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EVALUATION OF EFFECT OF CORNEAL COLLAGEN CROSS LINKING FOR KERATOCONUS ON CORNEAL TOPOGRAPHY

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Abstract

Background: Keratoconus is a condition in which the cornea assumes a conical shape as a result of non-inflammatory thinning of the corneal stroma. The corneal thinning induces irregular astigmatism, myopia, and protrusion, leading to mild to marked impairment in the quality of vision. It is a progressive disorder ultimately affecting both eyes, although only one eye may be affected initially. Corneal collagen crosslinking (CXL) is a technique which use UV light and photosensitizer to strengthen chemical bonds in the cornea. The aim of this study was to study the changes in corneal topographic indices after CXL for Keratoconus.

Patients and Methods: this study was conducted 30 eyes for patients with keratoconus, with corneal thickness of more than 400µm, with clear cornea and with primary keratoconus Exclusion criteria were Patients with corneal thickness of 400µm or less, Previous ocular surgery, Secondary keratoconus and history of tissue healing defect . Full ophthalmological examination were done. UVA with a wavelength 370 nm will be applied to the area of the cornea debrided for 30 minutes

Results: There was a statistically significant decrease in the average K readings from the preoperative values. Non-significant decrease as regard Pre- and postoperative cylinder .there was statistically significant difference as regard Pre- and postoperative UCVA. There is statistically significant decrease in keratoconus index.

Conclusion: CXL presents an important strategy to halt the progress of keratoconus and improve it, while it can also play an effective role in limiting vision loss.

Keywords: keratoconus, cornea, corneal collagen crosslinking, riboflavin

Introduction:

Keratoconus is a bilateral asymmetric progressive corneal dystrophy which causes corneal ectasia, irregular astigmatism, and reduced vision. The onset of keratoconus typically occurs during puberty, and the progression can generally continue to the midthirties **(1).** Only 10–20 % of patients with keratoconus need keratoplasty either lamellar or penetrating due to the thinning and/or scarring of the cornea with the progression of the disease (2) **.**

Mild cases of myopia and astigmatism can be managed with spectacle correction. Once the corneal surface becomes too irregular, glasses fail to provide adequate visual quality and contact lens fitting is required. Rigid lenses are the lenses of choice because they mask the underlying irregularity of the cornea and create a perfectly regular anterior refractive surface for the eye. Rigid lenses can be accurately adjusted to the ametropia of the eye correcting visual acuity very efficiently in all stages of keratoconus. The limiting

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factor for contact lens correction is corneal scarring with opacification at the corneal apex so that a good visual acuity is no longer obtainable (3) .

Contact lenses represent the treatment of choice in about 75 to 95 % of the patients (4) . The sole inconvenience of these rigid gas permeable (RGP) corneal lenses remains discomfort: patients continue to feel the presence and movement of the lens on the ocular surface; for patients intolerant to this type of lenses, several options have become available in the last decade.

Several lens alternatives have become available to compensate for the discomfort that is the major drawback of corneal rigid lenses. The piggyback concept is the fitting of a soft contact lens with a rigid lens on top. The soft lens provides comfort by avoiding contact between the lens and the cornea, while the rigid lens provides better acuity than the soft lens could ever do (5) .

In the Dresden studies, progression indicating the necessity for treatment was based on an increase in Kmax at the apex of keratoconus of 1 diopter (D) in 1 year, deterioration of VA or the need for new contact lens fittings more than once in 2 years. Vinciguerra and co-workers defined keratoconus progression as a change in either myopia and/or astigmatism of ≥3 D in the previous 6 months, a mean central K-reading change of ≥1.5 D observed in three consecutive topographies during the preceding 6 months or a mean central corneal thickness decrease of ≥5 % in three consecutive topographies performed in the previous 6 months (6).

Corneal collagen crosslinking (CXL) is a technique which use UV light and photosensitizer to strengthen chemical bonds in the cornea. The goal of the treatment is to halt progressive and irregular changes in corneal shapes known as ectasia. The most common form of ectasia is keratoconus, and less often ectasia is seen after laser vision correction such as LASIK (7).

Corneal collagen crosslinking for Keratoconus cause changes in the corneal shape and structure which may affect the corneal Topography indices (8).

Today, the accepted protocol for CXL includes de-epithelialization of the cornea prior to the administration of riboflavin to increase its penetration throughout the corneal stroma in order to achieve a high level of UVA absorption (9).

There are several means of measuring the success or failure of CXL. These include morphological measures (such as keratometry), functional outcomes (such as uncorrected and corrected VA and improvement in quality of life), depth of riboflavin penetration (as confirmed by anterior segment optical coherence tomography) and the rate of complications. The availability of newer clinical instrumentation, such as the ocular response analyzer now also enable us to determine the extent of corneal stiffening by CXL (10).

Temporary corneal haze is a common adverse effect of CXL, and has been reported in 9.8 % of cases by Caporossi and colleagues with a mild degree of haze observed in all patients studied by Wittig-Silva et al (11, 12). Transient stromal oedema has been observed on slit-lamp examination in 70 % of patients in the first 30 days following treatment. Unresolving corneal oedema, although less frequent, has also been described in

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up to 2.9 % of patients in a retrospective case series of 350 patients with a mean follow-up of 14 months (13) **.**

Keratitis is one of the more serious potential complications following CXL, which may be either infectious or sterile .Patients with keratoconus who are known to have poor epithelial healing or active ocular diseases/inflammation (including atopic conjunctivitis) are in fact contraindicated for CXL due to the increased risk of infection. Other serious complications are rare and include corneal melting and perforation, and stromal scarring, while other minor complications such as pain are present in most to all patients treated with CXL (14)**.**

The aim of this study was to study the changes in corneal topographic indices after CXL for Keratoconus.

Patients and Methods:

After obtaining approval from the institutional review board and after writing an informed consent, this study was conducted 30 eyes for patients with keratoconus attending the ophthalmology department at Tanta university hospital for cross linking intervention from period of January 2018 to June 2018**.**

Inclusion Criteria were Patients with corneal thickness of more than 400µm, with clear cornea and with primary keratoconus

Exclusion Criteria were Patients with corneal thickness of 400µm or less, previous ocular surgery, Secondary keratoconus, history of tissue healing defect, Penetrating trauma. Glaucoma. Aphakia. Corneal scar and History of recurrent erosions.

Initial assessment of patients included: including age, sex, history of ocular diseases, using of contact lens, history of trauma, family history and previous ophthalmological interference.

Full ophthalmological examination (including slit lamp biomicroscopy, applanation tonometry, fundus examination, corneal pachymetry for corneal thickness, and corneal topography for corneal topographic indices).

All patients were subjected to the following:

1. Topical anesthesia (benoxinate hydrochloride) will be used.
2. A lid speculum will be applied.
3. Central 8mm of the epithelium will be removed cautiously with Amolis brusher.
4. Riboflavin 0.1% solution will be applied to the cornea every 1 minute for 20 minutes to achieve adequate penetration of the solution into the corneal stromal lamella
5. UVA with a wavelength 370 nm will be applied to the area of the cornea debrided for 30 minutes during which riboflavin will be applied every 5 minutes together with topical anesthesia whenever needed to ensure maximum comfort to the patient.
6. A soft bandage contact lens will be applied at the end of the procedure until re-epithelization will be complete.

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7. Ofloxacin eye drops will be given 4 times daily for 1 week, fluorometholone eye drops 3 times daily for 20 days, and artificial tears eye drops for 6 months post operatively.

Postoperative follow-up: Postoperative follow up by corneal topography for corneal topographic indices six months after CXL (index of surface variance, index of vertical asymmetry, Keratoconus index, central Keratoconus index, minimum radius of curvature, index of height asymmetry, index of height decentration).

Results

Thirty eyes fulfilled the inclusion criteria were included in the study with 11 males and 19 females; mean age of the patients was 24.53±3.79 years (range: 14–32 years), this show in table [1].

The preoperative K1 was 45.01 ± 3.65 D (range 40.60 – 53.60) and changed to 44.13 ± 3.27 D (range 40.0 – 53.10) (p 0.013*).The preoperative K2 was 48.67 ± 4.71 D (range 41.5 – 60.1) and changed to 47.52 ± 4.30 D (range 41.80 – 59.20) (P 0.223) .There was a statistically significant decrease in the average K readings from the preoperative values (*P* 0.052,). The preoperative average K was 46.84 ± 3.58 D (range 41.05 – 55.60) and changed to 45.83 ± 3.65 D (range 40.90 – 55.35) Table [2].

Preoperatively, the cylinder was -3.74±1.94 (range from -0.4 to -10.4, median -3.5). At 6 months, it had reduced to -3.56±2.02 (range - 0.40 to -10.50, median -3.05) which was not statistically significant (*P*=0.524) Table [3].

The mean preoperative UCVA was 0.40 ± 0.17. Postoperative UCVA at6 months was 0.51 ± 0.23. Pre- and postoperative UCVA differences were statistically significant (*P*, 0.005). Table [4]

There is statistically significant decrease in keratoconus index. From the preoperative values (*P* 0.039*,). The preoperative KI was 1.18 ± 0.09 (range 1.02 – 1.35) and changed to 1.16 ± 0.09 (range 1.01 – 1.34) .Also, there is statistically significant decrease in central keratoconus index. From the preoperative values (*P* 0.001*). The preoperative CKI was 1.04 ± 0.04 (range 0.99 – 1.16) and changed to 1.01 ± 0.06 (range 0.88 – 1.15) Table [5].

IHA was statistically significant decreased postoperatively from baseline (from 31.79 ± 20.04 to 27.15 ± 17.77) (P, 0.018*). While no change in IHD (from 0.07 ± 0.05 to 0.07 ± 0.04). (P, 0.289) table [6].

Six months postoperatively, the index of surface variance was decreased from baseline (from 70.70 ± 33.44 to 69.93 ± 25.57: P, 0.872). Also Index of vertical asymmetry was decreased from 0.74 ± 0.39 to 0.72 ± 0.31: P, 0.991) .table [7].

Rmin was increase postoperatively from baseline **(**from 6.41 ± 0.74 **to** 6.63 ± 0.81**)** (P, 0.035*) table [8].

Discussion

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CXL is a minimally invasive procedure. It was introduced by Wollensak et al as a promising treatment to stabilize progressive KC. It is indicated only in early-to-moderate KC (15)**.**

In this study, we evaluated the postoperative changes in 7 Pentcam topography indices and looked for associations with 6 months visual acuity outcomes. Changes in these measurements provide a more comprehensive analysis of the potential improvement in the shape and optical properties of the cornea after crosslinking

The present study revealed that there was a statistically significant improvement in the UCVA postoperatively. The mean preoperative UCVA was 0.40 ± 0.17, whereas the mean postoperative UCVA at the last visit (after 6 months) was 0.51 ± 0.23. (*P*, 0.005).

Postoperative improvement of VA has been noted in numerous other CXL studies as well. Derakhshan, Shandiz (16)) have published their observational study on the effect of cross-linking as primary treatment for patients with early KC, with mean follow-up of 6 months. Their results show significant improvement in UCVA and BCVA, and reduction in SE and keratometric readings. Visual improvement in most patients began after the first month, slightly increased by the third month, and remained stable until 6 months

In the present study, there was a statistically significant reduction in mean K reading. The preoperative mean K was 46.84 ± 3.58 D (range 41.05 –55.60) and changed to 45.83 ± 3.65 D (range 40.90 – 55.35). This finding was also addressed by Caporossi, Mazzotta (7) who recorded topographic mean reduction in dioptric power of 2.1±0.13 D.

In addition Raiskup-Wolf, Hoyer (17) reported that the improvement in vision after cross-linking is caused by a decrease in corneal curvature and by topographical homogenization of the cornea as a result of the increased rigidity in the cross-linked cornea. Other studies addressed by Mihältz, Kovács (18) recorded topographic mean reduction in dioptric power of 2.1±0.13 D.

Initial worsening of keratometric readings observed by Caporossi, Baiocchi (11) may be due to transient haze and corneal edema. Doors, Tahzib (19) postulated that it may be due to corneal remodeling. In contrast, Vinciguerra, Albe (6) suggested that it may be, in part, due to the epithelial layer being thickest around the cone and thinnest at its apex, masking the underlying steepness. Immediately after the removal of epithelium, they found that the steepest K reading changed from a mean of 58.82–61.05 D.

Our study revealed significant improvements of central keratoconus index (CKI), Minimum radius of curvature, keratoconus Index (KI), Index of height asymmetry (IHA). Postoperative improvement of Pentacam indices has been noted in numerous other CXL studies as well.Koller, Iseli (20) reported a significant improvement in four of seven Pentacam indices [central keratoconus index (CKI), Keratoconus index (KI), index of height asymmetry (IHA), and minimum radius of curvature (Rmin) 1 year after CXL.

Conclusion:

Corneal collagen cross linking is a promising new treatment to stabilize and even improve the visual acuity and topogaphy of patients with keratoconus. Our study showed improvement in topographic corneal changes and UDVA results in patients with keratoconus after the CXL

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Table (1): Distribution of the studied cases according to demographic data (n = 30)

Sex	**No.**	**%**
Male	11	36.7
Female	19	63.3
Age (years)	**No.**	**%**

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≤18	1	3.3
>18	29	96.7
Min. – Max.	14.0 – 32.0	
Mean ± SD.	24.53 ± 3.79	
Median	25.0	

Table (2): Comparison between the two studied periods according to K1 and K2 (n = 30)

	Preoperative	**After**	**t**	**p**
K1			2.657*	0.013*
Min. – Max.	40.60 – 53.60	40.0 – 53.10		
Mean ± SD.	45.01 ± 3.65	44.13 ± 3.27		
Median	43.90	43.30		
Change	↓0.88 ± 1.81			
K2			1.244	0.223
Min. – Max.	41.50 – 60.10	41.80 – 59.20		
Mean ± SD.	48.67 ± 4.71	47.52 ± 4.30		
Median	46.70	46.65		
Change	↓1.15 ± 5.06			
Average			1.943	0.052
Min. – Max.	41.05 – 55.60	40.90 – 55.35		
Mean ± SD.	46.84 ± 3.58	45.83 ± 3.65		
Median	46.13	45.0		
Change	↓1.02 ± 2.86			

t: Paired t-test

p: p value for comparing between before and after

*: Statistically significant at $p \leq 0.05$

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Table (3): Comparison between the two studied periods according to cylinder (n = 30)

	Preoperative	**After six month**	**Z**	**p**
Cylinder Max-Min Mean ± SD. Median	-10.40 – -0.40 -3.74 ± 1.94 -3.50	-10.50 – -0.40 -3.56 ± 2.02 -3.05	0.637	0.524
Change	↑0.18 ± 1.03			

Table (4): Comparison between the two studied periods according to VA (n = 30)

VA Min. – Max. Mean ± SD. Median **Change**	0.17 – 0.67 0.40 ± 0.17 0.33 ↑0.11	0.17 – 1.0 0.51 ± 0.23 0.58 ± 0.21	2.796*	0.005*

Z: **Wilcoxon signed ranks test**
p: p value for comparing between before and after
*: Statistically significant at $p \leq 0.05$

Table (5): Comparison between the two studied periods according to KI and CKI (n = 30)

	Preoperative	**After six**	**t**	**p**
KI Min. – Max. Mean ± SD. Median	1.02 – 1.35 1.18 ± 0.09 1.16	1.01 – 1.34 1.16 ± 0.09 1.13	2.162*	0.039*

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Change	↓0.03 ± 0.06			
CKI			4.039*	<0.001*
Min. – Max.	0.99 – 1.16	0.88 – 1.15		
Mean ± SD.	1.04 ± 0.04	1.01 ± 0.06		
Median	1.03	1.01		
Change	↓0.03 ± 0.05			

t: Paired t-test

p: p value for comparing between before and after

*: Statistically significant at $p \leq 0.05$

Table (6): Comparison between the two studied periods according to IHA And IHD (n = 30)

	Preoperative	**After six month**	**Z**	**p**
IHA Min. – Max. Mean ± SD. Median	6.20 – 90.40 31.79 ± 20.04 27.20	5.0 – 84.30 27.15 ± 17.77 26.65	2.376*	0.018*
Change	↓4.65 ± 22.06			
IHD			1.060	0.289
Min. – Max.	0.01 – 0.20	0.01 – 0.16		
Mean ± SD.	0.07 ± 0.05	0.07 ± 0.04		
Median	0.06	0.06		
Change	0.0 ± 0.03			

Z: **Wilcoxon signed ranks test**

p: p value for comparing between before and after

*: Statistically significant at $p \leq 0.05$

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Table (7): Comparison between the two studied periods according to ISV and IVA (n = 30)

	Preoperative	After six month	Test of Sig.	p
ISV Min. – Max. Mean ± SD. Median	16.0 – 136.0 70.70 ± 33.44 65.0	27.0 – 120.0 69.93 ± 25.57 69.0	t=0.163	0.872
Change	0.77 ± 25.78			
IVA			Z=0.011	0.991
Min. – Max.	0.15 – 1.79	0.28 – 1.59		
Mean ± SD.	0.74 ± 0.39	0.72 ± 0.31		
Median	0.69	0.69		
Change	0.02 ± 0.23			

t: Paired t-test Z: **Wilcoxon signed ranks test**

p: p value for comparing between before and after

Table (8): Comparison between the two studied periods according to Rmin (n = 30)

Rmin	Preoperative	After six month	t	p
Min. – Max. Mean ± SD. Median	5.05 – 7.70 6.41 ± 0.74	5.06 – 7.90 6.63 ± 0.81	2.213*	0.035*
Change	↑0.22 ± 0.55			

t: Paired t-test

p: p value for comparing between before and after

*: Statistically significant at $p \leq 0.05$

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الملخص العربي

المقدمه : القرنية المخروطية هي حالة تتخذ فيها القرنية شكلاً مخروطيًا نتيجة ترقق سدى القرنية غير الالتهابي. يؤدي ترقق القرنية إلى الاستجماتيزم وقصر النظر ، مما يؤدي إلى ضعف خفيف إلى ملحوظ في جودة الرؤية. إنه اضطراب تدريجي يؤثر في النهاية على كلتا العينين ، على الرغم من أن عين واحدة فقط قد تتأثر في البداية. تشابك كولاجين القرنية (CXL) هي تقنية تستخدم ضوء الأشعة فوق البنفسجية ومُحسِس للضوء لتقوية الروابط الكيميائية في القرنية

الهدف من هذه الدراسة: دراسة التغيرات في المؤشرات الطبوغرافية للقرنية بعد CXL للقرنية المخروطية.

المرضي : أجريت هذه الدراسة 30 عين لمرضى القرنية المخروطية ، بسمك القرنية أكثر من 400 ميكرون ، مع القرنية الصافية تم استبعاد من لديهم سمك القرنية 400 ميكرومتر أو أقل او لديهم جراحة في العين مسبقا ، القرنية المخروطية الثانوية وتاريخ من عيب التئام الأنسجة . تم إجراء فحص كامل للعيون. سيتم استخدام UVA بطول موجي 370 نانومتر على منطقة القرنية لمدة 30 دقيقة

النتائج : يوجد فروق ذات دلاله احصائيه فيما يتعلق قياسات القرنية وايضا كان يوجد اختلافا ذو دلاله احصائيه فيما يتعلق ب حدة البصر غير المصححة و مؤشر القرنيه المخروطيه

الاستنتاج : تقدم CXL استراتيجية مهمة لوقف تقدم القرنية المخروطية وتحسينها ، في حين أنها يمكن أن تلعب أيضًا دورًا فعالًا في الحد من فقدان البصر.