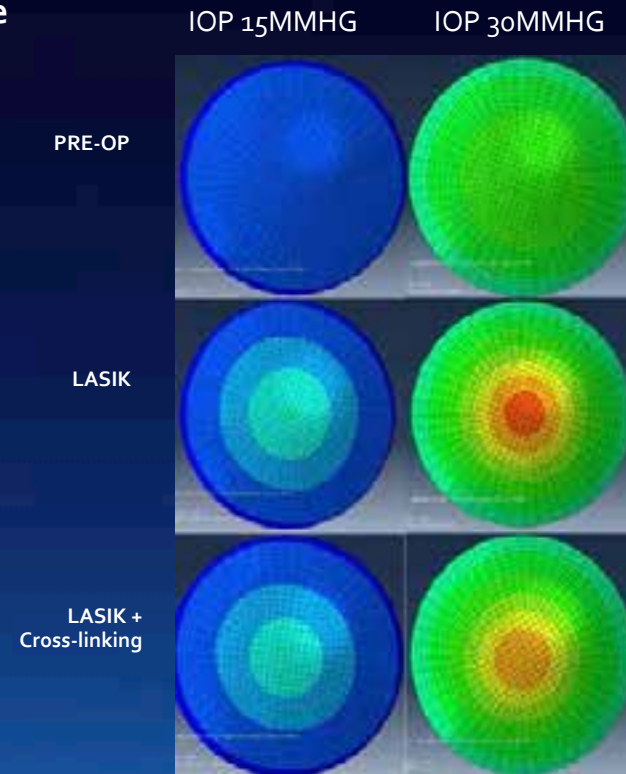
Adjunctive Collagen Crosslinking of the Residual Stromal Bed in LASIK: Finite Element Analysis of Impact on Refractive Outcome and Surgically Induced Deformation

Seven I, Roy ASR, Dupps BJ, Cleveland Clinic Cole Eye Institute. ARVO; 2014

SIMULATION: -4.25D LASIK procedure, wavefront optimized ablation profile with OZD 6.5mm. CXL of the central 9mm of the RSB with depth 200 micron and stiffening factor 1.5. Tangential curvatures of anterior surface points were calculated

	LASIK 15MM (microns)	LASIK + CXL 15MM (microns)	LASIK 30MM (microns)	LASIK + CXL 30 MM (microns)
1	194	183	393	371
2	206	195	419	396
3	205	194	416	394
4	270	254	547	516
	P<0.05		P<0.05	

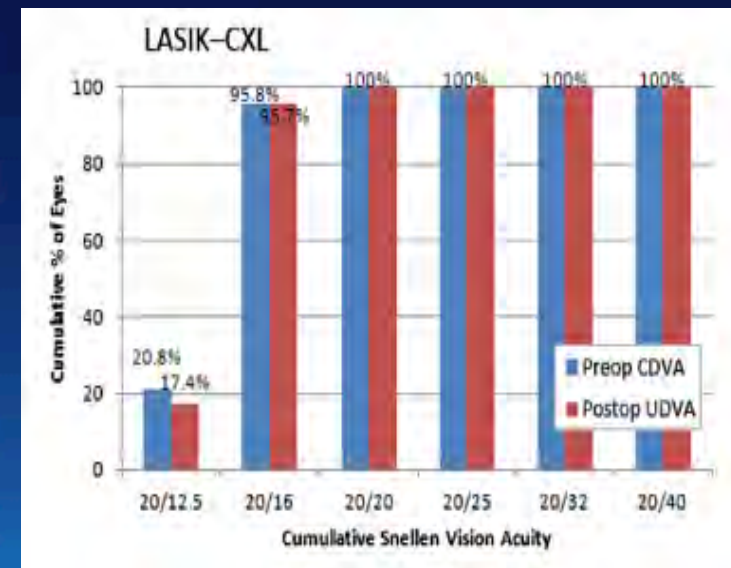
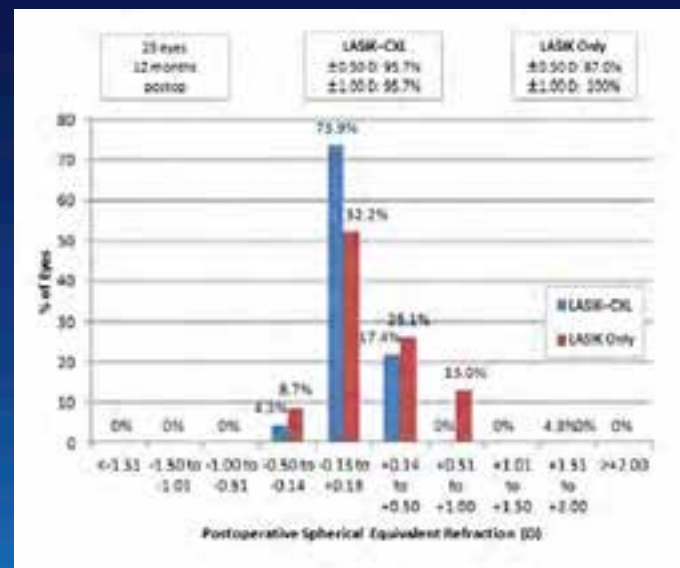
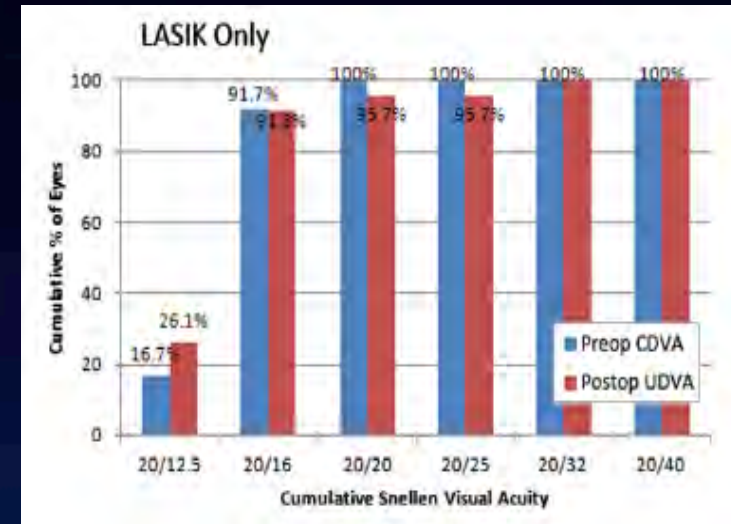
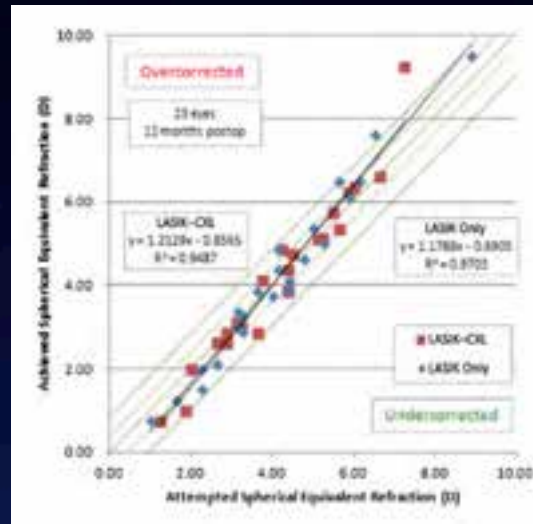
RESULT: LASIK with CXL of the RSB employing a 50% increase in anterior RSB stiffness contributed less than 0.25D of hyperopic effect to the postoperative refractive error and significantly reduced corneal displacements after LASIK.



Lasik Xtra: Predictability

In vivo confocal laser microscopy of morphologic changes after simultaneous LASIK and accelerated collagen crosslinking for myopia: One-year results

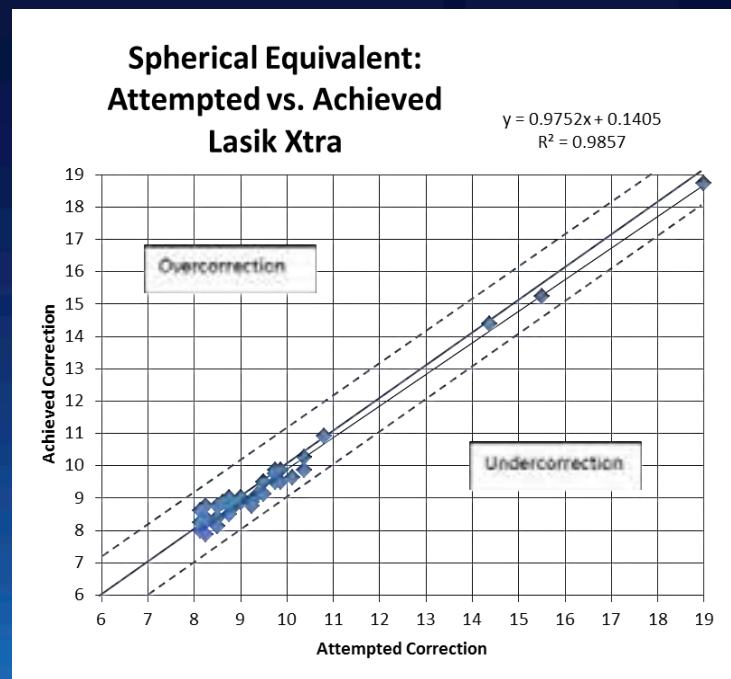
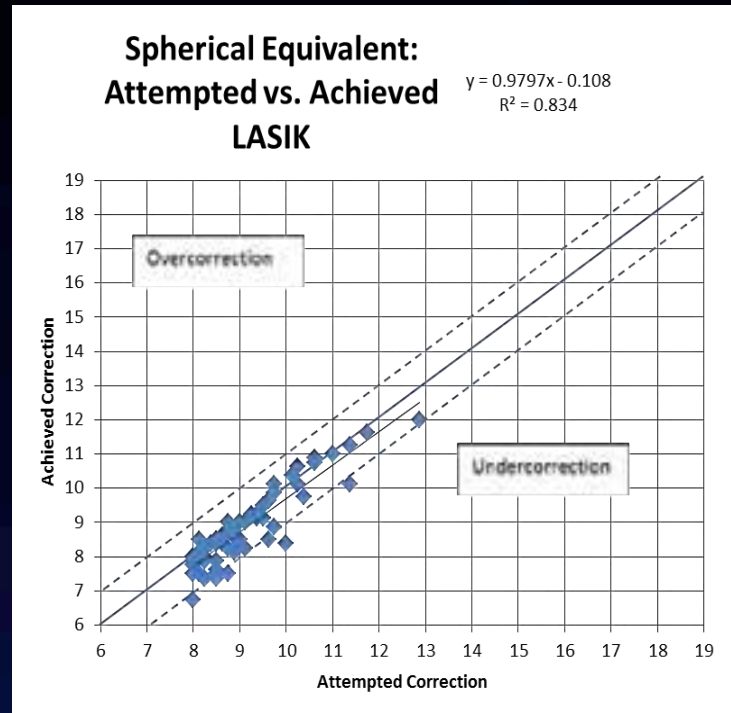
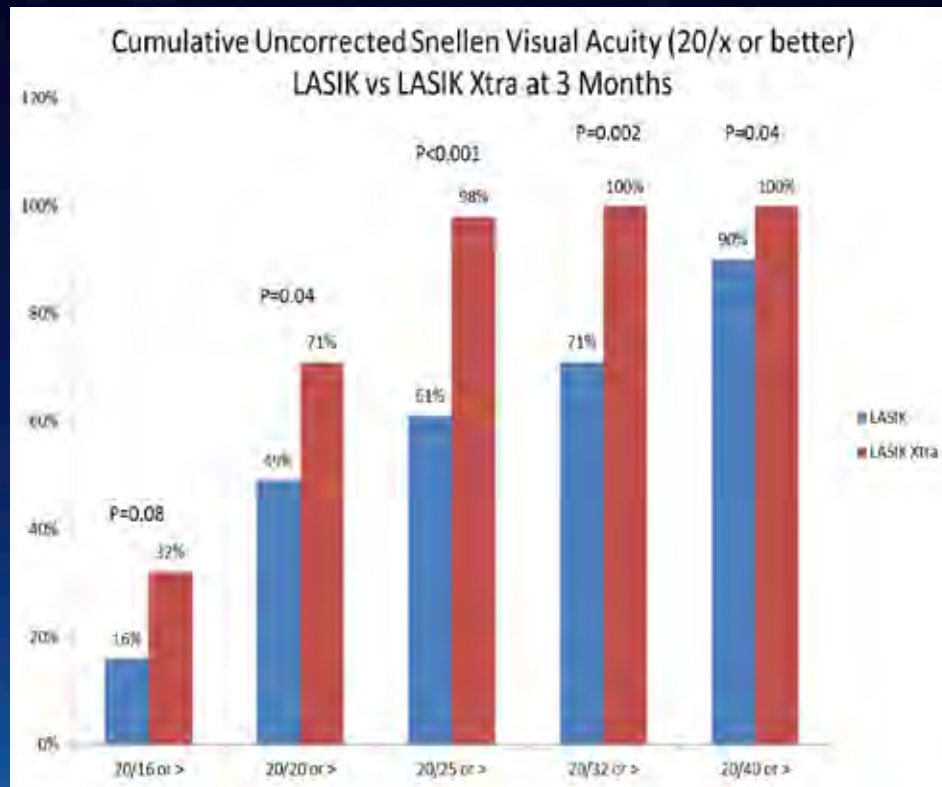
Minoru Tomita, Yuko Yoshida,
Yusuke Yamamoto, Mariko Mita,
George Waring IV,
JCRS Vol 40, JUNE 2014



Lasik Xtra: Predictability

Spherical Equivalent Refractive Accuracy LASIK vs. LASIK Xtra at 3 Months

Jerry Tan, MD Eur J of Ophthalmology 2015



Lasik Xtra: Predictability



Short-term Variance of Refractive Outcomes After Simultaneous LASIK and High-Fluence Cross-linking in High Myopic Correction

Tommy C. Y. Chan, FRCS; Marco C. Y. Yu, PhD; et. al. *J Refract Surg.* 2016;32(10): 664-670

While the previous studies of Lasik Xtra conducted with 30mW/cm² irradiance (KXL) show equivalent or better predictability than LASIK alone, this study conducted using 18mW/cm² irradiance (CXL-Vario) demonstrated better predictability in the LASIK-only group than in the Lasik + CXL group.

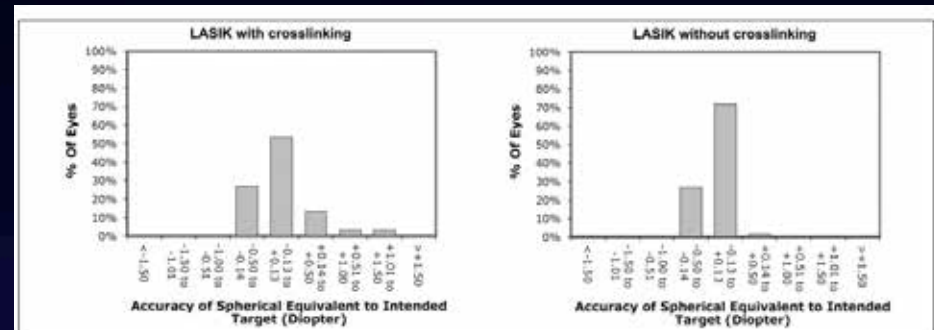


Figure 1. Change in preoperative and postoperative corrected distance visual acuity for LASIK with (left) and without (right) cross-linking by 6 months.

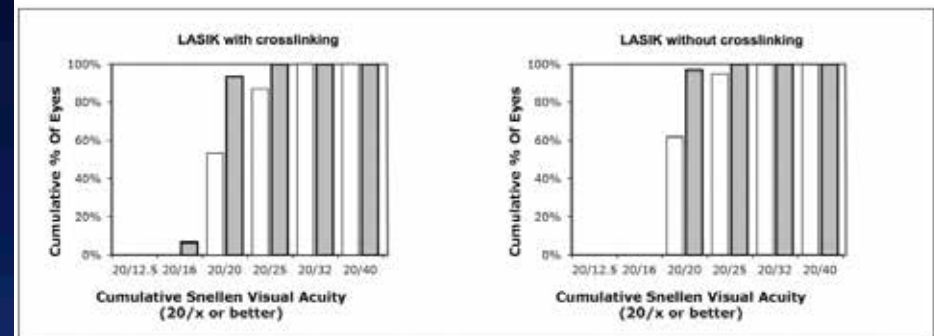
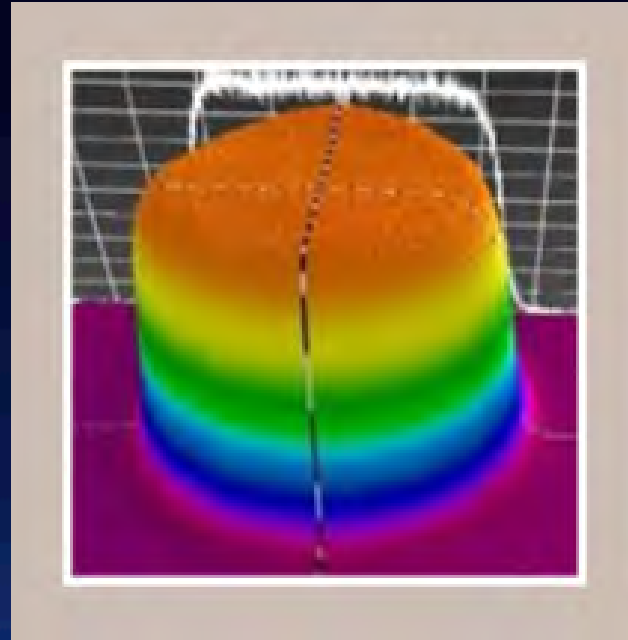
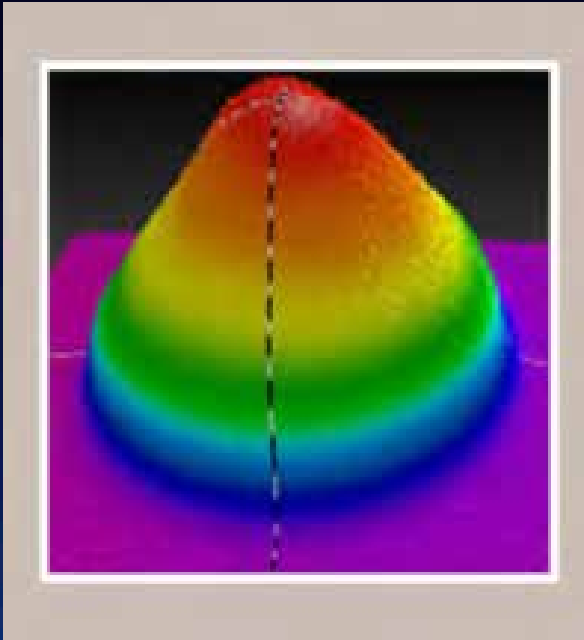


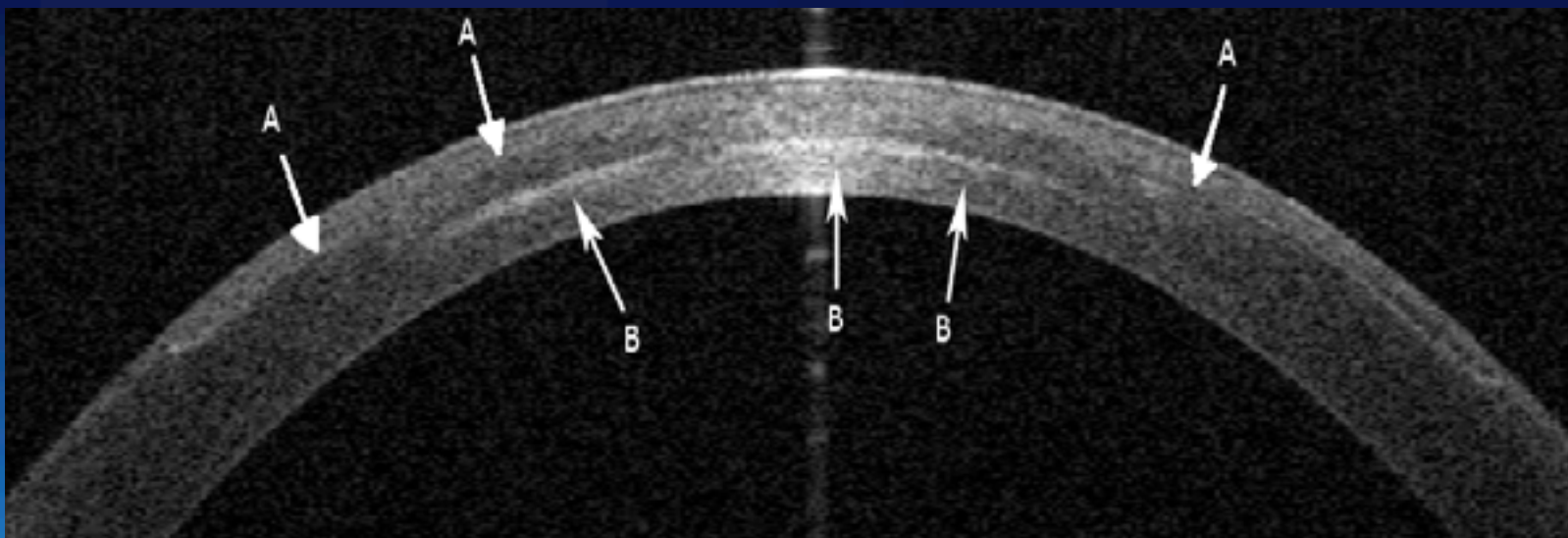
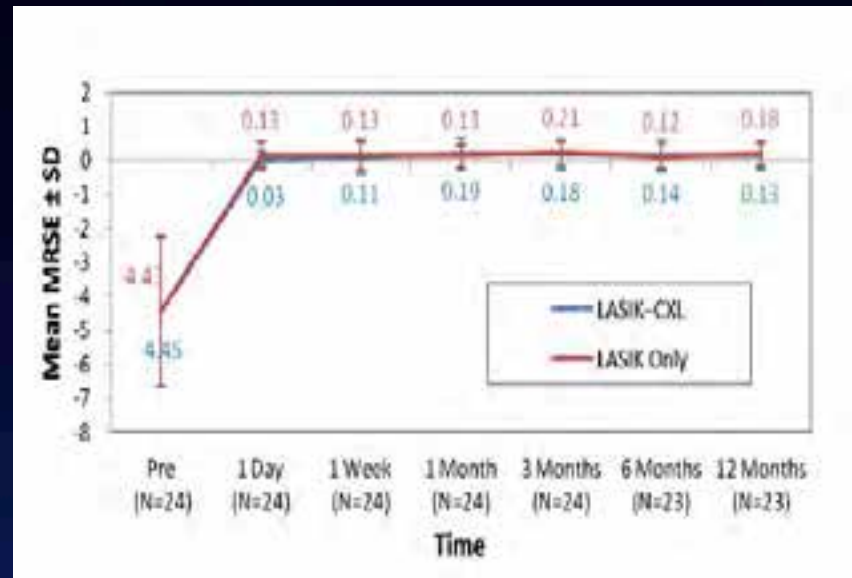
Figure 2. Cumulative percentage of eyes attaining specified cumulative levels of postoperative uncorrected distance visual acuity (UDVA) and preoperative corrected distance visual acuity (CDVA) for LASIK with (left) and without (right) cross-linking by 6 months. gray = preoperative UDVA; white = postoperative CDVA



Lasik Xtra: Stability

In vivo confocal laser microscopy of morphologic changes after simultaneous LASIK and accelerated collagen crosslinking for myopia: One-year results

Minoru Tomita, MD, PhD, Yuko Yoshida, BA, Yusuke Yamamoto, MD, Mariko Mita, MD, PhD, George Waring IV, MD. J CATARACT REFRACT SURG - VOL 40, JUNE 2014

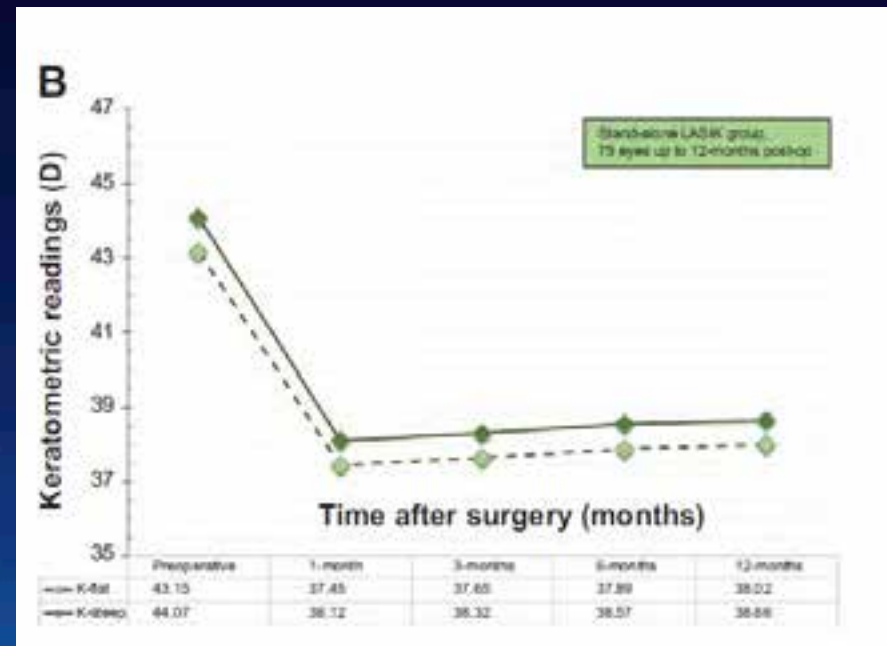
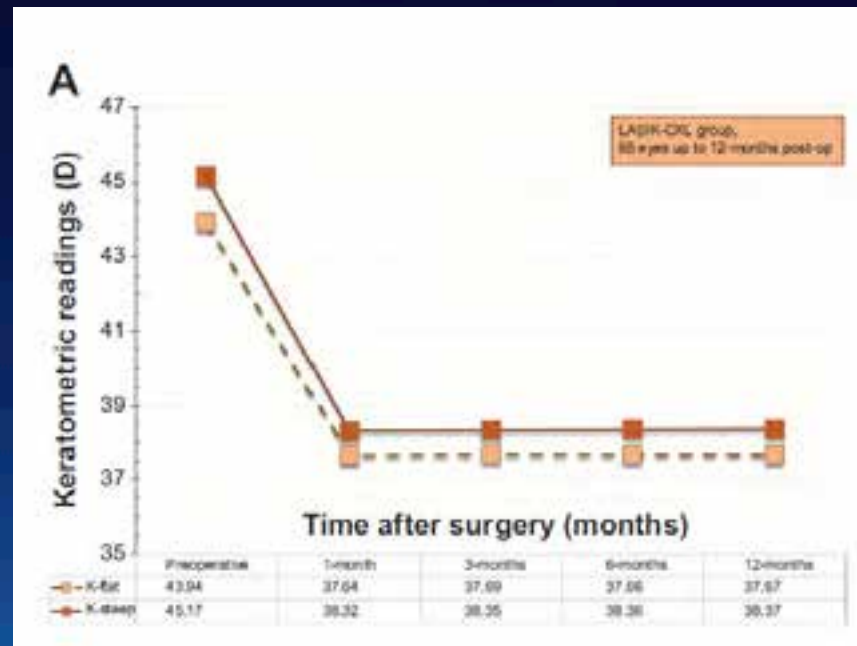


Lasik Xtra: Stability

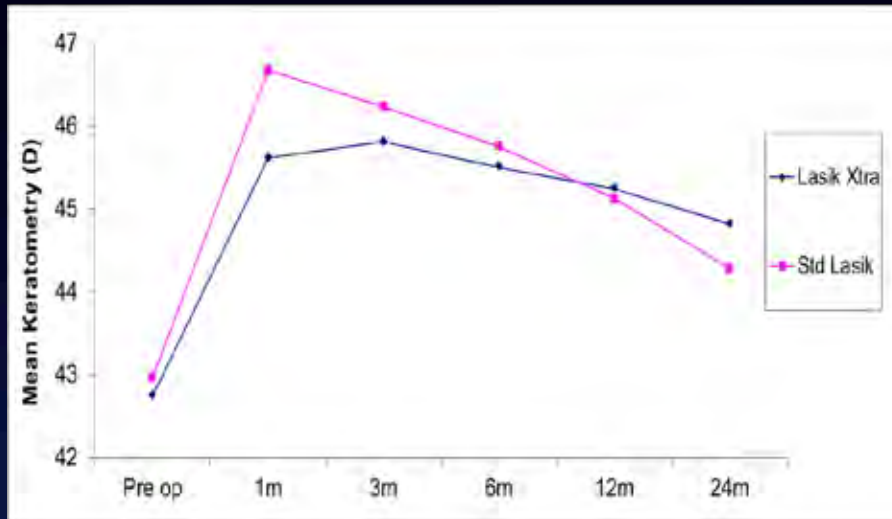
Comparison of prophylactic higher fluence corneal cross-linking to control, in myopic LASIK, one year results.

Kanellopoulos AJ, Asimellis G, Karabatsas C. Clin Ophthalmol. 2014 Nov 27;8:2373-81

Stability of corneal keratometry for (A) the LASIK-CXL group and (B) the stand-alone LASIK group, expressed in diopters (D), up to 1-year postoperatively.

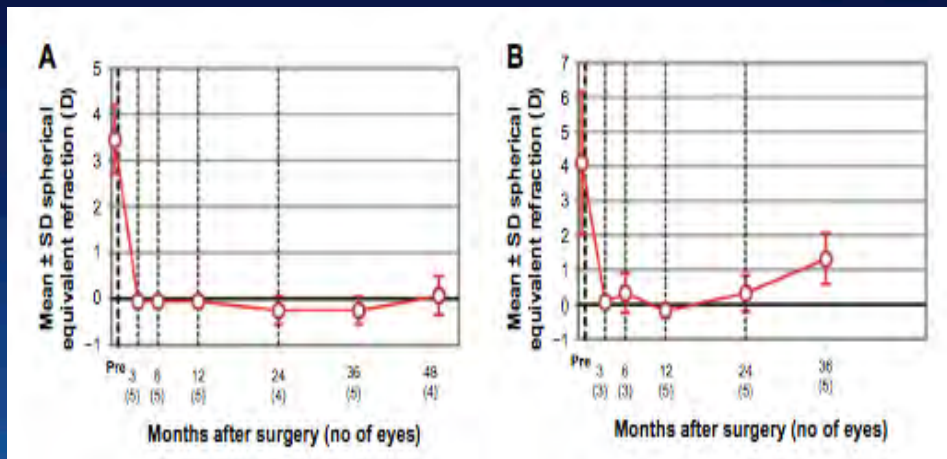


Lasik Xtra: Stability



Topography-guided Hyperopic LASIK With and Without High Irradiance Collagen Cross-linking: Initial Comparative Clinical Findings in a Contralateral Eye Study of 34 Consecutive Patients.

Kanellopoulos AJ, Asimellis G. *Journal of Refractive Surgery* 2012



Adjuvant corneal crosslinking to prevent hyperopic LASIK regression.

Aslanides IM, Mukherjee AN. *Clin. Ophthalmol.* 2013

Figure 3 Stability of refractive correction in (A) hyperopic LASIK with simultaneous corneal crosslinking (LASIK-CXL); and (B) a matched control group. **Abbreviations:** LASIK, laser assisted in situ keratomileusis; CXL, crosslinking; SD, standard deviation; D, diopter.

Confocal Microscopy

- Hyper-reflectivity and keratocyte apoptosis to a stromal depth of 150-160µm
- Keratocyte repopulation complete by 6 months postoperatively
- No endothelial damage was observed
- Findings suggest microstructural changes similar to those found with conventional cross-linking

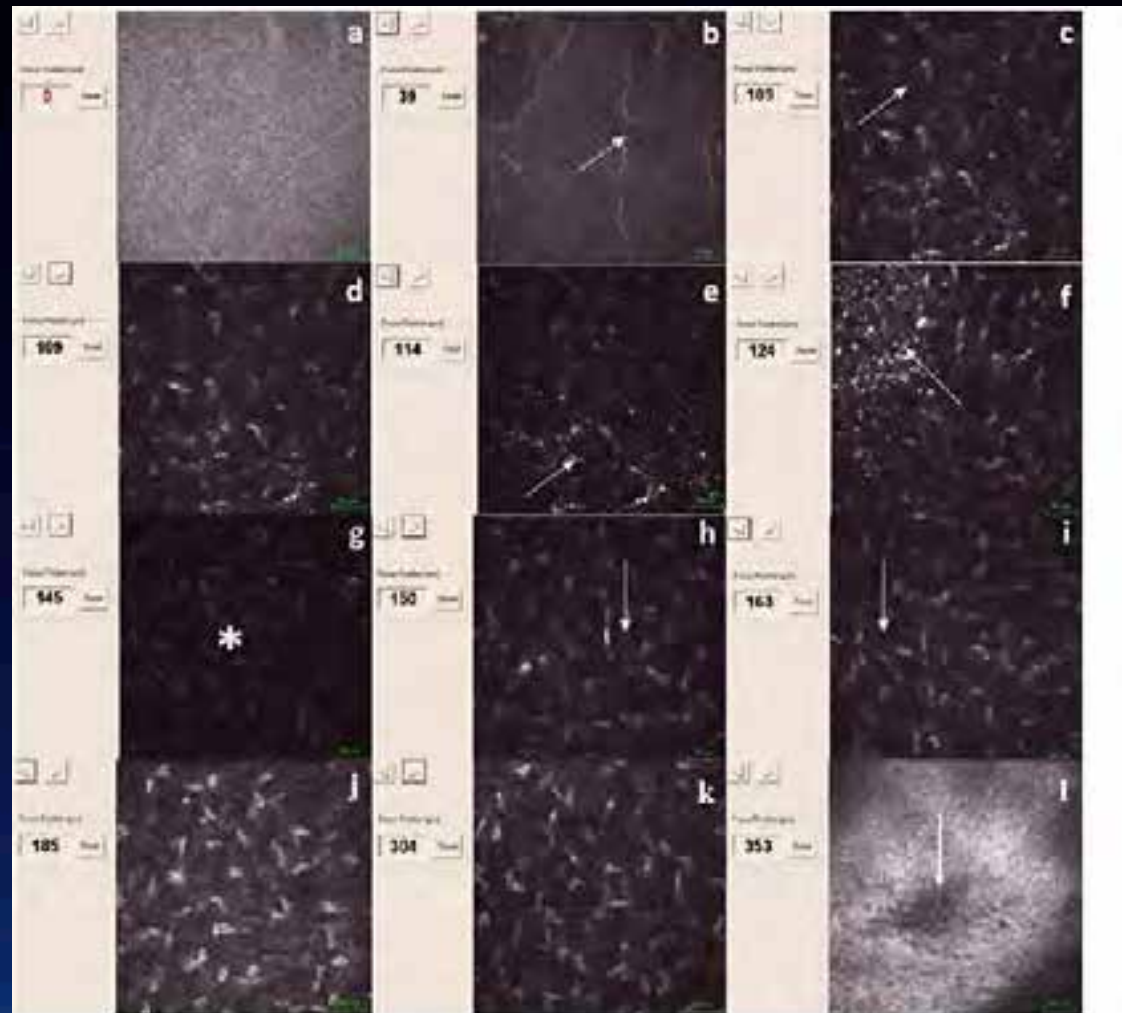


Fig. 2. Confocal microscopy overview in the first week after Lasik Xtra. a Undamaged basal epithelium. b Subepithelial plexus fibers did not disappear after treatment (arrow). c, d Slight keratocyte apoptosis associated with edema into the corneal flap before Lasik interface (arrow). e, f Lasik interface with bright hyperreflective particles (arrows). g Keratocyte apoptosis and increased edema beyond the interface until 150 µm showing the area of maximum photooxidative impact. Le. maximum riboflavin UV-A-collagen interaction (asterisk). h, i Vertical transition area delimiting the end of photooxidative damage and apoptosis at 160 µm. Le. riboflavin UV-A interaction (white arrows). j Intermediate stroma unreached by photooxidative damage. Le. riboflavin UV-A interaction. k Deep stroma unreached by photooxidative damage. Le. riboflavin UV-A interaction. l Corneal endothelium showing a circular area of pseudo-guttae (arrow).

Mazzotta C, Balestrazzia A, Traversia C, Caragiulia S, Caporossib A Case Rep Ophthalmol 2014;5:125–

Lasik Xtra: Review Articles

REVIEW



Combined laser in-situ keratomileusis and accelerated corneal cross-linking: an update

Misere Kevita

Purpose of review

The purpose is to review the literature of combined laser in-situ keratomileusis (LASIK) and accelerated corneal collagen crosslinking (CXL) in terms of its indications/contraindications, biomechanical, visual and safety outcomes, particularly with reference to preventing the development of post-LASIK ectasia.

Recent findings

LASIK + accelerated CXL has been developed with the rationale that the addition of CXL after LASIK may strengthen the LASIK flap/corneal lamellae and minimize the complications such as post-LASIK ectasia. Different clinical studies have also assessed the safety and efficacy of LASIK + accelerated CXL for the correction of myopia or hyperopia and in the patients with low residual myopia and astigmatism.

Summary

Available literature shows that refractive and keratometric outcomes of LASIK + accelerated CXL are comparable or better than LASIK alone. Less regression has been observed after LASIK + accelerated CXL compared with LASIK alone and no case of post-LASIK ectasia development has been reported among 872 eyes with the follow-up ranging from 2 months to 4.2 years. Future studies with large numbers of patients and longer postoperative follow-ups are needed to establish the efficacy of LASIK + accelerated CXL in preventing the development of post-LASIK ectasia.

Keywords

accelerated collagen crosslinking, corneal collagen crosslinking, ectasia, laser in-situ keratomileusis + accelerated collagen crosslinking, laser in-situ keratomileusis flap, regression

Laser in-situ keratomileusis (LASIK) is the most commonly performed procedure for the correction of refractive errors as it offers rapid visual rehabilitation, minimal postoperative discomfort, and low incidence of haze [1–3]. However, LASIK requires the creation of a flap and ablation of tissue which inevitably weakens the corneal integrity [4] and is believed to be the fundamental cause in the development of ectatic corneal disorder [2,4,5]. Recently, the use of corneal collagen cross-linking (CXL) in association with LASIK has been studied for improving the biomechanical integrity of post-LASIK cornea and preventing the risk of post-LASIK ectasia development [1,4,6–7,9]. In the current study, we aimed at reviewing all the published literature of combined LASIK and accelerated CXL procedure to elucidate its principles, indications/contraindications, and clinical outcomes.

We searched PubMed, Google Scholar, and Google search engine on 18 December 2015 for relevant

www.evidencebasedophth.com

Volume 27 • Number 4 • July 2014

Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.

Updated from
DOI: 10.1097/ICU.0000000000000000



REVIEW

Lasik Xtra® Provides Corneal Stability and Improved Outcomes

Rajesh K. Rajpal - Christine B. Winczorek - Dawn Williams

Sachin D. Rajpal - Rhonda Enos - Miki Mammis - Grace Lytle

Khoa Hoang

To view enhanced content go to www.evidencebasedophth.com

Received July 20, 2014

© The Author(s) 2015. This article is published with open access at Springerlink.com

ABSTRACT

A new procedure which combines LASIK and corneal crosslinking (Lasik Xtra®) has been proposed as an alternative to traditional LASIK. It is aimed at providing strength to the cornea, increasing stability in visual outcomes, increasing the accuracy of the refractive correction, and potentially lowering enhancement rates. This article reviews the current clinical evidence which has been published on the topic and reviews both the safety and efficacy arguments for the procedure.

Keywords: Laser in-situ keratomileusis; LASIK; Ektivivis; UVB mediated corneal cross-linking

R. K. Rajpal (✉), C. B. Winczorek, D. Williams,
S. D. Rajpal, K. Hoang
See Clearly Vision Group, 8118 Watson Street,
Milton, MA, USA
e-mail: rajpal@seeclarity.com

R. Kevita - S. Mammis
I.L.C. Laser Eye Center, Toronto, ON, Canada




G. Lytle
Imvivo, Inc., Waltham, MA, USA

Published online: 26 October 2015

5/146

LASIK + CORNEAL CROSS-LINKING: LASIK XTRA

KEY POINTS

- What do we know:
 - LASIK weakens the cornea
 - Cross-linking stiffens the cornea
- What Do We Need to Know?
 - Can we safely add cross-linking to LASIK? 
 - Can we achieve predictable refractive outcomes with Lasik Xtra? 
 - Can Lasik Xtra improve corneal stability? 

THANK YOU

