

Refractive Corneal Correction with Topography-Assisted Customized and Variable Fluence CXL Photorefractive Collagen Crosslinking (PiXL)



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PURPOSE

To report safety and efficacy of a novel, customizable application of high-fluence collagen crosslinking (CXL) through the intact epithelium (transepithelial) with a novel device, aiming in refractive myopic, astigmatic, and hyperopic changes in virgin corneas.

METHODS

20 cases were treated with a novel device employing very high-fluence CXL, applied in a customized pattern aiming to achieve myopic (10 cases), hyperopic (5 cases), and astigmatic (5 cases) predictable refractive changes.

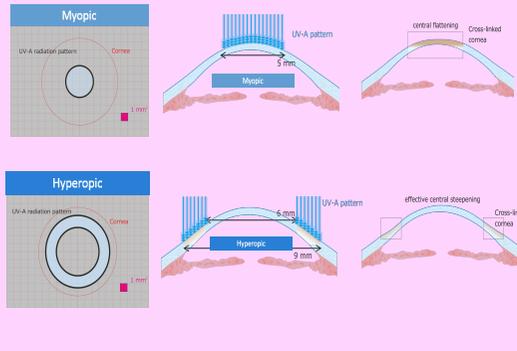
Riboflavin penetration through the intact epithelium was applied with specially formulated solutions in a two-step process.

The CXL device (KXL II, Avedro, Waltham MA) was employed to deliver a total of 12 J/cm², in pre-determined pattern, in a procedure termed Photorefractive Intrastromal Cross-linking (PiXL)

One year postoperatively we evaluated

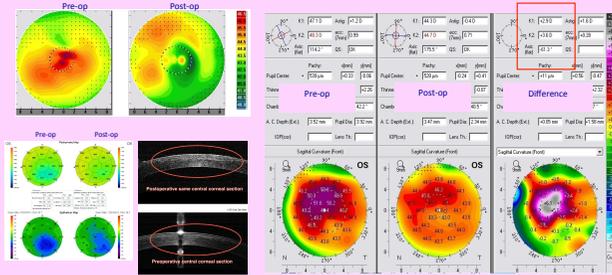
- cornea clarity,
- cornea keratometry,
- cornea topography, (with Placido disc and Scheimpflug imaging,
- cornea anterior segment Optical Coherence Tomography (OCT)), and
- endothelial cell counts (ECC)

CUSTOMIZED PHOTOREFRACTIVE INTRASTROMAL TREATMENTS

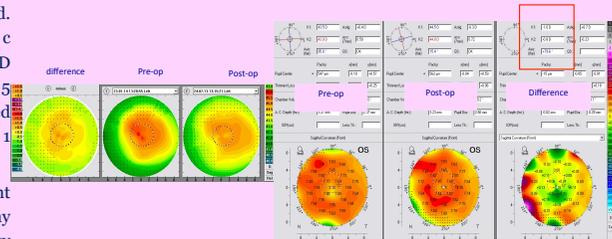


RESULTS

10 **myopic** cases treated. An average of -1.50D correction was achieved. Mean keratometry change was from 44.90D to 43.46D. Epithelial thickness showed a homogeneous reduction, from 52µm to 44µm on average over the treated area.

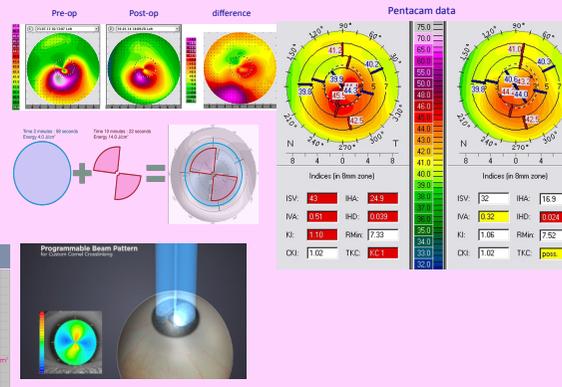


5 **hyperopic** cases treated. A mean hyperopic refractive increase of +1.2D was achieved. Of the 5 patients involved, 4 gained one Snellen line, while 1 had no gain.



There was no significant change in ECC, nor was any change in the cornea clarity in any case.

5 **astigmatic** cases treated, employing preferential corneal flattening along the flat refractive axis. A mean astigmatic reduction of -1.8D, and significant cornea surface normalization was achieved, along with modest epithelial thickness normalization.



DISCUSSION

Facilitated by the development of a customizable differential UV delivery system by Avedro and the ability to perform feasibility studies with the KXL II device, the current study provides additional evidence for the potential of patterned CXL in the deliberate treatment of refractive error.

These interim data appear promising with regard to the potential for correcting low myopic refractive errors without tissue removal in an excimer-like fashion or other previously described thermal techniques combined with CXL. Myopic, hyperopic and astigmatic corrections are other novel applications that are currently under study with this technology.

The procedure was relatively simple for the patient and surgeon. Because it is essentially performed through the intact epithelium, the procedure required minimal post-operative adjustment of daily activities by the patient and produced essentially no pain or discomfort even within the first few hours after the procedure. The rapid recovery and relative safety of transepithelial CXL may additionally offer the possibility to titrate the effect through two or more treatments over time as needed.

CONCLUSIONS

- This work introduces a novel technique based on refractive collagen cross-linking on virgin corneas as an alternative refractive correction technique. In the follow-up time evaluated, these patients showed an impressive and stable reduction in their refraction.
- Topographically customized and variable-to-very high-fluence CXL offered predictable well-defined myopic refractive (flattening), astigmatic, and hyperopic (steepening) corneal effect.
- This novel technique carries the advantage of essentially no post-operative morbidity, immediate visual rehabilitation and a potential for it to be tapered until the desired result is reached.
- This pilot work may represent a landmark study of a potentially revolutionary new refractive procedure.



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Commercial Relationship(s) Disclosure:

A. John Kanellopoulos: Consultant for Alcon, Avedro, OptoVue, i-Optics
I. Kontari, G. Asimellis: none