

# Updated Protocol to Provide Best Vision after CXL in Keratoconus

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## What is after CXL??



## Results



(Fig. 3); Maximum keratometric reading before and after cross linking  
K-max = maximum keratometric reading. D = diopters



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**2009**

- Collagen Cross Linking
- Glaucoma
- SD-OCT Versus TD-OCT
- Ocular Deviations
- Lateral Orbitotomy

**Corneal Changes After Collagen Cross Linking For Keratoconus**

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*Purpose:* To study topographic and tomographic corneal changes after collagen cross-linking (CXL) in patients with progressive advanced keratoconus, and to report the outcome of laser photorefractive keratotomy (PRK) and visual quality of these eyes.

*Design:* Prospective, nonrandomized, single-center study.

*Methods:* This study was carried out on 34 eyes (34 patients) having progressive keratoconus. They were recruited, diagnosed and treated at El-Dokki Vision Correction Center, Alexandria, Egypt. Corneal topography (cross linking CXL) was performed on the studied eyes by installation of 0.1% riboflavin for 15 minutes followed by UVA irradiation of these corneas for 30 minutes. Preoperative and postoperative visual acuity and refractive error (spherical, astigmatic, and toric) were measured using Hirschman Refraction HR reading (Hirschman Refraction, All patients were followed up for 6 months postoperatively).

*Results:* Mean preoperative spherical equivalent (MSE) was  $-3.8 \pm 1.1$  D. Mean LogMAR preoperative visual acuity (DVA) was  $0.81 \pm 0.2$ , and mean LogMAR best corrected visual acuity (BCVA) was  $0.29 \pm 0.1$ . These values were  $0.1 \pm 0.1$  D (MSE),  $0.46 \pm 0.1$  (DVA) and  $0.19 \pm 0.1$  (BCVA) after 1 month of the procedure and  $0.09 \pm 0.1$  D (MSE) and  $0.11 \pm 0.1$  D (BCVA) after 6 months. The postoperative keratoconus was  $50.5 \pm 0.1$  D, then  $47.7 \pm 0.1$  D at 1 month after the procedure and  $45.1 \pm 0.1$  D at 6 months visit. All the above mentioned changes were statistically significant after 1 month of CXL ( $p < 0.001$ ), but were insignificant after 6 months of the procedure.

*Conclusions:* CXL is effective in reducing the DVA and BCVA in eyes with progressive keratoconus. This improvement is a result of progressive flattening of the cornea. The improvement in the corneal refractive error is due to treatment induced by the visit 1 month after the procedure. A refractive vision correction procedure can be planned starting from the 6<sup>th</sup> month post CXL as the corneal stability is expected to be achieved (DOI:10.1186/1675-1521-10-127).

Keratoconus is a slowly progressive, non-inflammatory corneal dystrophy characterized by corneal protrusion, astigmatism, and distortion of the cornea due to changes in collagen structure and organization.<sup>1-3</sup>

The average age of incidence of the disease is the second decade of life.<sup>4</sup> The pathogenesis of this condition includes reduction of the overall stiffness of the corneal tissue to below 60% of its normal value due to increased proteolytic digestion and lesser synthesis of collagen constituents of the connective tissue.<sup>5</sup> The biomechanical characteristics of the cornea result from the collagen scaffold and collagen component and their bonding with the collagen fibers. The biochemical configuration of the collagen fibrils, biochemically, substantiates the role of the collagen biochemical and structural studies of the cornea throughout these differences between normal and keratoconic corneas.<sup>6-8</sup> Topographic alterations with an increased expression of basement and proteolytic enzymes,<sup>9-11</sup> decreased concentration of protease inhibitors,<sup>12</sup> decreased thickness<sup>13</sup> and modified configuration<sup>14</sup> of the normal collagen fibrils<sup>15</sup> have been observed.

The course of the disease varies from slight corneal astigmatism to severe visual impairment due to increasing corneal protrusion and corneal astigmatism. Visual deterioration caused by keratoconus has a significant negative effect on the quality of life.<sup>16</sup>

Current methods of vision correction for keratoconus include spectacles, rigid gas permeable contact lenses, and even recently, refractive surgical procedures and soft contact lenses.<sup>17</sup>

Intensified drug regimen, topographic guided refractive laser surgery (DVA) and laser assisted corneal cross-linking (DVA) are the most widely used to moderate keratoconus and control visual deterioration.<sup>18-20</sup> However, long-term follow-up shows that refractive surgery appears to provide a permanent flattening effect. A significant improvement of keratoconus in treated patients has been observed<sup>21</sup> demonstrating that this device can only temporarily correct the biomechanical refractive error. Flattening keratoconus (FK) is indicated in rapidly progressive cases with corneal scarring. Recently, a new technique, corneal collagen cross-linking (CXL), has been introduced by Watzdorf et al.<sup>22</sup> to stabilize progressive

## The KC Topic is So controversial!!!! Do we have a guideline/Answer for cases?

SPECIAL ARTICLE

### Global Consensus on Keratoconus and Ectatic Diseases

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Michael W. Belin, MD,§ Renato Ambrosio, Jr, MD, PhD,¶ José L. Girell, MD,||  
François Mollat, MD, PhD,\*\* Kohji Nishida, MD,†† and Frederic S. Sangnani, MD,‡‡, the Group  
of Panelists for the Global Delphi Panel of Keratoconus and Ectatic Diseases*

**Background:** Despite extensive knowledge regarding the diagnosis and management of keratoconus and ectatic corneal diseases, many controversies still exist. For that reason, there is a need for current guidelines for the diagnosis and management of these conditions.

**Purpose:** This project aimed to reach consensus of ophthalmology experts from around the world regarding keratoconus and ectatic diseases, focusing on their definition, concepts, clinical management, and surgical treatment.

**Methods:** The Delphi method was followed with 3 questionnaire rounds and was complemented with a face-to-face meeting. Thirty-six panelists were involved and allocated to 1 of 3 panels: definition/diagnosis, nonsurgical management, or surgical treatment. The level of agreement considered for consensus was two thirds.

**Results:** Consensus statements were constructed in definitions

and other ectatic diseases. It also provides an insight into the current worldwide treatment of these conditions.

**Key Words:** keratoconus, corneal ectasia, corneal cross-linking, corneal transplantation.

(Cornea 2015;34:359–389)

Keratoconus and ectatic corneal diseases have been recognized for more than 130 years.<sup>1,2</sup> Over the last 2 decades, there has been a revolution in the knowledge related to the diagnosis and management of these conditions. In terms of diagnosis, the advent of corneal topography, and more recently corneal tomography, has increased the ability of ophthalmologists to identify corneal ectasia at a much earlier stage than was previously possible.<sup>3</sup> As a result, the previously

## We Should Revise the Definition of KC!!

- KC is considered now as a **“Controllable”**  
**“Treatable”**

Primary ectatic disease in which we can now:

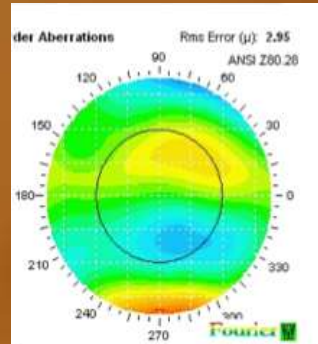
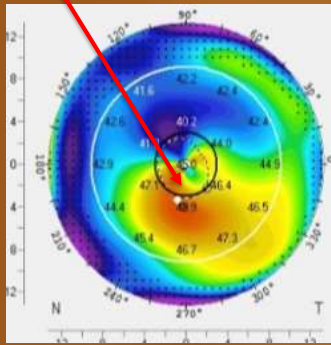
**Early diagnose/**

**halt the progression/**

**provide good vision** using the patient own cornea.



## The extreme irregularity of the pupil entrance is the main reason for visual degradation



### WFG Laser Vision Correction using the iDesign System

- High-resolution sensor maximizes capture rates
  - High-resolution Hartmann-Shack wavefront sensor (5 times higher than **WaveScan**)
  - Fourier reconstruction algorithms using up to 1257 micro-refractions over a 7 mm diameter wavefront
  - Outstanding accuracy, and ability to measure complex wavefronts or highly aberrated eyes for treatment planning
- Increasing resolution provides
  - Ability to capture more patients
  - Improved spot quality, reduces spot cross over effect
  - Detection of HOAs
  - Better reconstruction



Dr. Mohamed Shafik  
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## High-Definition Hartman-Shack Sensor

- **WaveScan** vs. **iDesign** system comparison
  - Improved spot quality
  - Better detection of highly aberrated eyes<sup>1</sup>
  - For example: keratoconus, post incisional refractive procedures, irregular ablation profiles

High Resolution MeasurementLow Resolution Measurement



Keratoconus Eye with 400µm Resolution



Keratoconus Eye with 210µm Resolution

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## A Topo-guided ablation profile:

**Uses the elevation topography to create an essential surgical plan to regularize the corneal surface**

**This is a crude concept of the Cause / Effect relation!**

*Tamayo G, Serrano MG. Early clinical experience using custom excimer laser ablations to treat irregular astigmatism. J Cataract Refract Surg 2000;26(10):1442-50.*

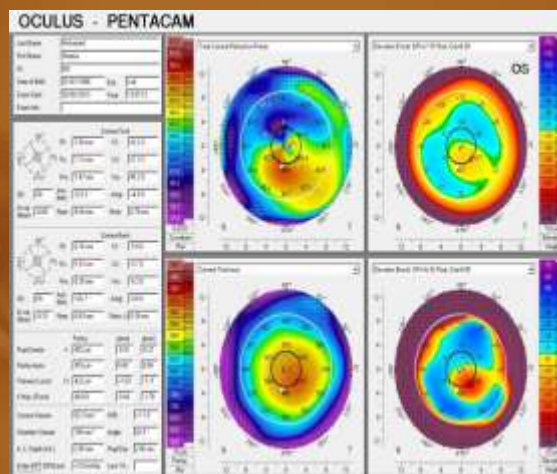
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## CASE 1.

- 24 years old lady with grade II KC
- Had CXL 13 month ago. Presented with a stable irregular cornea
- UCVA 0.05
- Manifest Refraction + 0.75 -4.00 x 110
- BCVA 0.3
- CCC 453  $\mu\text{m}$

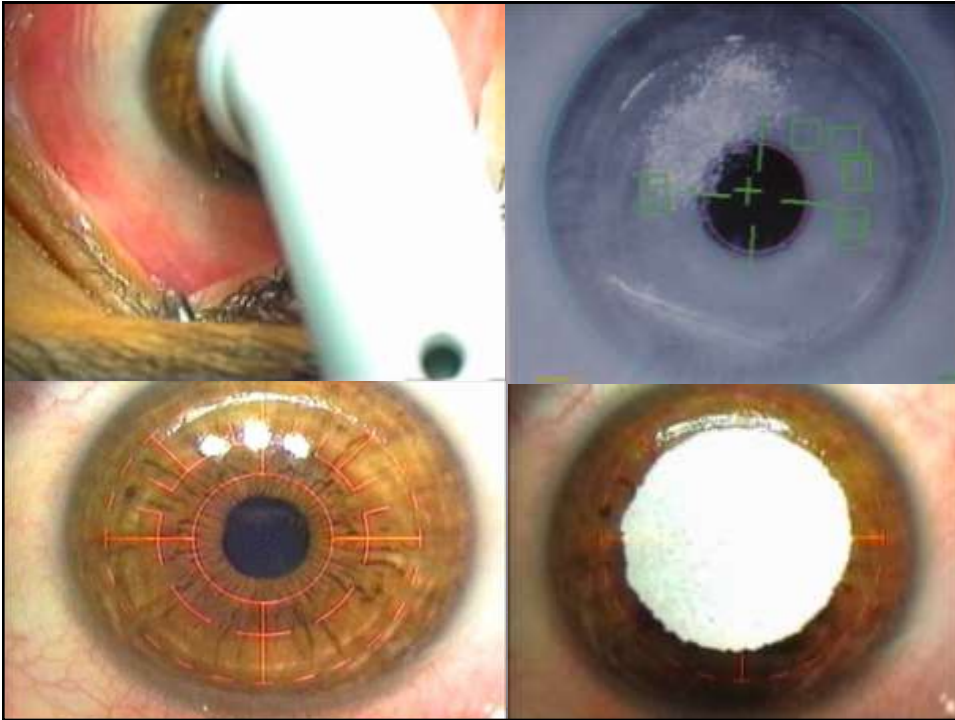


## CASE 1. Preop Pentacam

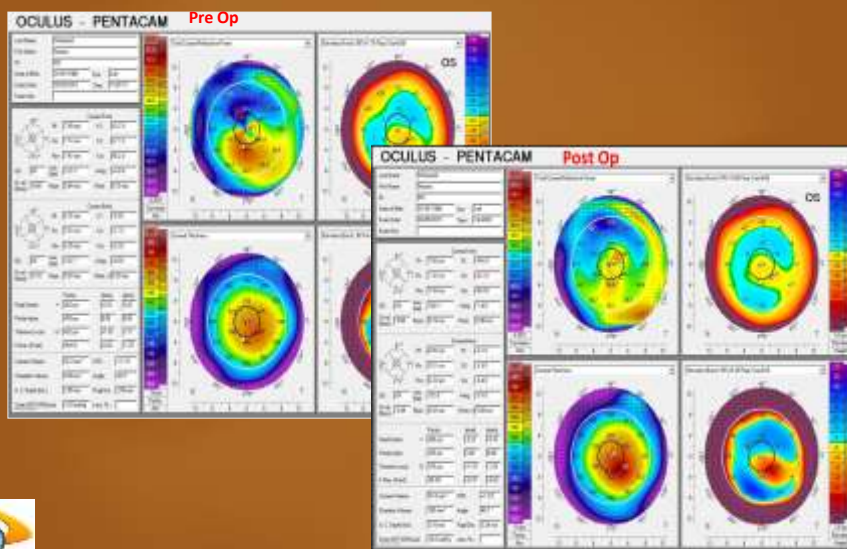








## Preop vs Postop Pentacam



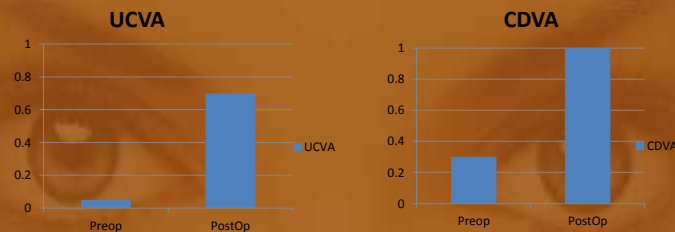


## CASE 1.

### Results:

3 months after CustomVue PRK powered by iDesign

- Ablated tissue thickness 47  $\mu\text{m}$
- ✓ Manifest Refraction -0.25 -1.00 X155

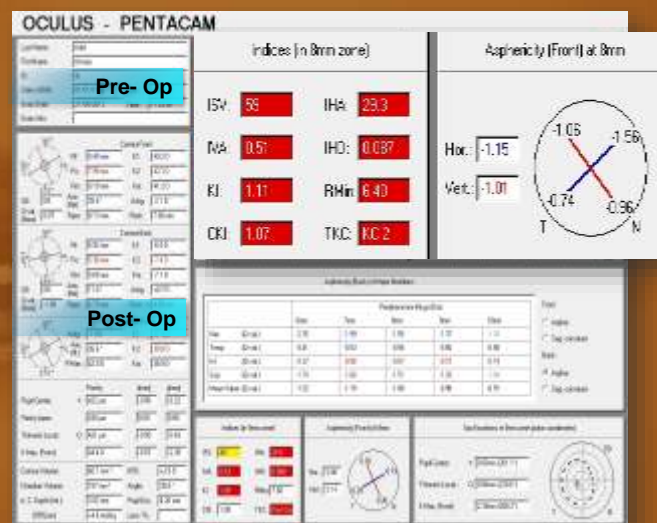


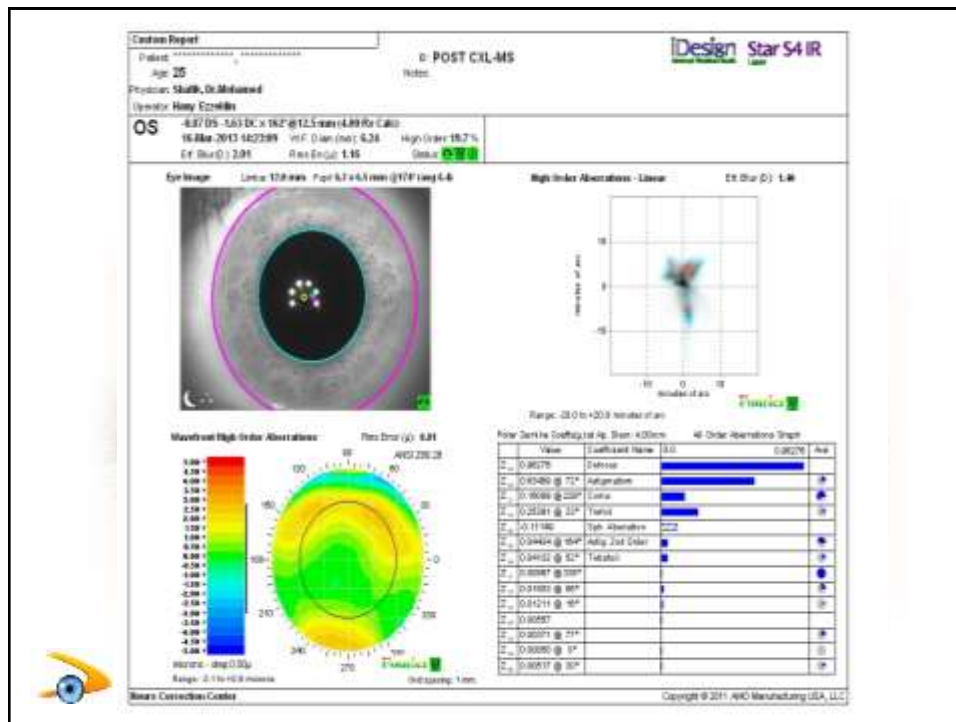
- ✓ Very significant improvement in Corneal Irregularity indices and Aberrations



## CASE 1

### Preop vs one year Postop. Corneal Irregularity Indices





we're committed to

# Athens Protocol

## Comparison of Sequential vs Same-day Simultaneous Collagen Cross-linking and Topography-guided PRK for Treatment of Keratoconus

Ioannis John Kanellopoulos, MD

### ABSTRACT

**PURPOSE:** The safety and efficacy of sequential collagen cross-linking (CXL) and topography-guided photorefractive keratectomy (PRK) using a different refractive index (RI) with sequential CXL in keratoconus treatment.

**DESIGN:** This study involved a total of 120 eyes with keratoconus. Eyes were divided into two groups. The first group (n=60) sequential CXL and topography-guided PRK performed 4 months after CXL and the second group (n=60) sequential CXL and PRK in a sequential procedure on the same day. Postoperative visual acuity, corneal topography, keratometry (K), and pachymetry were measured at 1, 3, 6, 12, 18, 24, 36, 48, 60, 72, 84, 96, 108, 120, 132, 144, 156, 168, 180, 192, 204, 216, 228, 240, 252, 264, 276, 288, 300, 312, 324, 336, 348, 360, 372, 384, 396, 408, 420, 432, 444, 456, 468, 480, 492, 504, 516, 528, 540, 552, 564, 576, 588, 600, 612, 624, 636, 648, 660, 672, 684, 696, 708, 720, 732, 744, 756, 768, 780, 792, 804, 816, 828, 840, 852, 864, 876, 888, 900, 912, 924, 936, 948, 960, 972, 984, 996, 1008, 1020, 1032, 1044, 1056, 1068, 1080, 1092, 1104, 1116, 1128, 1140, 1152, 1164, 1176, 1188, 1200, 1212, 1224, 1236, 1248, 1260, 1272, 1284, 1296, 1308, 1320, 1332, 1344, 1356, 1368, 1380, 1392, 1404, 1416, 1428, 1440, 1452, 1464, 1476, 1488, 1500, 1512, 1524, 1536, 1548, 1560, 1572, 1584, 1596, 1608, 1620, 1632, 1644, 1656, 1668, 1680, 1692, 1704, 1716, 1728, 1740, 1752, 1764, 1776, 1788, 1800, 1812, 1824, 1836, 1848, 1860, 1872, 1884, 1896, 1908, 1920, 1932, 1944, 1956, 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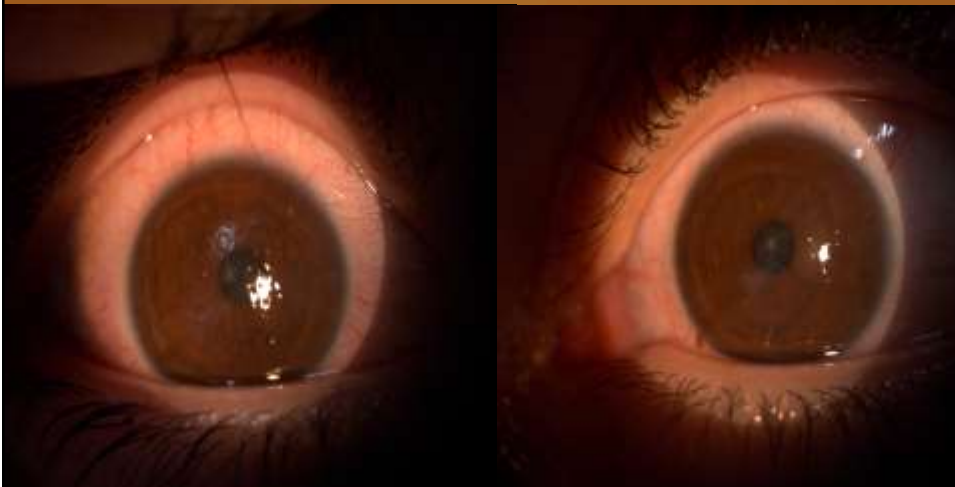
## Why Sequential and not Simultaneous PRK???

Cons of Simultaneous “Athen’s Protocol”:

- **Too Invasive (two techniques, Same Sitting)**
- Does not take into account the effect of CXL
- Does not Address Emmetropia
- The drawbacks of Topo-guided profiles



## Bilateral Delayed Epithelial Healing



## Why Sequential and not Simultaneous PRK???

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- The drawbacks of Topo-guided profiles



# ????????

**What if the CXL effect is too strong?**



## Why Sequential and not Simultaneous PRK???

Cons of Simultaneous “Athen’s Protocol”:

- Too Invasive (two techniques, Same Sitting)
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## Why Sequential and not Simultaneous PRK???

Cons of Simultaneous “Athen’s Protocol”:

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- **The drawbacks of Topo-guided profiles**





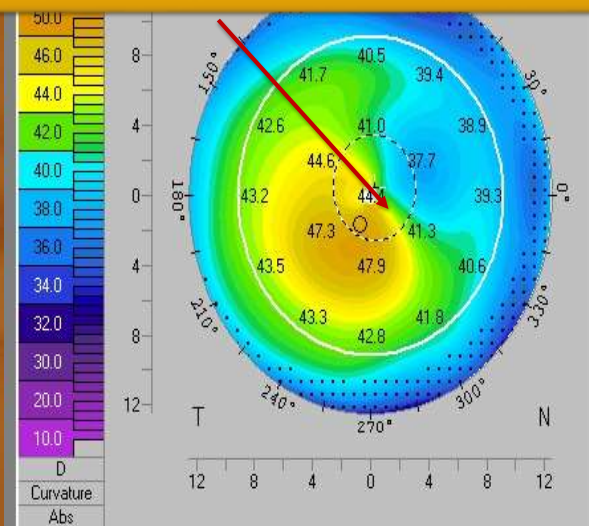
## Why I am against Simultaneous Topo-PRK + CXL ?

- Topo-Guided Profile Uses the elevation topography to create an essential surgical plan to regularize the corneal surface

This is a crude concept of the Cause / Effect relation



The main problem is in the center!!!!







CLINICAL SCIENCE

## Evaluation of a Toric Implantable Collamer Lens After Corneal Collagen Crosslinking in Treatment of Early-Stage Keratoconus: 3-Year Follow-up

Mohamed Shafik Shalaby, MD, PhD,\* Mohamed El-Kash, MD, PhD,\*  
 Mohamed A. El-Sherpieny, MD, PhD,\* and Marwan Zaghloul, MD†

**Purpose:** The aim of this study was to assess the predictability, efficacy, safety, and stability in patients who received a toric implantable collamer lens (TICL) after collagen crosslinking in early-stage keratoconus.

**Methods:** This prospective interventional case series study was conducted at the Alexandria Main University Hospital, University of Alexandria, Egypt. Sixteen eyes underwent implantation of a TICL (STAAR Surgical Inc) after crosslinking. The mean spherical refraction was  $-3.98 \pm 4.59$  diopters (SD range,  $-0.25$  to  $-10.00$  D), and the mean cylinder was  $-0.71 \pm 1.13$  D (range,  $-0.20$  to  $-1.73$  D). Uncorrected distance visual acuity (UDVA), manifest and cycloplegic refraction, corrected distance visual acuity (CDVA), corneal topography, and endothelial cell count (using specular microscopy) were evaluated during a 3-year follow-up.

**Results:** The mean baseline distance CDVA improved from  $0.36 \pm 0.13$  (range,  $0.40$ – $0.80$ ) preoperatively to  $0.97 \pm 0.17$  (range,  $0.90$ – $1.20$ ) at 3 years of the follow-up ( $P < 0.0002$ ). The mean UDVA also improved significantly from  $0.61 \pm 0.14$  before KXL to  $0.94 \pm 0.18$  at 3 years of the follow-up ( $P < 0.0002$ ). At 3 years, the mean spherical and cylindrical manifest refraction were  $-0.86 \pm 0.10$  D and  $-0.46 \pm 0.14$  D, respectively. At the end of the follow-up, the mean was  $108.71 \pm 10.47$  per page (SD range,  $100$ – $160$ ) and the intraocular pressure was  $14.94 \pm 1.17$  mm Hg. No complications occurred during the surgical procedure. No corneal ectasia, regression, or repositioning of the TICL. The endothelial cell count was after 3 years was  $\geq 97\%$ .

**Conclusions:** Corneal and cylindrical refraction were in tolerance even by TICL implantation 33 months after crosslinking given significantly preexisting astigmatism, particularly in the astigmatic component of refraction.

**Key Words:** keratoconus, crosslinking, toric implantable collamer lens.

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The authors have no funding or conflicts of interest to declare.

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**Keratoconus** is a corneal degeneration characterized by mechanical corneal protrusion and corneal thinning.<sup>1</sup> The average age of onset of keratoconus is the twenties.<sup>2</sup> The onset of this disease occurs from slight irregular astigmatism to severe visual impairment because of increasing protrusion and subepithelial scarring.<sup>3</sup> Because of the young age of the patients, keratoconus often has a significant negative effect on the quality of life.<sup>4</sup> The results of currently available treatment options are not encouraging because the treatments do not stop the progression of keratoconus. Thus, because of its progressive nature, keratoconus was the most frequent reason for keratoplasty to be performed in the past 3 decades.<sup>5</sup>

Keratotomy leads to biomechanical alterations, and its specific uses are well known.<sup>6,7</sup> The biomechanical characteristics of the cornea result from the collagen scaffold and collagen component and their bonding with the collagen fibrils. The 3-dimensional configuration of the collagen lamellae fundamentally underlies the resistance of the cornea.<sup>8,9</sup> Biomechanical and biomechanical studies of corneal photorefractive treatments have shown that crosslinking of the corneal collagen lamellae have been observed. A photo crosslinking technique using riboflavin and ultraviolet (UV)-A light was developed to counteract the progressive corneal thinning and thus the progression of keratoconus. By crosslinking, additional covalent bonding between collagen molecules can be achieved, which stabilizes the collagen scaffold and changes corneal tissue properties.<sup>10</sup>

As increase in the corneal stiffness and enhanced resistance against postoperative myopia caused by the riboflavin and UV-A light was shown in human eyes.<sup>11</sup> The crosslinking effect is not distributed homogeneously over the corneal depth. The stiffening effect is concentrated in the anterior 500 to 700  $\mu$ m of the cornea because of the high absorption of UV light in this area.<sup>12</sup>

The Implantable Collamer Lens (ICL; STAAR Surgical, Walden, Vermont) is a posterior chamber phakic intraocular lens, which has been reported not only for its appropriateness in postoperative visual performance but also for its safety and effectiveness in the correction of medium to high myopic astigmatism.<sup>13,14</sup>

By definition, keratoconus often has low corneal astigmatism. Therefore, additional corneal astigmatism should be taken into consideration for

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# CORNEA

*The Journal of Cornea and Contact Lens Research*

Mediterranean Diet and Dry Eye  
 Toric Phakic IOL After Cross-Linking  
 Smoking Effects on Corneal Healing  
 Double Pass Processing of DSAEK Donors

## Case Series

- 51 eyes (32 patients: 21 females & 11males)
- CXL (9 ms. to 14 ms. Before ICL)
- Stable refraction for the past 3 monthly visits
- Mean age:  $25.6 \pm 4.1$  ys. (21 – 33 ys.)
- First case was implanted in July 2008
- 32 eyes are followed up for > 86 months

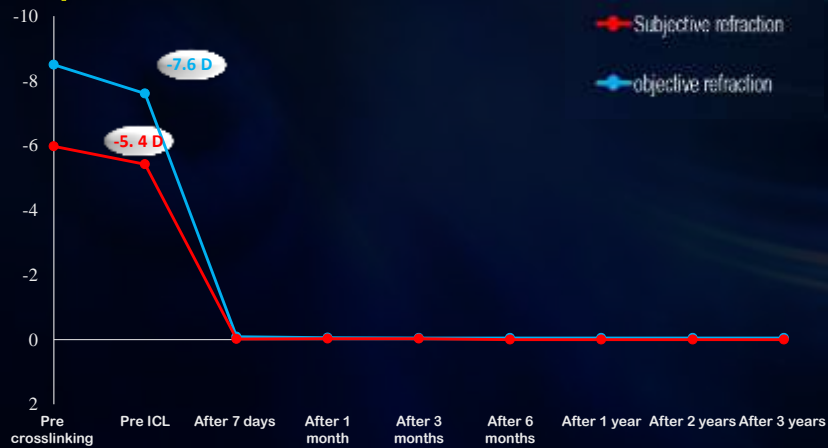
## Case Series

- Cycloplegic (Objective) Refraction:
  - Sph.  $-7.62 \pm 4.66$  D (-2.00 to -16.00)
  - Cyl.  $-5.23 \pm 1.67$  D (-2.75 to -8.00)
  - Sph. Eq.  $-10.24 \pm 4.35$  (-4.75 to -18.50)
- Subjective Refraction:
  - Sph.  $-5.42 \pm 4.45$  D (0.00 to -14.50)
  - Cyl.  $-4.34 \pm 1.62$  D (-2.00 to -7.50)
  - Sph. Eq.  $-7.61 \pm 4.10$  (-2.25 to -15.75)

### Corneal Multifocality ???????

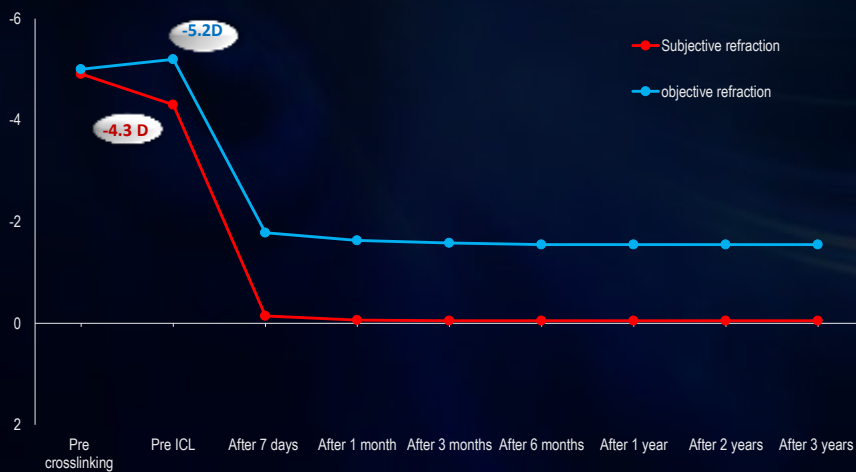
- BCVA:  $0.63 \pm 0.14$  (0.4 – 0.8)

## Sphere



Mean baseline sphere of subjective refraction= -5.42 Diopter  
 Mean baseline sphere of objective refraction= -7.62 Diopter  
 Mean 1Yr sphere of subjective refraction= 0 diopter  
 Mean 1Yr sphere of objective refraction= -0.05

## Cylinder



Mean baseline cylinder of subjective refraction= -4.34 Diopter  
 Mean baseline cylinder of objective refraction= -5.23 Diopter  
 Mean 1Yr cylinder of subjective refraction= -0.05 Diopter  
 Mean 1Yr cylinder of objective refraction= -1.55 Diopter

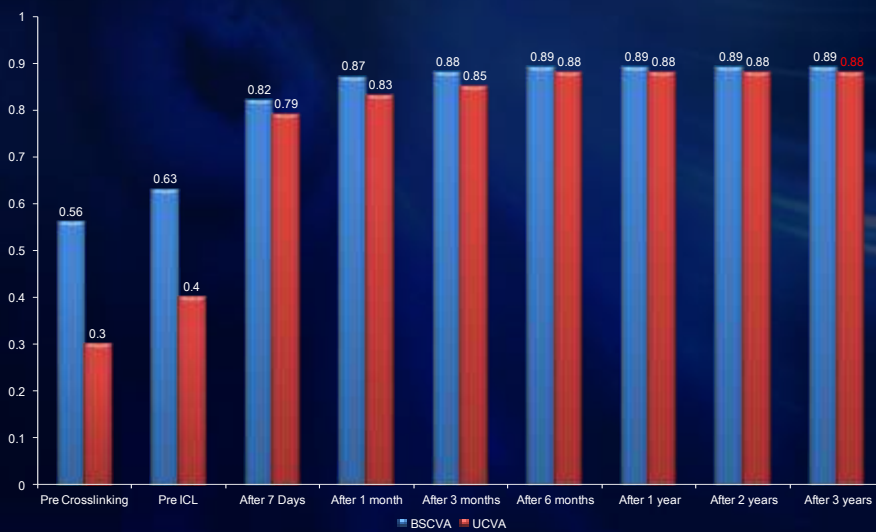


## Vaulting (el abovedamiento central) measured by Sheimpflug imaging



Mean vaulting at 1Yr = 509.75 µm

## BSCVA & UCVA





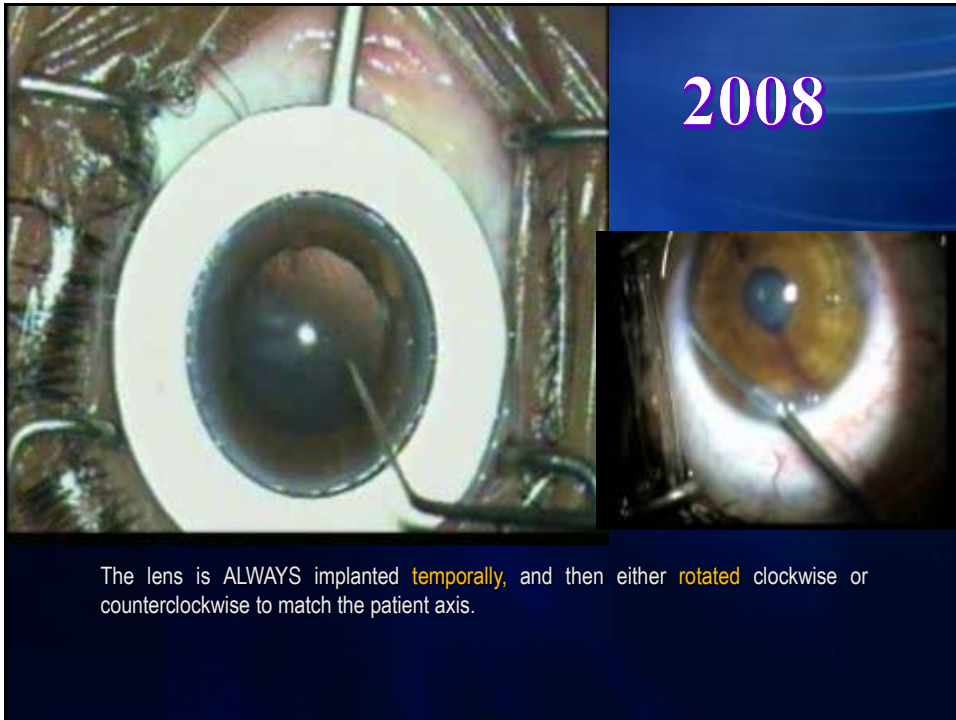
## Postoperative Results:

- UCDVA improved to  $0.88 \pm 0.18$  (0.6 to 1.2!)  
100% gained one line or more
- Glasses independent
- No single major complication
- Residual Sphere and Cylinder  
(Objective but not Subjective!)

## Surgical Technique

- Position TICL at proper axis according to diagram.





## CONCLUSIONS

- High-definition aberrometers are able to read highly aberrated corneas (such as in stable keratoconus) and generate out of them a dependable ablation profile which can be used to reduce refractive error / HOAs in such eyes and provide better quality of vision for those patients using their own corneas without the need for any type of keratoplasty.
- Wavefront-guided ablation profile seems to be a better alternative than the crude topography-guided ablation profile to address visual rehabilitation in stable keratoconic eyes.

- Sequential PRK for keratoconic eyes after doing corneal CXL seems to be a better alternative than simultaneous approach as it can address precisely the visual rehabilitation after having the maximum effect of CXL.
- Toric-ICL can do whenever the Sphere and Cylinder are beyond the limits of LVC

2017



**VIENNA 2018**  
36th Congress of the ESCRS  
27-30 September

**IC- Modern Diagnostic and Therapeutic Techniques for Irregular Cornea**

**Course Leader : Mohamed Shafik**

**Speakers:** Michael Belin  
Theo Sieler  
Jose Guell  
Georges Baikoff  
Farhad Hafezi

Thank You

