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ORIGINAL ARTICLE

Combined Intacs SK and Corneal Collagen Cross-linking for the Treatment of Keratoconus

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ABSTRACT

Purpose: To evaluate the efficacy of the combined treatment of Intacs SK (Severe keratoconus) and corneal collagen cross-linking in the management of advanced keratoconus (KC).

Setting: Private laser center, Haifa, Israel. Affiliated to Hadassah Hospital, Jerusalem.

Methods: This is a retrospective study. Intacs SK were implanted using manual technique in eyes with moderate-to-severe keratoconus followed by collagen corneal cross-linking (CXL). Evaluation included uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), manifest refraction, slit-lamp examination and corneal topography. Ocular response analyzer (ORA) was used to assess the corneal hysteresis (CH) and the corneal resistance factor (CRF).

Results: We report on improvement of the UCVA, BSCVA, decrease in myopia, astigmatism and keratometry readings. No significant change in CRF or CH was noted.

Conclusion: The combined treatment of Intacs SK and corneal CXL for the treatment of advanced keratoconus is safe and effective. The combined treatment resulted in improved UCVA, BSCVA, keratometry readings and regularization of the topography but no significant change in CRF and HS.

Keywords: Keratoconus, Cornea, Intacs, Intacs SK, Collagen corneal cross-linking UVA, Corneal topography, Corneal biomechanics, Ocular response analyzer, Orbscan.

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INTRODUCTION

Keratoconus (KC) is an ectatic degenerative disease which causes protrusion and thinning of the cornea. As a result the corneal surface becomes irregular with consequent irregular astigmatism which cannot be corrected by glasses. Hence, contact lenses (CL) are needed to improve the visual acuity (VA) but many patients suffering from KC cannot tolerate the CL due to the irregularity and protrusion of the cornea on the one hand and due to the atopic and allergic conjunctivitis that are often associated with the disease. The disease is usually progressive and in almost 20% of cases necessitates corneal grafting.

Intacs are intrastromal corneal ring segments approved by the Food and Drug Administration (FDA) for the correction of mild-to-moderate myopia.[1] Moreover, they have been shown to be effective in treating KC.[2-9] They improve the VA flatten and regularize the cornea by an arc-shortening effect.[10] Intacs severe keratoconus (SK) are a new design of intracorneal ring segments developed by Addition Technology Inc. They are indicated for the treatment of moderate-to-severe keratoconus (SK) with steep keratometric values >55.00 diopters (D). They are oval shaped rings with a diameter of 6 mm and thickness of 0.40 and 0.45 mm.[11,12] Two nomograms are used to determine the thickness of the intracorneal ring segment that is needed. The first is keratometry-based and the second is cylindrical-based (Table 1).

Table 1: The two nomograms: Keratometry and cylindrical-based used to decide the thickness of the Intacs SK to be implanted

Segment thickness	*Mean keratometry*	*Cylinder*
400 µ	55-62	<5 D
450 µ	>62	>5 D

Corneal collagen cross-linking (CXL) is a relatively new therapy using ultraviolet A (UVA) with a photosensitizer riboflavin to increase corneal stiffness. It has been shown that CXL is effective in arresting the progression of keratoconus.[13]

To our knowledge, there are no published reports on the combined treatment of Intacs SK and CXL for the treatment of moderate-to-severe keratoconus. We used Intacs SK because of their increased efficacy in advanced keratoconus. CXL was used to stabilize the cornea. Our hypothesis was that combining the two treatments would yield an additive effect.[14]

PATIENTS AND METHODS

This is a retrospective study of the combined treatment of Intacs SK and CXL for moderate-to-severe KC. The indications for treatment were (1) unsatisfactory VA with glasses, (2) contact lens (CL) intolerance, (3) progressive KC with clear cornea except one eye which had a superficial corneal scar. Data collected since June 2008. Fifteen eyes had CXL treatment immediately after Intacs SK implantation and two eyes had CXL weeks after Intacs SK implantation. In the latter case, the patient was diagnosed earlier with severe KC and was scheduled for PKP and in his case we were not certain that the Intacs SK will improve the patient's vision significantly, so we postponed the CXL

for a later date till improvement in uncorrected visual acuity (UCVA) and best-spectacle corrected visual acuity (BSCVA) was evident. Our aim was to spare the patient the inconvenience and pain following CXL until we were sure that the Intacs SK were effective in his case.

Three cases were treated bilaterally, in three eyes of the only one ring implanted and two eyes had asymmetric rings. The rest of the eyes had the Intacs SK 0.4 mm pair or 0.45 mm pair implanted.

CRF and CH were measured using the Reichert ocular response analyzer preoperatively and at each visit postoperatively.

SURGICAL TECHNIQUE

Seventeen eyes of 14 keratoconic patients had implantation of Intacs SK by the manual technique. Surgical procedure was performed by one surgeon (AB) under topical anesthesia. Standard draping was performed. The eye was washed with polidine 4%. The cornea was marked with the special Intacs SK marker and manual dissection was performed using the special dissector of Intacs SK (provided by the Addition Technology). The incision was made along the steep axis at a depth of 80% of the corneal thickness as measured by pachymetry in the operation room. Pachymetry was done onto the incision site and on the hypothetical channels as marked by the special Intacs SK marker.

Dissection was performed using a channel guide in clockwise and counterclockwise directions. The Intacs SK segments were soaked in zymar 0.3%, (gatifloxacin) and then inserted as planned in the channels. Sinskey hook was used to adjust the final position. The procedure was suture less. Immediately following the implantation of the rings the epithelium was removed from the central 8 mm of the cornea and the patient was seated. Riboflavin 0.1% combined with Dextran 20% was instilled every 5 minutes for 30 minutes in corneas thicker than 400 µ. Riboflavin without dextran (isotonic solution) was used in cases where corneal thickness was less than 400 µ. Ultrasound pachymetry was performed after the removal of the epithelium and half an hour after instillation of riboflavin 0.1% of hypotonic riboflavin solution and treatment was performed only after the following:

1. Increase in corneal thickness at the thinnest point to more than 350 µ without epithelium.
2. Appearance of strong yellow flare in the anterior chamber.

Speculum was inserted and the patient was asked to look into UVA (365-370 nm) light source 5 mm from the eye (UVX produced by Peschke GmbH) with a light intensity of 3 mW/cm^2. During treatment, riboflavin was instilled every 5 minutes the eye and BSS every 3 minutes during the 30 minutes exposure of the cornea to the UVA. Riboflavin with and without dextran 20% were used as given pre-CXL treatment in accordance to corneal thickness. A therapeutic contact lens was inserted following the treatment till full epithelialization.

In two eyes the CXL was performed few weeks in the first case and few months in the second case after the insertion of the Intacs SK because we were not sure that Intacs SK implantation will yield a satisfactory improvement of the VA and we did not want to perform CXL immediately after the rings implantation as we did in the remaining 15 eyes. We wanted to spare the patients an unnecessary treatment in case failure of the rings to improve the VA to a satisfactory level to the patient.

Vigamox (moxifloxacin 0.3%) antibiotics were prescribed for 1 month and FML was added for 2 weeks only following epithelial healing which occurred after 3 days.

There were no intraoperative complications. In two eyes a migration of one ring segment close to the incision site with protrusion occurred few months postoperatively. The segments were extracted, cut, soaked in polidine 4%, washed with BSS and reinserted successfully with no further postoperative complications.

The mean thinnest corneal thickness was 407 µ with a range between 291 and 493 µ.

CASE REPORTS

Case 1

A 31-year-old female was diagnosed with advanced KC in her right eye. She was CL intolerant and was scheduled for corneal transplant. Her UCVA was counting fingers from 1.5 meters and BSCVA was 6/15 partial with manifest refraction of plano –12.00 × 50°. K minimum, K maximum and K average were 48.87, 55.5 and 52 respectively with a central corneal thickness of 388 µ.

On the 18/05/2009 she had an Intacs SK 0.4 mm pair inserted followed immediately by CXL using the method mentioned above few months postoperatively one segment extruded partially. The segment was extracted, cut, soaked in polidine 4%, washed with BSS and reinserted successfully with no further postoperative complications. Thirty-five months postoperatively, her UCVA was 6/18 and her BCVA was 6/6 partial with manifest refraction of + 4D = –4.0 Cyl *40°. K minimum, K maximum and K average were 47.12, 49.75 and 48.37 respectively.

The combined treatment has resulted in improvement in her UCVA, BSCVA and reduction of the K readings and the astigmatism (Figs 1 to 5).

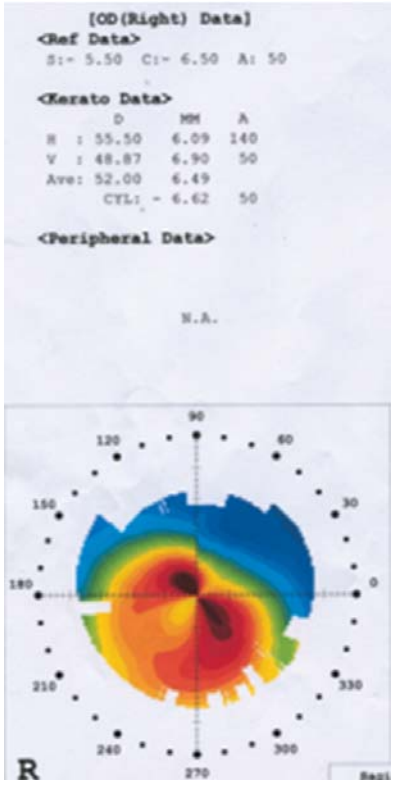

Fig. 1: Preoperative topography demonstrating KC with high K-values

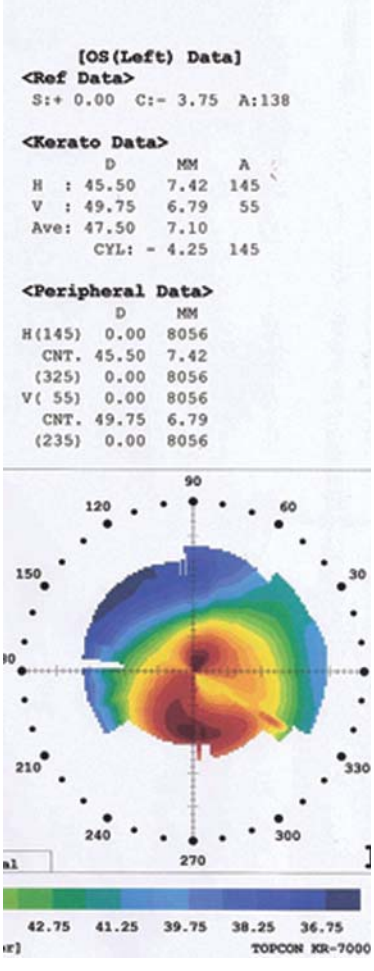

Fig. 2: Regularization of the corneal topography postoperatively and reduction in the K-values

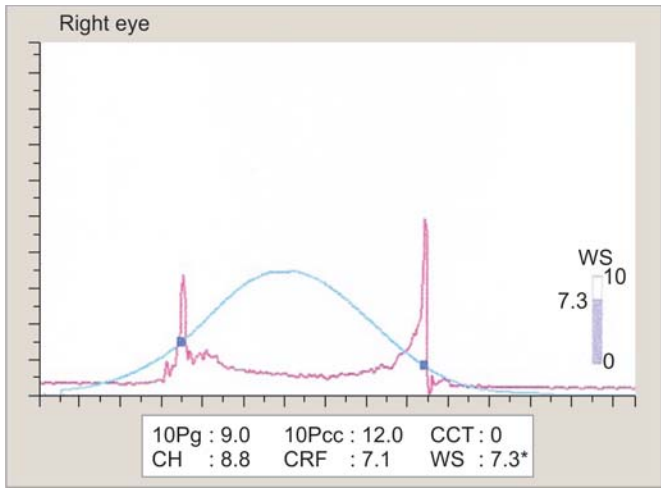

Fig. 3: Preoperative ORA

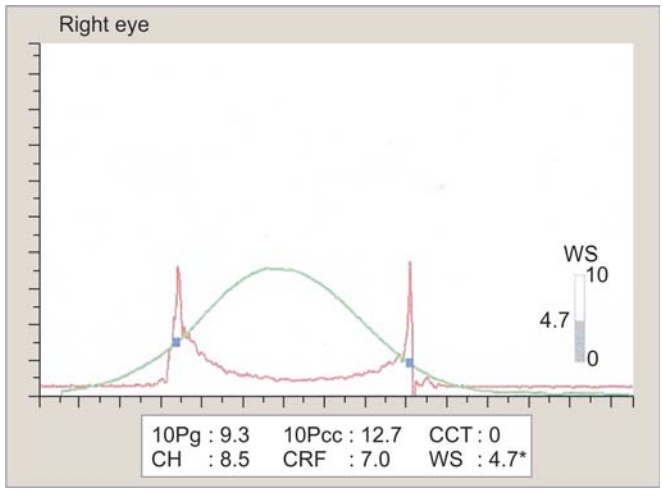

Fig. 4: Postoperative ORA

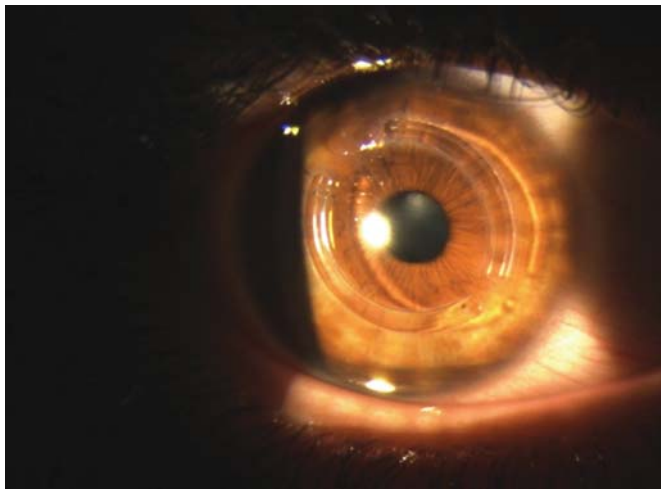

Fig. 5: Intacs SK in the cornea note the cut inferior edge of the temporal Intac SK in the LE

Case 2

A 27-year-old female, suffering from KC, with unsatisfactory VA with glasses and CL intolerant in her LE, Intacs SK were implanted on the 10th of February 2010

followed by CXL, preoperatively UCVA and BSCVA were 1/120 and 6/18 respectively, the K readings were: K minimum, K maximum and K average 61.12, 64.0 and 62.62 respectively with a refraction of +6.0 D and –11.0D Cyl*90 and central corneal thickness of 420 µ.

Twenty-two months postoperatively: UCVA and BSCVA were 6/30 and 6/15 respectively with a refraction of –0.5D and –4.0 D Cyl*130. The K readings were : K minimum, K maximum and K average 47.50, 52.62 and 49.87 respectively, a reduction of of more than 12 D in the K-values. BCVA with a soft keratoconus lens is 6/9. Scarring was noted in the channels where Intacs SK were inserted, and this may explain the increased effect of Intacs SK combined with CXL (Figs 6 to 8).

STATISTICAL ANALYSIS

Statistical analysis was performed with SPSS software using (version 16, SPSS Inc). Nine parameters were analyzed pre- and postoperatively. The data was analyzed using the pair t-test for each parameter. Data is expressed as mean differences between pre and post for each parameter (Tables 2 and 3).

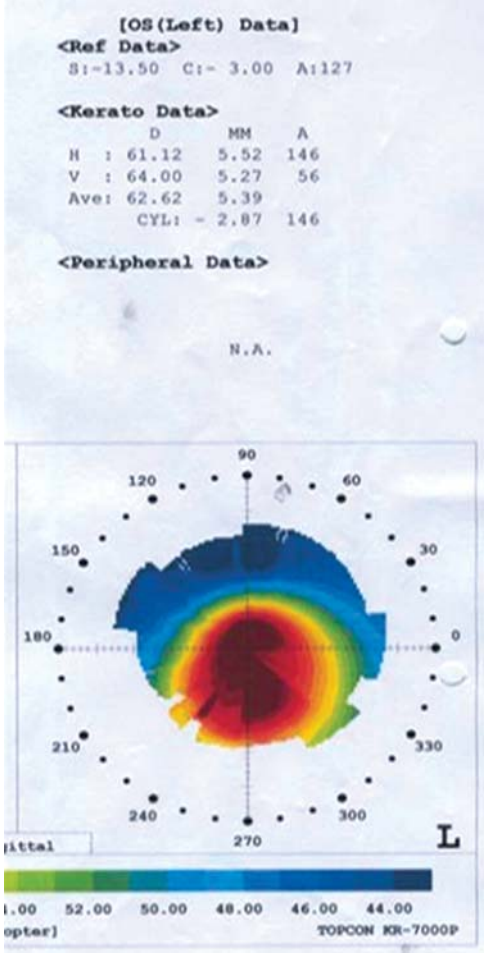

Fig. 6: Preoperative topography demonstrating KC with high K-values

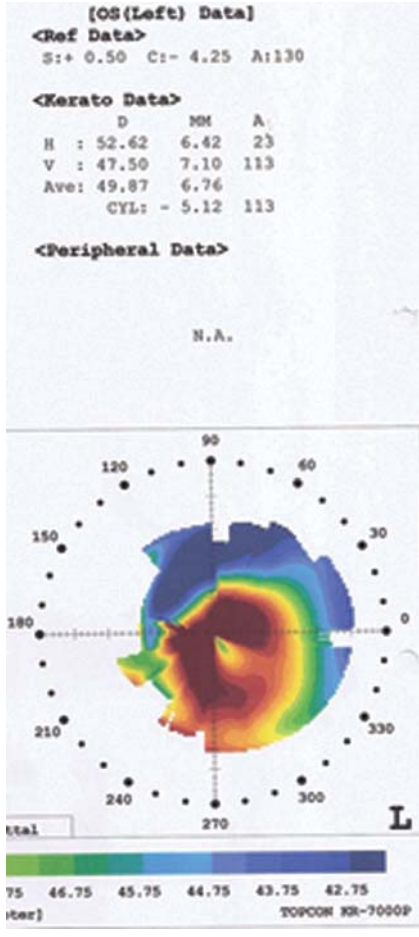

Fig. 7: Regularization of the corneal topography postoperatively and reduction in the K-values

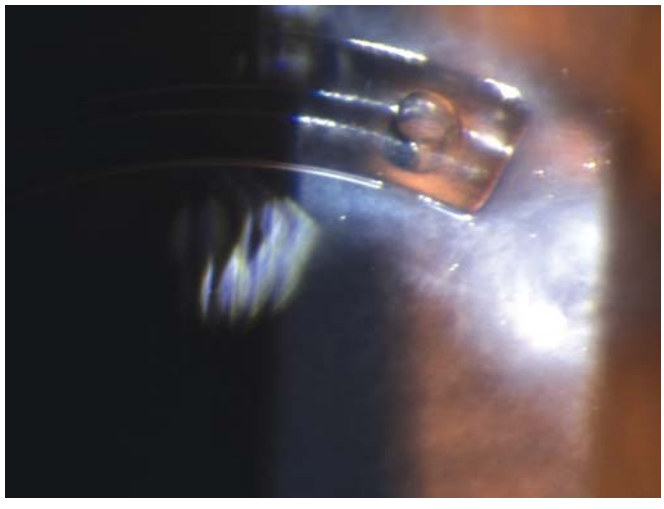

Fig. 8: Haze in the channel with the Intac SK, the haze (scaring) may explain the increased effect of the combined treatment

RESULTS

The study included 17 eyes of 14 patients 9 males and 5 females , The mean age was 25.7 years (range, 14-45 years). Mean follow-up (FU) was 15.4 months. FU ranged between 5 and 35 months (Tables 2 and 3).

Table 2: Preoperative and postoperative mean values for the nine parameters

	Descriptive statistics[a]				
	N	*Minimum*	*Maximum*	*Mean*	*Std. deviation*
Age when operated	17	14.00	45.00	25.7059	7.77628
Months to follow-up	17	5	35	15.41	7.641
Pre-UCVA	17	0.002	0.100	0.03393	0.038464
Post-UCVA	17	0.017	0.600	0.23863	0.172902
Pre-SPH	17	–19.00	6.00	–3.2500	6.72449
Post-SPH	17	–10.00	5.00	0.1471	3.77808
Pre-CYL	17	–12.00	–3.50	–9.7059	2.19416
Post-CYL	17	–8.00	–1.50	–4.6176	1.60594
Pre-BSCV	17	0.025	0.630	0.28341	0.171498
Post-BSCV	17	0.100	1.000	0.53641	0.241572
Pre-K_{max}	15	46.50	72.21	59.8540	8.30478
Pre-K average	15	45.50	70.50	56.8987	7.99119
Pre-K_{min}	15	43.62	69.12	54.2540	7.84223
Post-K_{max}	17	43.25	66.50	54.9841	7.96856
Post-K average	17	42.87	63.50	52.2671	7.30470
Post-K_{min}	17	40.10	60.50	49.7835	6.86875
CCt	17	291.00	493.00	407.0000	55.37034
Pre-CRF	17	5.00	8.20	6.6353	1.00557
Post-CRF	16	5.00	10.90	6.9063	1.63808
Pre-CH	17	5.50	11.20	8.3647	1.51201
Post-CH	16	6.50	13.50	8.8812	1.90935
Valid N (listwise)	15				

a. CXL: yes; UCVA: Uncorrected visual acuity; SPH: Sphere; CYL: Cylinder; BSCV: Best spectacle corrected visual acuity; ORA H: Ocular response analyzer corneal hysteresis; ORA RF: Ocular response analyzer corneal resistance factor; K_{max}: K maximum; K_{min}: K minimum

Table 3: Comparable results between the nine parameters measured using the t-test

		Paired sample test[a]							
		Paired differences							
					95% confidence interval of the difference				
		Mean	*Std. deviation*	*Std. error mean*	*Lower*	*Upper*	*t*	*df*	*Sig (2-tailed)*
Pair 1	pre-UCYA—post-UCVA	–0.204702	0.163323	0.039612	–0.288675	–0.120729	–5.168	16	0.000
Pair 2	pre-SPH—post-SPH	–3.39706	4.42565	1.07338	–5.67252	–1.12160	–3.165	16	0.006
Pair 3	pre-CYL—post-CYL	–5.08824	2.23072	0.54103	–6.23516	–3.94131	–9.405	16	0.000
Pair 4	pre-BSCY—post-BSCY	–0.253000	0.217112	0.052657	–0.364629	–0.141371	–4.805	16	0.000
Pair 5	pre-K_{max}—post-K_{max}	5.05600	3.85403	0.99511	2.92171	7.19029	5.081	14	0.000
Pair 6	pre-K average—post-K average	4.77600	3.65277	0.94314	2.75316	6.79884	5.064	14	0.000
Pair 7	pre-K_{min}—post-K_{min}	4.53933	3.79177	0.97903	2.43952	6.63914	4.637	14	0.000
Pair 8	pre-CRF—post-CRF	–0.25625	1.59121	0.39780	–1.10415	0.59165	–0.644	15	0.529
Pair 9	pre-CH—post-CH	–0.69375	1.79980	0.44995	–1.65280	0.26530	–1.542	15	0.144

a. CXL: yes; UCVA: Uncorrected visual acuity; SPH: Sphere; CYL: Cylinder; BSCV: Best spectacle corrected visual acuity; ORA H: Ocular response analyzer corneal hysteresis; ORA RF: Ocular response analyzer corneal resistance factor; K_{max}: K maximum; K_{min}: K minimum

VISUAL ACUITY

There was statistically significant improvement in the UCVA and BSCVA (decimal). The mean preoperative UCVA was 0.034. The mean postoperative UCVA was 0.24. The postoperative UCVA was significantly better than the preoperative UCVA ($p < 0.01$). The mean preoperative BSCVA was 0.28. The mean postoperative BSCVA was 0.54. The mean preoperative BSCVA was significantly better than postoperatively ($p < 0.001$) (Fig. 9).

Spherical and Cylindrical Change

There was statistically significant reduction in the sphere and significant reduction in astigmatism ($p < 0.001$) with a mean reduction of 3.1 and 5.1 D respectively (Fig. 10).

Keratometry

There was statistically significant change in the K minimum, K maximum and K average ($p < 0.01$) of 4.9, 5.1 and 4.5 D respectively (Fig. 11).

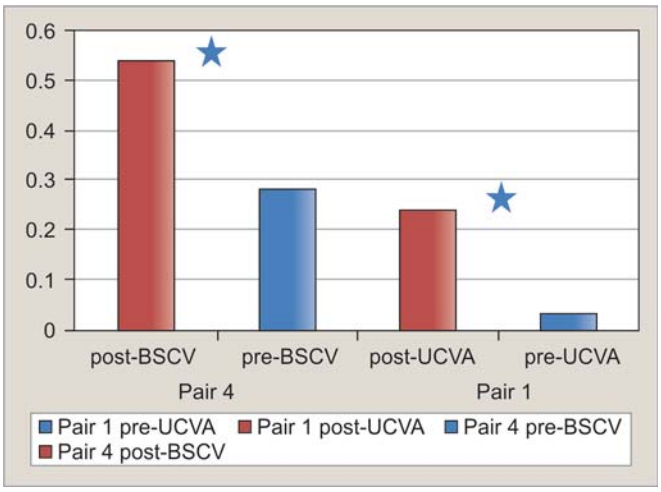

Fig. 9: Preoperative and postoperative UCVA and BSCVA

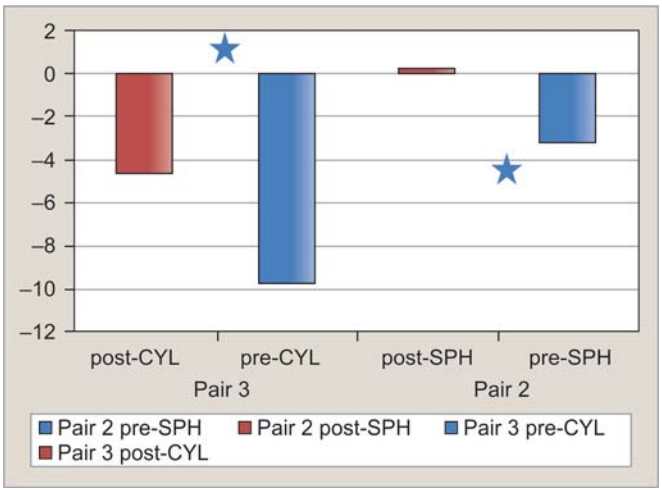

Fig. 10: Preoperative and postoperative sphere and cylinder values

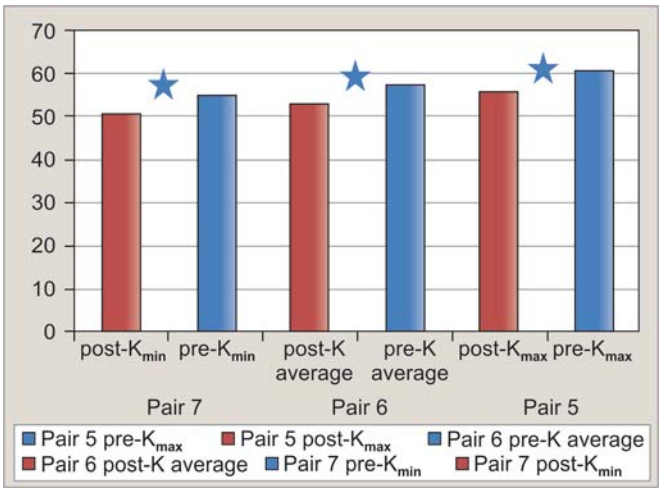

Fig. 11: Preoperative and postoperative keratometry readings

Corneal Resistance Factor and Corneal Hysteresis

No statistically significant change in corneal resistance factor (CRF) or corneal hysteresis (CH) (p = 0.529, 0.144 respectively) (Fig. 12).

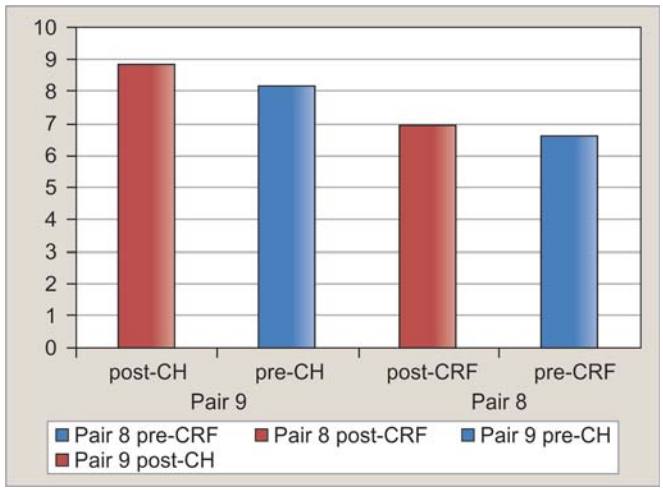

Fig. 12: Preoperative and postoperative CRF and CH values

DISCUSSION

This is a retrospective study on the effect of the combined treatment of Intacs SK and CXL in moderate to advanced KC.

In 15 of the 17 eyes, the CXL was performed immediately after the implantation of the Intacs SK. In two, CXL was performed few weeks in one eye and few months in another eye of another patient after Inatcs SK implantation and not immediately. These two patients suffered from severe KC and were scheduled for corneal transplant and we were not certain that the Intacs SK implantation would yield improvement in their vision significantly hence, we postponed the CXL till improvement in UCVA and BSCVA was evident. Our aim was to spare the patients the inconvenience and pain following CXL until we were sure that the Intacs SK implantation was effective in their case.

It has demonstrated improvement in the UCVA, BSCVA, and reduction of myopia, astigmatism and keratometry readings.

Intacs SK corneal rings seem to be a compromise between the traditional Intacs with the 7 mm diameter and the Ferrara rings which are 5 mm in diameter. The effect is is proportional to thickness of the ring inversely proportional to the diameter of the ring. Intacs with the 7 mm diameter were demonstrated to have less effect on corneas with advanced keratoconus with a K reading of more than 55°.[15]

There is only on study in the literature regarding the use of Intacs SK in keratoconus by Sansanayudh et al. They reported on Intacs SK in 10 eyes with a minimum FU of 6 months. There was improvement in UCVA and BCVA and a decrease in high order aberrations and increased tolerance to CL tolerance postoperatively.[12]

Intrastromal corneal rings combined with CXL are assumed to have an additive effect. This additive effect was demonstrated in few studies; Chan et al conducted a

retrospective randomized study which demonstrated that the combination of CXL with Intacs led to better results than Intacs alone. They demonstrated a greater than 2-fold reduction in the combined group compared to Intacs alone group in steep and average K-values. They also assumed that the pooling of riboflavin into the intacs channels may produce increased effect of the CXL.[16]

Ertan and Colin referred to a presentation of El Cadarso on six pig eyes. Each pig was randomly assigned either CXL alone or a combined Intacs and CXL. The eyes with the combined treatment demonstrated additional flattening compare to eyes receiving CXL alone. The effect was maintained even when Intacs were withdrawn from the corneas in the combined group.[17]

Kamburoglu et al also demonstrated the additive effect of the combined treatment. They treated cases of bilateral ectasia. The combined treatment of Intacs SK and CXL was compared to Intacs SK alone. The combined treatment was performed in an interval of 24 hours. In the immediate postoperative time, the Intacs SK group demonstrated satisfactory improvement in UCVA, BCVA and keratometry readings, however, these parameters had deteriorated 1 month postoperatively and the Intacs SK only group had to have CXL performed, regaining some of the improvement that was achieved with Intacs SK alone.[18]

Ertan et al compared the combined treatment of Intacs and transepithelial CXL to a matched group of Intacs alone on 25 eyes. They noted more improvement in the combined treatment modality, concluding that CXL has an additive effect.[14]

The combination of Intacs and CXL is a logical approach as the corneal rings reshape and regularize the cornea while CXL stabilizes it. The logic behind the additive effect of Intacs SK and CXL is that Intacs are more effective in keratoconic corneas than normal corneas. The uncross-linked keratoconic cornea is weaker than the cross-linked one and in the uncross-linked corneas the effect of rings is stronger. This hypothesis was confirmed by a recent study of Coskunseven et al.[19] He did a comparative study using intrastromal rings and CXL in different sequence. The two groups were followed for 13 ± 1 month. The interval between treatments was 7 ± 2 months. The two groups demonstrated improvement in UCVA, BCVA, and decrease in mean spherical equivalent (SE), cylinder and K-values. Nevertheless, the group which had intrastromal rings followed by CXL demonstrated more improvement in BCVA and decrease in mean SE and K-values compared to the other group.[19]

In our study, the patients had the two procedures at the same day to spare them the inconvenience of having two procedures done at two different occasions and save them days off work, pain and travel.

CRF and CH reflect the biomechanical characteristics of the cornea as measure by ocular response analyzer (ORA). CRF and CH are lower in keratoconic than normal corneas.[20-22] These values are supposed to increase after the combined treatment; nevertheless, as our results show they did not change significantly. These values do not reflect the clinical and topographic improvement achieved. ORA possess the sensitivity to detect keratoconus but lacks the specificity of detecting changes in these corneas at least with the software that we used , Reichert Ltd, purchased a new software which may be able to detect the changes in the biomechanical values after CXL . Our results confirm the study of Dauwe et al[23] which demonstrated that intrastromal rings implantation did not alter the viscoelastic biomechanical parameters of CH and CRF.

CONCLUSION

The combined treatment of Intacs SK and CXL for the treatment on keratoconus is safe and effective in improving vision of advanced and even very thin keratoconic eyes. It is another tool to face keratoconus challenges. Further studies are needed to evaluate the long-term efficacy and results of this combined treatment.

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