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Preliminary Clinical Outcome of CXL in Keratoconus Patients

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Abstract **Original Research Article**

Background: Corneal collagen cross-linking (CXL) is a promising method in the treatment of keratoconus (KCN); however, long-term results of this treatment modality are under-represented in the literature. ***Objective*:** In this study our main goal is to evaluate the preliminary clinical outcome of CXL in Keratoconus patients in Bangladesh after 1 year follow up. Method: This retrospective observational type of study was conducted among 40 patients who fulfilled criteria from Bangladesh Eye Hospital, Chittagong January 2014 to January 2019. ***Results:*** During the study, most of the patients belong to 31-40 years age group, 48%. Treated eyes showed a flattening of the steepest simulated keratometry value (K-max) by an average of 0.74 diopters (D) (P=.004) at 3 months, 0.92 D (P=.002) at 6 months, and 1.45 D (P=.002) at 12 months. A trend toward improvement in best spectacle-corrected visual acuity was also observed. In the control eyes, mean K-max steepened by 0.60 D (P=.041) after 3 months, by 0.60 D (P=.013) after 6 months, and by 1.28 D (P<.0001) after 12 months. Best spectacle-corrected visual acuity decreased by logMAR 0.003 (P=.883) over 3 months, 0.056 (P=.092) over 6 months, and 0.12 (P=.036) over 12 months. ***Conclusion*:** From our study we can conclude that, CXL could be considered as a promising first line treatment for most patients with progressive KCN, especially considering our encouraging long-term results.

Keywords: Keratoconus, cornel collagen cross linking (CXL), corneal condition.

INTRODUCTION

Keratoconus is a relatively common ectatic corneal condition causing significant visual disability. It is characterized by progressive irregular myopic astigmatism with central corneal thinning and protrusion [1]. Keratoconus affects both eyes in the majority of cases but may be markedly asymmetric. The Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Group has presented findings related to keratoconus in a large cohort of patients from diverse ethnicities in the USA [2]. Similarly the Dundee University Group has published a longitudinal study on a more homogenous population from Scotland [4]. However, characteristics of keratoconus in Asian populations seem to vary from those reported from other ethnic groups. In a population-based cohort analysis, the Central India Eye and Medical Study reported the prevalence of keratoconus in central India to be 1.4% [5]. The incidence of keratoconus has been shown to range from 1 in 4,000 to 5,100 persons per year in Asian populations.

Several studies support the role of corneal collagen cross-linking (*CXL*), which is a therapeutic procedure aiming at increasing the corneal stiffness in the keratoconus eyes; however, there is a paucity of long-term data. According to some studies long term efficacy and safety of CXL are uncertain; indeed, there are few publications with more than 5 years of follow up [3, 4].

In this study our main goal is to evaluate the preliminary clinical outcome of CXL in Keratoconus patients in Bangladesh.

OBJECTIVE

General Objective

- To assess the preliminary clinical outcome of CXL in Keratoconus patients in Bangladesh.

Specific Objective

- To detect clinical characteristics of the patients
- To identify post-operative findings in patients.

METHODOLOGY

Type of study	Retrospective observational study
Place of study	Bangladesh Eye Hospital, Chittagong
Study period	January 2014 to January 2019.
Study population	40 patients included in the study who were fulfilled criteria.
Sampling technique	Purposive

STUDY PROCEDURE

During the Study

Face to face interview of the participants were conducted with the semi-structured, pre-tested questionnaire. The interview was conducted anonymously and privately as much as possible. Before preceding the data collection, the detail of the study was explicitly explained to each eligible respondent and informed written consents from the respondents were obtained.

Corneal collagen crosslinking was performed using 0.1% riboflavin (in 20% dextran T 500) and ultraviolet A (UVA) irradiation (370 nm, 3 mW/cm2, 30 min) under sterile conditions. The UV-X 1000 machine (IROC Innocross AG, Zurich, Switzerland) and the Innocross-R riboflavin isotonic solution (riboflavin 5-phosphate (0.1%) plus 20% Dextran T500 in 2 mL syringes) were used. The procedure was performed under general anaesthesia in very young patients and under topical anaesthesia in older patients. After anaesthesia, a lid speculum was inserted and the corneal epithelium was soaked with 20% alcohol for 40 seconds. The epithelial tissue was then removed in a 9.0 mm diameter area with a cellulose surgical spear to allow penetration of riboflavin into the corneal stroma. Thereafter, the photosensitizer 0.1% riboflavin was applied (2 to 3 drops every 3 minutes) to the cornea for 30 minutes before irradiation to allow sufficient saturation of the stroma.

Corneal soaking of riboflavin was assessed and then the central 8.0 mm cornea was exposed to UVA light (wavelength of 370 nm and irradiance of 3 mW/cm2) for 30 minutes. Throughout the UVA exposure, riboflavin solution was instilled (2 to 3 drops every 3 minutes). Upon completion of treatment, the eye was washed with balanced salt solution and antibiotic eye drops (ofloxacin 0.3%) and steroid eye drops (dexamethasone 0.1%) were applied. A bandage contact lens was placed in the eye until complete reepithelialization. Subsequent follow-up examinations were performed at 1 week and thereafter at 1, 6, 12, months and annually thereafter. The BSCVA, corneal topography, and central corneal thickness (CCT) were recorded at each visit.

Data Analysis

Data were entered in the template of Statistical program, SPSS-15 after necessary editing and coding. Descriptive statistics were generated for socio-demographic variables and were presented with relative frequency.

RESULTS

In Table-1 shows age distribution of patients where most of the patients belong to 31-40 years age group, 48%. The following table is given below in detail:

Table-1: Age distribution of patients

Age group in years	Percentage
(>20) years	36%
(21-30) years	48%
(31 - 40) years	11%
>40 years	5%
Total=	100%

In Figure-1 shows distribution of patients according to the gender where 57% patients were male, which was 14% higher than female. The following figure is given below in detail:

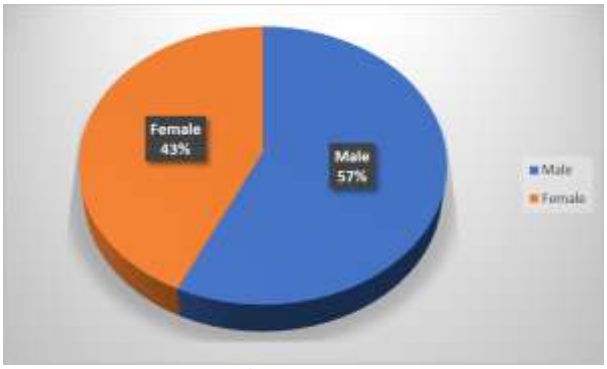

Fig-1: Distribution of patients according to the gender

In Table-2 shows comparison of BCVA baseline and last follow-up of 30 keratoconic eyes patients after corneal collagen crosslinking (CXL) with a 1-year follow-up. Where after CXL most of the patient's log MAR BSCVA improved. The following table is given below in detail:

Table-2: Comparison of BCVA baseline and last follow-up of 30 keratoconic eyes patients after corneal collagen crosslinking (CXL)

Before CXL	Before CXL, BCVA	After CXL, BCVA
R/E	6/18	6/12
L/E	6/12	6/9
R/E	6/18	6/12
R/E	6/12	6/9
L/E	6/18	6/12
L/E	6/24	6/12
R/E	6/18	6/12
L/E	6/12	6/9
R/E	6/12	6/9
R/E	6/18	6/12
L/E	6/18	6/12
L/E	6/18	6/12
R/E	6/12	6/9
L/E	6/12	6/9
R/E	6/12	6/9
R/E	6/24	6/12
L/E	6/24	6/12
L/E	6/18	6/12
R/E	6/18	6/12
L/E	6/18	6/12
R/E	6/12	6/9
R/E	6/12	6/9
L/E	6/24	6/12
L/E	6/24	6/12
R/E	6/18	6/12
L/E	6/18	6/12
L/E	6/12	6/9
R/E	6/12	6/9
L/E	6/18	6/12
R/E	6/12	6/9
R/E	6/12	6/9
L/E	6/18	6/12
R/E	6/18	6/12
L/E	6/12	6/9
R/E	6/18	6/12
R/E	6/12	6/9
L/E	6/18	6/12
L/E	6/24	6/12
R/E	6/18	6/12
L/E	6/12	6/9
R/E	6/12	6/9
R/E	6/18	6/12

In Table-3 shows pre- and post-crosslinking data for treated eyes where there was a significant reduction in keratometry values following crosslinking. The following table is given below in detail:

Table-3: Pre- and post-crosslinking data for treated eyes

Before CXL K1	Before CXL K2	Before CXL Kmax	Before CXL, thinnest local	After CXL K1, 1 year follow up	After CXL K2,1 year follow up	After CXL, Kmax	After CXL, thinnest local	Before CXL K1
52.1	53.6	57.8D	394	52.7	53.2	58.9D	394	52.1
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
52.0	53.7	57.9D	395	52.5	53.2	58.8D	395	52.0
49.8	53.2	58.7D	407	49.4	52.3	57.7D	364	49.8
45.2	52	58.1D	405	52.0	53.7	57.9D	395	45.2
52.0	53.7	57.9D	395	52.1	53.6	57.8D	394	52.0
6/12	52.1	53.6D	57.8	52.7	53.2	58.9D	394	6/12
6/12	52.1	53.6D	57.8	52.7	53.2	58.9D	394	6/12
49.8	53.2	58.7D	407	49.4	52.3	57.7D	364	49.8
49.8	53.2	58.7D	407	49.4	52.3	57.7D	364	49.8
49.8	53.2	58.7D	407	49.4	52.3	57.7D	364	49.8
52.0	53.7	57.9D	395	52.5	53.2	58.8D	395	52.0
52.0	53.7	57.9D	395	52.5	53.2	58.8D	395	52.0
52.0	53.7	57.9D	395	52.5	53.2	58.8D	395	52.0
45.2	52	58.1D	405	52.0	53.7	57.9D	395	45.2
45.2	52	58.1D	405	52.0	53.7	57.9D	395	45.2
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
52.1	53.6	57.8D	394	52.7	53.2	58.9D	394	52.1
52.1	53.6	57.8D	394	52.7	53.2	58.9D	394	52.1
45.2	52	58.1D	405	52.0	53.7	57.9D	395	45.2
45.2	52	58.1D	405	52.0	53.7	57.9D	395	45.2
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
52.1	53.6	57.8D	394	52.7	53.2	58.9D	394	52.1
52.1	53.6	57.8D	394	52.7	53.2	58.9D	394	52.1
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
52.1	53.6	57.8D	394	52.7	53.2	58.9D	394	52.1
52.1	53.6	57.8D	394	52.7	53.2	58.9D	394	52.1
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
52.1	53.6	57.8D	394	52.7	53.2	58.9D	394	52.1
49.9	53.2	58.7D	407	49.4	52.3	57.7D	364	49.9
52.0	53.7	57.9D	395	52.5	53.2	58.8D	395	52.0
49.8	53.2	58.7D	407	49.4	52.3	57.7D	364	49.8
45.2	52	58.1D	405	52.0	53.7	57.9D	395	45.2
52.0	53.7	57.9D	395	52.1	53.6	57.8D	394	52.0
6/12	52.1	53.6D	57.8	52.7	53.2	58.9D	394	6/12

In Figure-2 shows corneal topography showing a reduction in keratometry after CXL where at 18 months after CXL, there was a reduction in *K2* by 1.8 D in the treated eye. The following figure is given below in detail:

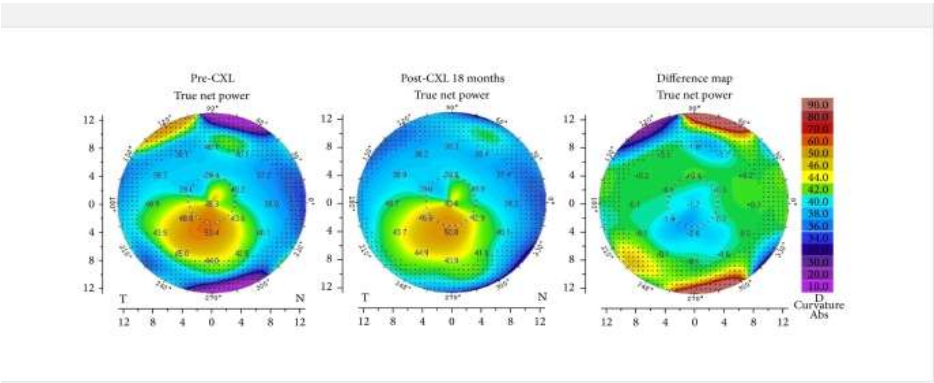

Fig-2: corneal topography showing a reduction in keratometry after CXL
Source by: https://www.hindawi.com/journals/bmri/2014/140461/

DISCUSSION

In one study reported that, there was a higher percentage of male subjects indicating a trend toward earlier diagnosis in this gender. Mean age at the time of diagnosis of keratoconus is typically in the second decade of life [7].

In our series, most of the patients belong to 31-40 years age group, 48%. Also, 57% patients were male, which was 14% higher than female. Which was quite similar to other study [8].

One study reported that, younger age at diagnosis could mean that the condition has earlier onset and faster progression in Asian populations reflecting variability of the disease process [9].

Similar to the other studies, there were very few patients over 40 years of age in our series [7, 8]. Keratoconus patients demonstrate a period of stability 8 to 12 years after diagnosis, thus, most of them may seek care with local ophthalmologists/contact lens practitioners [5].

In one study found that, the mean preoperative spherical refractive error was -1.46 ± 2.31 diopters, the mean cylinder was -3.70 ± 1.81 diopters and mean spherical equivalent (SE) was -3.25 ± 2.44 diopters. Postoperatively the mean sphere was -1.34± 2.22 diopters, the mean cylinder was -3.12 ± 1.86 diopters and the mean SE was -2.90 ± 2.40 diopters [9]. Which was quite similar to our study. Another study documented a decrease in K max by an average of -2.57 D in their cohort of patients [10].

Another article reported significant improvement of -0.15 Log MAR in BSCVA at 36 months. They did not detect any change in spherical equivalent or cylindrical component of the subjective refraction. They also reported an improvement in Kmax by a mean of -0.74D after 12 months in cross linked group and progression by a mean of +1.28D [11].

CONCLUSION

From our study we can conclude that, CXL could be considered as a promising first line treatment for most patients with progressive KCN, especially considering our encouraging results.

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