

Why I still do Lasik-Xtra

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Femto Lasik Xtra

1. Theoretically: less CXL may be required to return a healthy cornea to its **native strength** subsequent to Lasik.
2. Restore corneal strength **without creating an additional change in refraction.**

ECTASIA

?Sweet Spot?

FLATTENING

Femto Lasik Xtra

- The procedure:
 1. The creation of the LASIK flap and the excimer ablation are performed.
 2. At the completion of the excimer ablation, eyes receive **1–5 drops of Dextran-free riboflavin formulation**, carefully applied to the stromal bed. The riboflavin solution is allowed to **soak for a period of up to 90 sec.**
 3. Riboflavin is rinsed from the stroma, flap is repositioned into place.
 4. A **375 nm UV source** with a homogenous **30mW/cm² top hat beam profile for 90sec.** is then used to apply a **2.7 J/cm²** dose of irradiation through the closed flap.



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Tissue morphology after Lasik Xtra

- **Mazzotta et al.** observed morphological changes including **hyper-reflectivity** and **keratocyte apoptosis**, which are consistent with conventional corneal cross-linking. The stromal depth of these features was **150–160 μm, shallower** than conventional CXL. **Keratocyte repopulation** occurred by 6 months PO & **no endothelial damage** was observed.

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In vivo Confocal Microscopy Report after Lasik with Sequential Accelerated Corneal Collagen Cross-Linking Treatment

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Key Words
LASIK, hyper-reflectivity, accelerated corneal collagen cross-linking, Confocal microscopy

Abstract
We report the first quantitative confocal microscopy analysis of a laser in situ keratomileusis (LASIK) treatment combined with sequential high-fluence accelerated corneal collagen cross-linking (accelerated LASIK Xtra) by means of 485 nm laser scanning in vivo confocal microscopy after a 6-month follow-up. After obtaining approval from the Santa Margherita Hospital Institutional Review Board, a 55-year-old female patient underwent a LASIK Xtra procedure in her left eye. Confocal analysis demonstrated reduced light scatter microstructural changes by the interaction between 485 nm, riboflavin and corneal stromal collagen, beyond the interface to a depth of 140 μm, without adverse events at the interface and endothelial levels. This application may be considered a prophylactic keratoconus treatment, offering the intermediate corneal density to prevent corneal edema and reducing the clinical results of refractive surgery. According to our preliminary experience, this combined approach may be useful in higher risk LASIK patients for hyperopic treatments, high myopia and laser-assisted cataract.

Lasik Xtra Treatment Safety

Clinical Ophthalmology
ORIGINAL RESEARCH

Long-term safety and efficacy follow-up of prophylactic higher fluence collagen cross-linking in high myopic laser-assisted in situ keratomileusis

Authors: Jee Kanneppala, Christopher James Hahn, David and Lee Park, Steven Park, Steven Park, MD, FRCS

Background: The purpose of this study was to evaluate the safety and efficacy of enhanced collagen cross-linking in conjunction with laser-assisted in situ keratomileusis (LASIK).

Methods: Forty-five consecutive LASIK eyes treated with prophylactic laser-assisted collagen cross-linking (LASX) were included in this study. All eyes were followed up for a minimum of 12 months.

Results: Mean uncorrected visual acuity (UCVA) at 12 months was 20/40 Snellen. The mean refractive error at 12 months was -2.50 diopters (D). There were no significant differences in UCVA or refractive error between the LASX and non-LASX groups.

Conclusion: Prophylactic collagen cross-linking in high myopia appears to be safe and effective in conjunction with LASIK. The application may be used as a prophylactic measure to reduce the risk of ectasia in high myopia.

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RESEARCH ARTICLE

Simultaneous Accelerated Corneal Crosslinking and Laser In situ Keratomileusis for the Treatment of High Myopia in Asian Eyes

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Background: LASIK has a relatively low incidence of ectasia when combined with accelerated corneal cross-linking (CXL) in the same setting. We hypothesized that the combination of LASIK and CXL would reduce the risk of ectasia in high myopia.

Methods: To compare the efficacy, predictability and safety of LASIK with and without CXL in patients with high myopia.

Results: This is a retrospective study comparing 17 consecutive eyes undergoing LASIK with the combination of high myopia and LASIK with accelerated CXL (LASIK-CXL) and accelerated corneal cross-linking (CXL) in the same setting. The mean uncorrected visual acuity (UCVA) at 12 months was 20/40 Snellen. The mean refractive error at 12 months was -2.50 D. There were no significant differences in UCVA or refractive error between the LASIK-CXL and CXL groups.

Conclusion: LASIK with accelerated CXL appears to be safe and effective in conjunction with LASIK. The application may be used as a prophylactic measure to reduce the risk of ectasia in high myopia.

Keywords: prophylactic collagen cross-linking, laser-assisted in situ keratomileusis, high myopia, LASIK, ectasia

Lasik Xtra Treatment Safety

Accelerated corneal crosslinking concurrent with laser in situ keratomileusis

H. Unger, PhD, MD, Steven Hahn, MD, Victor Vitvitsky, MD, Albert Agiza, MD, John Marshall, MD, PhD, FRCS(Ed), FRCS(Plas), Albert Chen, MD, Chien-Chia, MD, Steven Park, MD

PURPOSE: To assess accelerated corneal collagen crosslinking (CXL) applied concurrently with laser in situ keratomileusis (LASIK) in a small group of patients.

SETTING: Whang Sun Eye Research and Training Institute, Taiwan.

DESIGN: Prospective pilot intervention case series.

METHODS: In May 2010, patients had LASIK with concurrent accelerated CXL. At 1 year and LASIK only in the fellow eye in their contralateral eye. The follow-up time 12 months. The accelerated corneal crosslinking procedure ranged from -0.50 to -3.00 diopters (D) in the LASIK-CXL group and from -0.50 to -1.25 D in the LASIK-only group. Mean values represent mean spherical equivalent (SE) and spherical (SE) and spherical (SE) and spherical (SE) and spherical (SE).

RESULTS: Eight eyes (42.1%) had 1 or more eyes (27.6%) with some residual. At the 12-month follow-up, the LASIK-CXL group had a LASIK and refractive error equal to or better than those in the LASIK-only group. The eyes had 1 or more eyes (27.6%) at the 12-month follow-up. The refractive error was in the LASIK-CXL group was not greater than in the fellow eye. No side effects were associated with either procedure.

CONCLUSIONS: Laser in situ keratomileusis with accelerated CXL appears to be a promising modality for laser-assisted LASIK. It is a promising modality to reduce the risk of ectasia in high myopia. The study in this pilot series suggests that combination of a single study (LASIK) is important.

Financial Disclosure: Drs. Unger and Marshall are paid consultants to Amnion, Inc. No other author has a financial or proprietary interest in any material mentioned.

J. Cataract Refract Surg 2012; 38:1430-1437. © 2012 ASCRS and ESCRS

Laser in situ keratomileusis (LASIK) is the most commonly performed refractive surgical procedure for the correction of myopia. It consists of microkeratome

and results in faster visual recovery than surface ablation.¹

However, it is a serious complication that can arise after LASIK. Patients with this complication present with increasing myopia and astigmatism, loss of corrected distance visual acuity (DVA), and reduced line-of-corrected distance visual acuity (DLVA) due to progressive corneal steepening that occurs centrally or peripherally.² Actual changes can occur as early as 1 week after LASIK or can be delayed up to several years after the initial procedure.³ In many cases, progressive keratectomy is eventually performed to manage this complication. The incidence of keratectomy after LASIK has been estimated to range from 0.03% to 0.04%,⁴ however, accurate clinical studies of the incidence are not available.⁵ Although several clinical risk factors have been reported, the mechanism of post-LASIK keratectomy remains unclear.⁶

- Lasik Xtra treatment has been shown to significantly improve post-LASIK refractive stability, when compared to LASIK alone particularly in those with high diopter corrections who are at greater risk of refractive drift.

- while the number of treatments and follow-up is not sufficient to draw definitive conclusions regarding the ability of Lasik Xtra to reduce the risk of corneal ectasia, the treatment profile may support prophylactic use.

Lasik-Xtra in Hyperopia

- Recently it has been shown that progressive flattening of the central cornea has been observed by serial topography done over 6 months postoperatively .
- So if the cause of regression is , or is assisted by , postoperative change in corneal shape, then locking the ablation with CXL can be of help.

Journal Refract.
Surg. 2012

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

Anastasios John Kanellopoulos, MD; Jonathan Kahn, MD

ABSTRACT

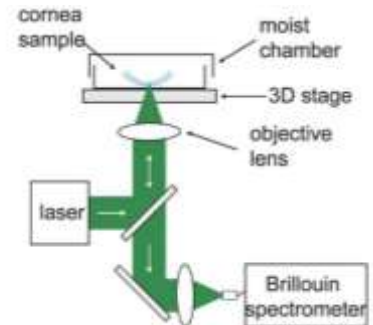
PURPOSE: To evaluate the safety and efficacy of intra-

T

he evolution of laser vision correction technology has made the treatment of myopia, hyperopia, and astigmatism more accurate. Numerous studies of hyper-

USC ROSKI Study

- **1st study** to use Brillouin microscopy to evaluate the biomechanical effect of accelerated CXL after Flap creation.
- Brillouin microscope was previously applied in investigating eyes with KC and different CXL protocols.
- **Ultra high resolution** to yield a lateral resolution approximately 1 μm and axial resolution approximately 8 μm with much larger separation between normal and ectatic corneas than (**ORA**).

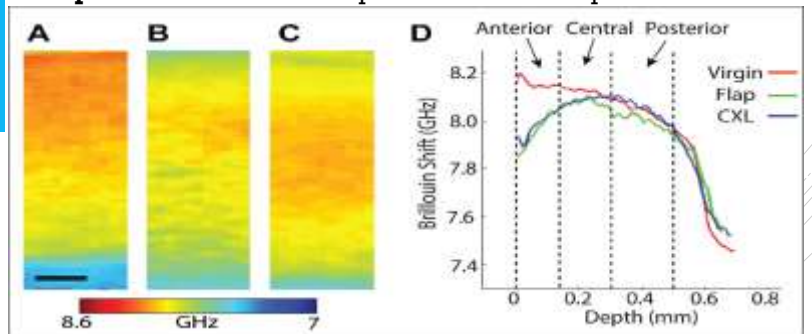


USC ROSKI Study

- 11 porcine eyes, Evaluated by Brillouin microscopy:
 1. Virgin state.
 2. After Lasik flap creation.
 3. After Accelerated CXL (served as its own control).
- The Brillouin microscopy measures **biomechanical properties of each layer** the light passes through without touching or otherwise disturbing it. The powerful microscopes measure natural light scattering that occurs when the cornea moves every millisecond due to constant, subtle changes in temperature.

USC ROSKI Study

- **Conclusion:**
- ❖ **LASIK flap** creation significantly **reduced** Brillouin shift in the **anterior third** of the stroma in porcine eyes.
- ❖ **Rapid CXL** had **no significant effect** on Brillouin shift after LASIK flap creation.
- ❖ With further validation, non-contact Brillouin microscopy could become a **useful monitoring tool** to evaluate the biomechanical **impact** of corneal refractive procedures and CXL protocols.



USC ROSKI study

PubMed

Format: Abstract =

J Refract Surg. 2017 Jun 1;33(6):488-494. doi: 10.3090/1080-0879.20170421-01.

Biomechanical Changes After LASIK Flap Creation Combined With Rapid Cross-Linking Measured With Brillouin Microscopy.

Sedgeman JB, Su EJ, Scahill G.

Abstract

PURPOSE: To evaluate the biomechanical changes occurring after LASIK flap creation and rapid corneal cross-linking (CXL) measured with Brillouin light microscopy.

METHODS: Porcine eyes ($n = 11$) were evaluated by Brillouin light microscopy sequentially in the following order: virgin state, after LASIK flap creation, and after rapid CXL. Each eye served as its own control. Depth profile of the Brillouin frequency shift was computed to reveal the depth-dependent changes in corneal stiffness.

RESULTS: There was a statistically significant reduction of Brillouin shift (reduced corneal stiffness) after LASIK flap creation compared to virgin corneas across total corneal thickness (-0.035 GHz, $P = .0195$) and within the anterior stromal region (-0.104 GHz, $P = .0098$). Changes in the central ($+0.029$ GHz, $P = .0391$) and posterior ($+0.025$ GHz, $P = .90$) stromal regions were not significant. There was a small increase in Brillouin shift after rapid cross-linking that was not statistically or clinically significant across total corneal thickness (0.006 GHz, $P = .4858$ for any specific stromal region; 0.002 to 0.009 GHz, $P > .48$ for all).

CONCLUSIONS: LASIK flap creation significantly reduced Brillouin shift in the anterior third of the stroma in porcine eyes. Rapid corneal cross-linking had no significant effect on Brillouin shift after LASIK flap creation in porcine eyes. With further validation, non-contact, non-perturbative Brillouin microscopy could become a useful monitoring tool to evaluate the biomechanical impact of corneal refractive procedures and corneal cross-linking protocols. (*J Refract Surg.* 2017;33(6):488-494).

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CAIRO UNIVERSITY STUDY

Patients and methods

- Randomized trial including **40 eyes** of 20 patients who fulfilled the inclusion criteria were included in our study, the **mean age** was $24\pm(6)$ years in the femto Lasik group and $21\pm(3)$ years in the femto Lasik Xtra group.
- Mean spherical equivalent pre-operatively was $-5.33D$ in the **myopia eyes (24)** and $+3.25D$ for the **hyperopia eyes (16)**.
- Each Group had 12 myopic eyes and 8 hyperopic eyes.

Patients and methods

▪ **Femto LASIK XTRA procedure:**

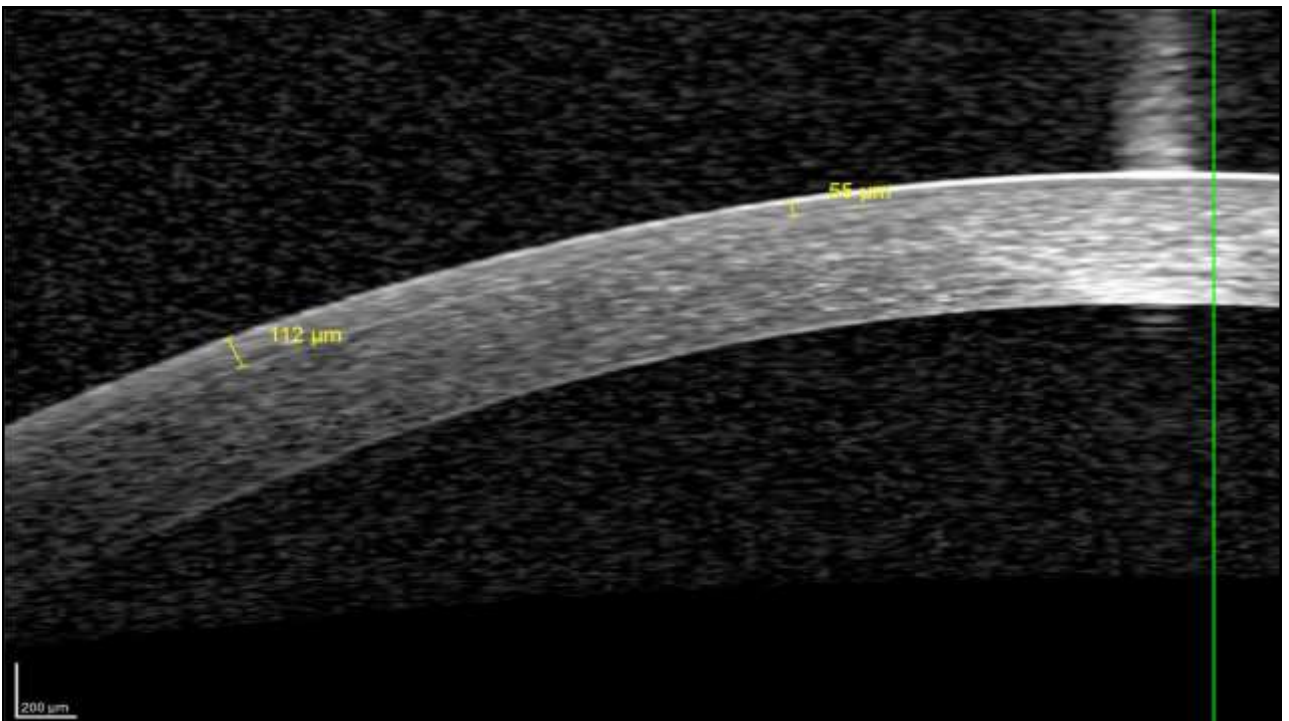
- **0.1% dextran free riboflavin** is applied on the stromal bed and soaks the flap subsequent to laser ablation with a soak time of **90 sec.**
- The interface is washed thoroughly and the flap is repositioned. UV-A irradiance is delivered as a homogenous beam of **30 mW/cm² for 90 s to deliver a total fluence of 2.7J/cm².**

AS-OCT FINDINGS

1 week PO

▪ ***Non-crosslinked corneas:***

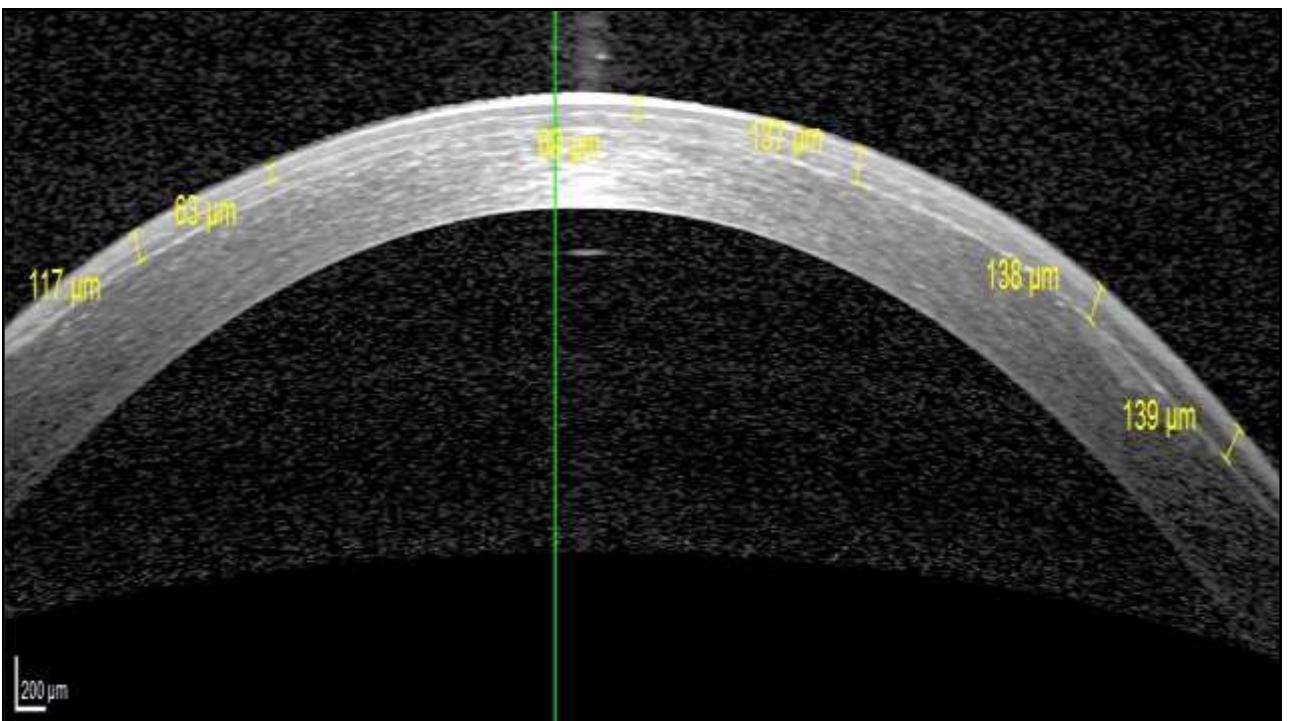
- ❖ corneas show a uniform flap thickness of about ($123\mu\text{m} \pm 30\mu\text{m}$), flap edge is hyper reflective with no demarcation line in corneal stroma.

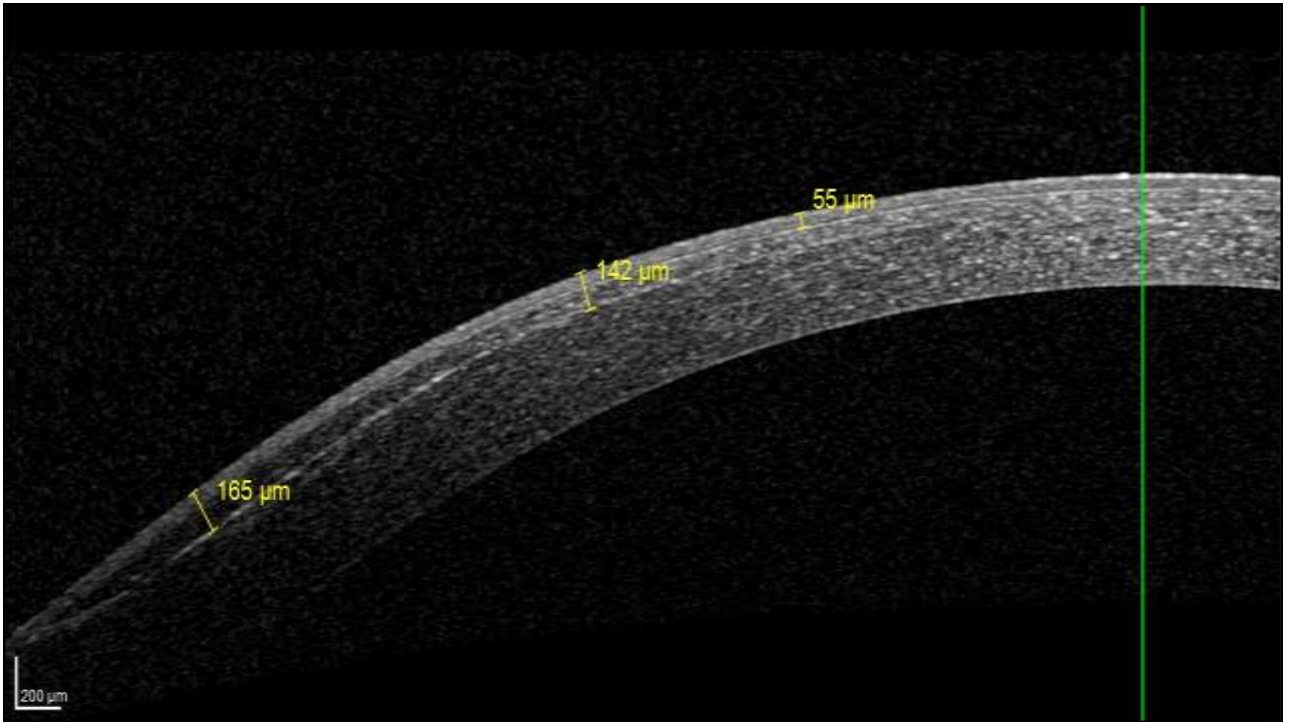


1 week PO

▪ ***Crosslinked corneas:***

- ❖ corneas show a hyper reflective line , starts at the hinge of the flap , it deepens in the anterior stroma approximately between the depth of $130\mu - 174 \mu\text{m}$.
- ❖ This line appears to be in different depth levels along the stroma and disappears at the central cornea.
- ❖ The edge of the flap appears to be more hyper reflective than the non-crosslinked corneas, especially at the hinge of the flap.
- ❖ Hyper reflectivity is noted in the anterior cross linked stroma and flap, finding that were absent in the non crosslinked flaps.

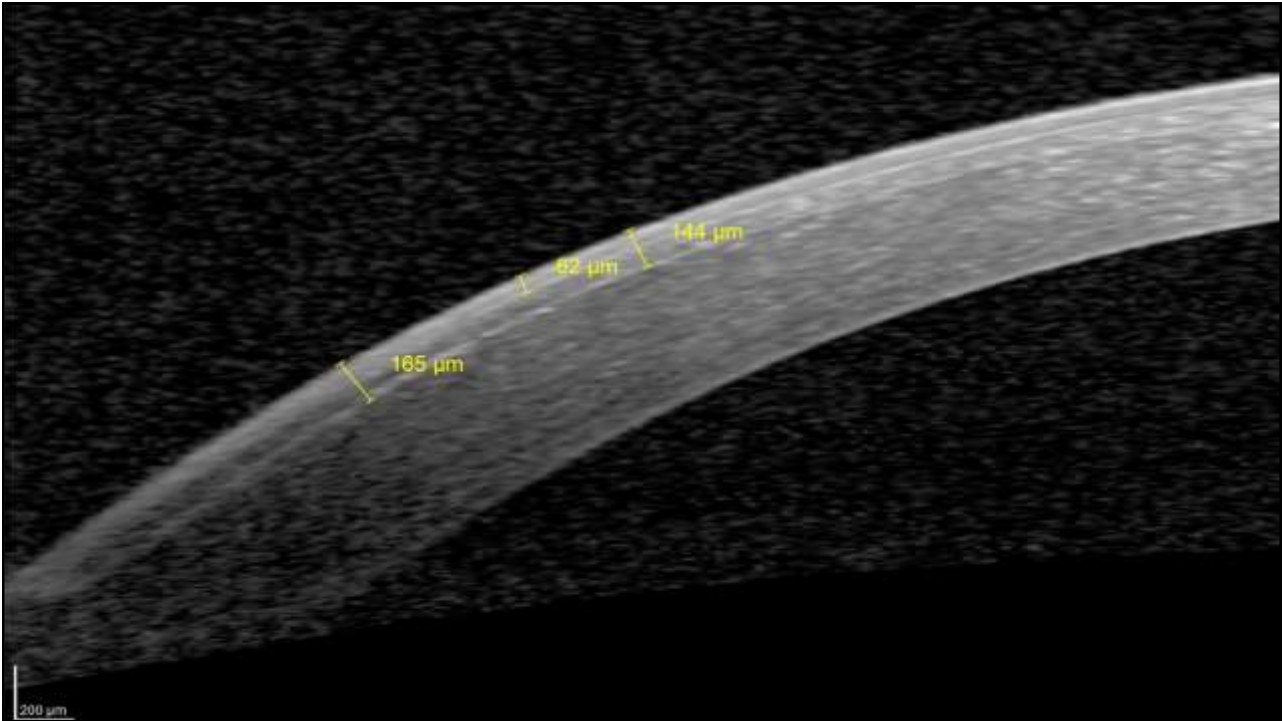
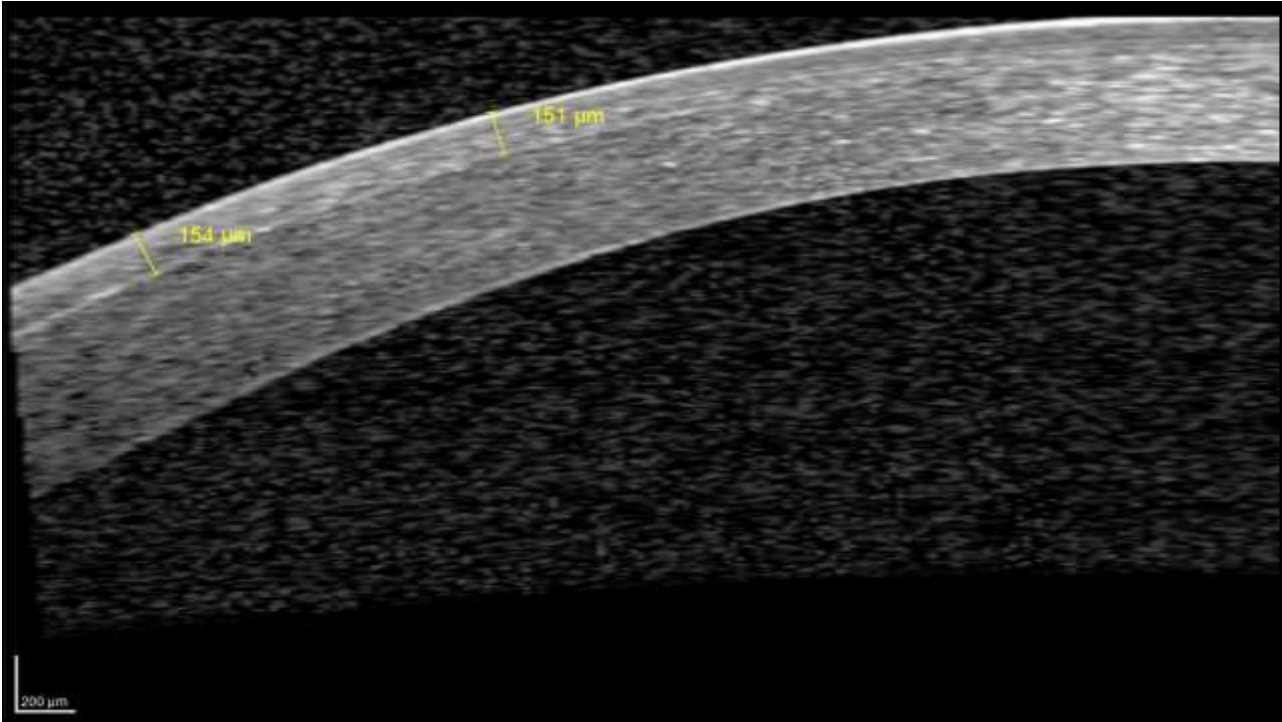




3 months PO

▪ **Cross-linked corneas:**

- ❖ A demarcation line remains, more evident in the peripheral cornea.
- ❖ Hyper reflectivity anterior to the demarcation line.
- ❖ Decreased flap thickness is noted with average thickness of $80 \pm 10 \mu\text{m}$.
- ❖ Flap hinge is more evident than Femto Lasik treated corneas.



Conclusion

- Our study concluded that there is a significant difference between Corneal AS-OCT findings in the Femto Lasik Xtra group when compared to the Femto Lasik group.
- The demarcation line pattern and the crosslinked stroma found in the Femto Lasik Xtra treated corneas changed over the period of 1 week, 1 month and 3 months post-operative respectively.
- These changes may have a role in our opinion in altering the corneal strength, biomechanics and incidence of post Lasik regression.

Conclusion

- We have been abiding by the lasik guidelines over the years but some of our patients developed ectasia.
- We are still abiding by the guidelines which became more limiting.
- How can we be sure that the guidelines will not become even MORE limiting in the future.

Conclusion

- In order to avoid the occasional slipping of one of our patients into ectasia, we have developed a clear set of indications for employing lasik-Xtra.
- The procedure is easy , rapid , safe , reassuring and can be implemented in a busy practice without impeding patients turnover.

THANK YOU