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Intrastromal Corneal Ring Segments (ICRS) insertion in steep Versus Flat axis for treatment of keratoconus

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Abstract

Keratoconus is an ectatic disorder that manifests itself around puberty. Despite the different ways of management of keratoconus, its management is a continuous field of research. The aim of this study was assessment of the efficacy of the Intrastromal corneal ring segments (ICRS) insertion in Steep Versus Flat axis for treatment of keratoconus. The study is a prospective, non-randomized, interventional clinical study, included a total of 30 eyes of 24 patients. We insert ICRS In two different site of cornea in the steep meridian vs. flat meridian and follow-up 1w,3m and 6 m. after surgery. this technique is statistically significant decreasing myopia, corneal steepness, and decentration of the of the corneal apex. The technique appears to be safe and is also potentially reversible. The corneal intrastromal implantation system provides a new option for keratoconus management.

1.Introduction

Keratoconus is a bilateral, corneal, ectatic, noninflammatory condition, the hallmark of which is progressive corneal steepening and thinning, which induces irregular astigmatism, myopia, and protrusion, leading to mild to marked impairment in the quality of vision and secondary loss of best-corrected visual acuity (BCVA) [1].

Over the last two decades, there has been a revolution in the knowledge related to the diagnosis and management of these conditions. In terms of diagnosis corneal topography has increased the ability of ophthalmologists to identify corneal ectasia at a much earlier stage than was previously possible [2].

Pentacam is a non-invasive system for measuring and characterizing the anterior segment using Scheimpflug photography. With this system a rotating Scheimpflug camera takes 100 images with 500 measurement points on the anterior and posterior corneal surfaces over a 180-degree rotation. The elevation data from all these images are combined to form a three-dimensional reconstruction of the corneal structure. After processing all this information, the internal software provides a large number of different calculations. It performs automatically the conversion of the corneal elevation profile into corneal wave front data [3].

Treatment for keratoconus include different procedures, such as rigid gas permeable contact lens wearing, thermokeratoplasty & intrastromal corneal ring segment(s) (ICRS), corneal cross linking (CXL), therapeutic excimer laser treatments including phototherapeutic keratectomy and photorefractive keratectomy (PRK), and phakic intraocular lens or in combination have been proposed to delay or even prevent the need for corneal transplantation [4].

The insertion of intrastromal corneal ring segments (ICRS) is one of the treatment options that have been gaining popularity during the last decade. First evaluated as a treatment for mild to moderate myopia, these polymethyl methacrylate (PMMA) segments modify the corneal curvature by an arc shortening, flattening effect and have proven especially effective in reducing the irregular astigmatism caused by keratoconus [5].

Prior to implantation, a tunnel is created at a 70%-80% corneal depth, either by manual dissection, or with the femtosecond technology, the latter having a better safety accuracy profile [6].

Once inserted within the tunnel, the ICRS interacts with the corneal tissue and produces local flattening of the cornea. This flattening effect is believed to be related to both the geometrical properties of the ICRS (shape, arc length and thickness), and to its position relative to the corneal steep or flat axis [7].

Nomograms are proposed by the rings' manufacturer to help physicians in choosing the appropriate segment that would induce the desirable flattening effect. However, a lot of controversy remains concerning many technical issues like the incision site-whether it should be performed over the steep versus the flat axis and like the number of rings to use and whether to insert superior rings or not [8].

The aim of this study was assessment of the efficacy of the Intrastromal corneal ring segments (ICRS) insertion in Steep Versus Flat axis for treatment of keratoconus.

2. Patient and method

The study included 30 eyes presenting with the diagnosis of keratoconus for ICRS implantation. Two groups created according to site of ICRS implantation (steep axis group, 15 eyes) and (Flat axis group, 15 eyes). ICRS will be indicated because of existence of reduced best spectacle- corrected visual acuity (BSCVA) or contact lens intolerance. The patients included in the study must have keratoconus with mild to moderate degree of the disease & clear optical

zone and who are contact lens intolerant, with visual acuity less than 0.3, kmax not less than 42D and not more than 65D and Patients must agree to undergo all clinical investigation plan require. Patients with central or para central scarring, opacity, or in the progressive phase of the disease, patients with kmax less than 42D and kmax more than 65D,who has undergone previous intra-ocular or corneal surgery, or with active ocular disease other than keratoconus, or patients with previous hydrops, scarring and severe Keratoconus, or patients with systemic diseases that likely affects wound healing such as insulin dependent diabetes mellitus, patients with collagen vascular diseases, autoimmune diseases will be excluded from the study.

2.1 Pre-operative evaluation

- Visual acuity (uncorrected and best corrected visual acuity).
- Cycloplegic refraction.
- Slit lamp examination.
- Dilated fundus examination.
- K-readings and corneal thickness.
- Pentacam

In all cases antibiotic prophlyaxis consisting of topical ciprofloxacin was prescriped every eight Hours for two days before surgery. all procedures were performed under topical anaethesia and complete aseptic measures.

2.2 Post-operative treatment

The following was prescribed for all patients:

- Topical moxifloxacin hydrochloride 0.5% eye drops five times daily for one week.
- Topical fluoromethalone 0.1% eye drops four times daily for one week.
- Topical lubricant refresh liquigel four times daily for one month.
- Vitamin C sachets once daily for one month.
- Voltaren tablets for pain as needed for first two days after meals.

Postoperative visits were scheduled for the first postoperative day,3months and the 6 months. On the first postoperative day, UCVA measurement and slit-lamp examination (intracorneal segment position and corneal integrity) were performed.

First week after surgery the treatment was adjusted & contact lens was removed. To assess the effect of femtosecond assisted intra corneal ring segment implantation in cases of keratoconus in the following:

- Uncorrected visual acuity (UCVA).
- Best corrected visual acuity (BCVA).
- Mean refractive astigmatism.
- Spherical equivalent.
- K- readings.
- Topographic cylinder.
- Corneal thickness at thinnest point.
- Y- orientation of thinnest point.

3. Results

In the present study, The age of the study population ranged from 20 to 47 years with mean age of 35.93 ± 8.12 years, Sixteen patients were males representing 53.3% of the study population, 14 were females representing 46.7% of the study population, 15 right eye representing 50% of the studied group while 15 left eye representing 50% of the studied group.

In the present study, The intrastromal tunnel for intra-corneal ring segments implantation was performed by means of the 150 kHz femtosecond technology (WaveLight® FS200 Femtosecond Laser).

In the present study the ICRS was inserted in the steep meridian in 15 eyes representing 50% of the studied group while inserted in the flat meridian in the other 15 eyes representing 50% of the studied group which represent novel technique.

In the present study procedure related complication include ring segment extrusion occurred in 6.7% of patients while Corneal neovascularization in 3.3 %, Corneal haziness in 3.3 %, Infectious keratitis in 3.3 %. ICRS decenetration in 3.3 %.Yellow white deposits in 3.3 %, Disc form keratitis in 3.3 %, Epithelial plug at the incision in 3.3 %.

Immediate post-operative keratometric changes In the steep group: shows the mean central corneal curvature (average K) was reduced from 51.1±1.65 to 47.47 ± 1.74 in the steep group with reduction about 3.6 D and that was stastically highly significant P value (<0.001). k1 was reduced from 48.28±1.64 to 46.22 ± 2.91 About 2.06 D and that was stastically significant P value (0.009) while k2 was reduced from 54.0 ± 1.72 to 49.31 ± 1.93 About 4.48 and that was stastically highly significant P value (<0.001). The spherical equivalent is reduced from 5.87 ± 0.76 to 2.61 ± 0.86 about 3.16 D that was stastically highly significant P value (<0.001). The mean preoperative refractive astigmatism reduced -5.35 \pm 0.97 to -1.82 \pm 0.96 About 3.81 with stastically highly significant P value (<0.001) While topographic cylinder reduced from 3.66 ± 0.729 about 2.11 that was 5.69 ±0.8 to stastically highly significant P value (<0.001).

Immediate post-operative Refractive changes In the steep group: The mean preoperative UCVA improved from 0.097 ± 0.035 to 0.27 ± 0.11 was stastically highly significant P value (<0.001). while the mean preoperative BCVA improved from $0.26 \pm$ 0.12 to 0.57 ± 0.17 with stastically highly significant P value (<0.001). UCVA improved in 93.3%, more than 2 lines gained in 60% of patients, While 26.6% gained 2 lines,6.6% Gained 1 line and 6.6% not improved. BCVA improved in 93.3% of the studied group, 53.3% gained more than 2 lines, While 33.3% of patients Gained 2 lines and 6.6% of patient Gained 1 line, 6.6% of patients not changed,none patient were worsened.

Immediate post-operative keratometric changes In flat group:

shows that the average K in the Flat group was reduced from 51.88 ± 1.81 to 50.19 ± 1.76 about 1.83 P

value (<0.001).The k1 was reduced from 49.12 \pm 1.9 to 47.68 \pm 1.77 about 0.57 P value (0.009) while The k2 was reduced from 54.83 \pm 1.76 to 52.72 \pm 1.71 about 2.16 and P value (<0.001).SE is reduced from 5.76 \pm 0.84 to 4.21 \pm 1.02 about 1.37 P value (<0.001). While topographic cylinder reduced from 5.74 \pm 1.07 to 5.04 \pm 0.97 about 0.08 P value (<0.001).

Immediate post-operative Refractive changes In the Flat group: UCVA was improved in 53.3% of the studied group with None patients improved more than 2 lines in snellen chart for V.A of the studied group While 13.3% Gained 2 lines and 40% Gained 1 line. 26.6% of patients showed no improvement. while 20% patients were worsened.

BCVA in the flat group was improved in 66.6% of the studied group with none patients improved more than 2 lines, 13.3% patients gained 2 lines 53.3% Gained 1 line.20% showed no improvement. While 13.3 were worsened

The Degree of improvement was better in the steep Fig(1)Vs The flat group Fig(2) so we changed the site of insertion in 9 patients from flat to steep who showed worsen or no improvements in K reading or refractive measurements Fig (3).

Post-operative keratometric changes after 6 Month These results after we change the site of insertion in 9 cases after 3months from the flat axis to tradional site (steep meridian)axis, at 6 months follow up the mean central corneal curvature (average K) was reduced from 51.49 ± 1.75 to 47.92 ± 1.88 with highly significant P value (<0.001) so decrease keratometric reading by (3-5) diopeter. The k1 was reduced from 48.7 ± 1.8 to 46.28 ± 2.42 and that was stastically highly significant P value (<0.001) while The k2 was reduced from 54.41 ± 1.76 to 49.87 ± 2.13 and that was stastically highly significant P value (<0.001). The preoperative spherical equivalent is reduced from 5.82 ± 0.79 to 2.72 ± 0.99 with significant P value (<0.001).

Post operative Refracive changes after 6 Month Fig (4) These results after we change the site of insertion in 9 cases after 3months from the flat axis to tradional site (steep meridian)axis. UCVA after 6 months improved in 90% of patients 50% gained more than 2 lines, 30% Gained 2 lines, 10% Gained 1 line, 10% showed no improvement. None patients were worsened at this group & BCVA was improved in 93.3% of patients,30% gained more than 2 lines, 53.3% Gained 2 lines and 10% patients Gained 1 line, 6.6% showed no improvement. None patients were worsened at this group of patients.



Fig (1) UCVA improved in the steep group



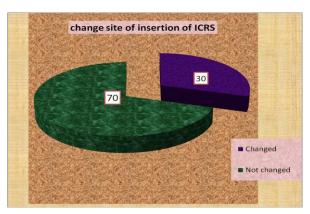


Fig (3) Change site of insertion

Changed group (9)	3 m Mean ±SD	6 m Mean ±SD	Paired t test	P value
k2	49.19±1.75	49.19±1.75	16.66	< 0.001**
KM	50.47±2.03	47.45±1.94	15.5	< 0.001**
Topographic cylinder	5.05 ± 0.62	3.48 ± 0.85	15.88	< 0.001**
UCVA	0.13±0.04	0.26±0.13	3.62	0.007**
BCVA	0.33±0.12	0.58±0.12	9.63	< 0.001**
Refraction		-4.19±0.92		
Sphere	-2.44 ± 0.58	-1.39±0.52	6.19	< 0.001**
Cylinder	-4.19±0.92	-1.72±0.46	12.52	< 0.001**
Pre seq	4.54±0.83	2.23±0.59	11.28	<0.001**
Pachy apex	423.89±14.77	423.89±14.77	-	-
Thinnest location	412.78±14.7	423.22±15.75	10.29	<0.001**
y-orientation	-0.51±0.08	-0.31±0.09	5.2	0.001**

Table (1) post-operative data at changed group at 6 Month.

Table (2) post operative data at All studied at 6 Month.

All study group (30)	Pre operative	6 months	Paired t test	P value
	Mean ±SD	Mean ±SD		
k1	48.7±1.8	46.28±2.42	7.02	< 0.001**
k2	54.41±1.76	49.87±2.13	30.81	< 0.001**
KM	51.49±1.75	47.92±1.88	29.49	< 0.001**
Topographic cylinder	5.72±0.93	3.88±1.07	20.28	< 0.001**
UCVA	0.096±0.035	0.25±0.12	8.77	< 0.001**
BCVA	0.25±0.11	0.54 ± 0.16	16.31	< 0.001**
Sphere	-2.82 ± 1.64	-1.93±1.24	2.49	0.019*
Cylinder	-5.28 ± 0.93	-2.04 ± 0.88	20.75	< 0.001**
Seq	5.82±0.79	2.72±0.99	30.19	< 0.001**
Pachy apex	416.33±12.72	421.07±12.74	37.49	< 0.001**
Thinnest location	400.43±12.93	419.1±13.78	46.76	< 0.001**
y-orientation	-0.716 ± 0.078	-0.34 ± 0.09	39.9	< 0.001**

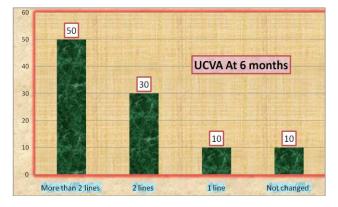


Fig (4) UCVAimprovement in total group at 6 Months

4. Discussion

This is a single center, The study was retrospective, non-randomized, interventional clinical study, included a total of 30 eyes of 24 patients with keratoconus diagnosed according to the standard criteria. Diagnosis was based on slit-lamp observation and corneal topography.

In the present study, The age of the study population ranged from 20 to 47 years with mean age of

 35.93 ± 8.12 years, Sixteen patients were males representing 53.3% of the study population, 14 were females representing 46.7% of the study population, 15 right eye representing 50% of the studied group while 15 left eye representing 50% of the studied group

A similar population were studied by [9]. Who Studied 40 eyes of 31 patients (19 men, 12 women) with a mean age of 38 years.

However [10] *Studied bigger group* with total of 611 consecutive keratoconic eyes of 357 patients

treated with ICRS implantation; 213 were male and 144 were female, ranging in age from 10 to 73 years (mean age: 35.15 years). In comparison to [11] who studied ICRS in pediatric Fourteen eyes of 14 patients, with a mean age of 15.36 years (range 10–18 years).

The present study The intrastromal tunnel for intracorneal ring segments implantation was performed by means of the 150 kHz femtosecond technology (WaveLight® FS200 Femtosecond Laser).

A similar population were studied by [12] who used the same femto second technology (WaveLight® FS200 Femtosecond Laser).

And concordnat with [13] used the same technology on 56 eyes with keartoconus using Femtosecond Laser.But Discordant with [14] who Compare the surgical vs Femtosecond Laser in insertion of the ICRS in patients with Keartoconus And discordant with [15] who use the tradictional surgical technique in insertion of the ICRS in patients with Keartoconus.

And also discordant with [16] Who insert ICRS By surgical technique in patients with Keartoconus & keratoectasia.

In the present study the ICRS was inserted in the steep meridian in 15 eyes representing 50% of the studied group while inserted in the flat meridian in the other 15 eyes representing 50% of the studied group which represent novel technique.

These data discordant with [11] who insert ICRS in the steep meridian axis.And also discordant with [13] who insert ICRS in the steep meridian axis also.

In the present study procedure related complication include ring segment extrusion occurred in 6.7% of patients while Corneal neovascularization in 3.3 %, Corneal haziness in 3.3 %, Infectious keratitis in 3.3 %. ICRS decenetration in 3.3 %.Yellow white deposits in 3.3 %, Disc form keratitis in 3.3 %, Epithelial plug at the incision in 3.3 %.These results are in agreement with El Araby et al [17] who found ring extrusion in (12.0%), ring decentration in (4.0%) and infectious keratitis in one case (4.0%).

And disagree with [18] who reported 0% Complication in his study on 15 eyes of 15 patients with the same device (Kera ring) ICRS.This can be explained by different site of insertion as in our study in the flat group the majority of complications 16.7% Vs 3.7 in the steep group.

Our result shows the mean central corneal curvature (average K) was reduced from 51.1 ± 1.65 to 47.47 ± 1.74 in the steep group with reduction about 3.6 D and that was stastically highly significant P value (<0.001). k1 was reduced from 48.28 ± 1.64 to 46.22 ± 2.91 About 2.06 D and that was stastically significant P value (0.009) while k2 was reduced from 54.0 ± 1.72 to 49.31 ± 1.93 About 4.48 and that was stastically highly significant P value (<0.001). The spherical equivalent is reduced from 5.87 ± 0.76 to 2.61 ± 0.86 about 3.16 D that was stastically highly significant P value (<0.001). The mean preoperative refractive astigmatism reduced -5.35 \pm 0.97 to -1.82 \pm 0.96

About 3.81 with stastically highly significant P value (<0.001) While topographic cylinder reduced from 5.69 ± 0.8 to 3.66 \pm 0.729 about 2.11 that was stastically highly significant P value (<0.001).

These results in agree with (18) significant improvement in spherical equivalent refractive error from -5.46 ± 1.52 diopters (D) preoperatively to -2.01 ± 1.63 (P < 0.001) postoperatively. The mean *K* readings improved in the same period, from $48.11\pm1.95D$ to 43.31 ± 2.31 (P < 0.001).

Our result, (5),Figure(28), Figure (29): The mean preoperative UCVA improved from 0.097 ± 0.035 to 0.27 ± 0.11 was stastically highly significant P value (<0.001). while the mean preoperative BCVA improved from 0.26 ± 0.12 to 0.57 ± 0.17 with stastically highly significant P value (<0.001). UCVA improved in 93.3%, more than 2 lines gained in 60% of patients, While 26.6% gained 2 lines,6.6% Gained 1 line and 6.6% not changed.BCVA improved in 93.3% of patients Gained 2 lines and 6.6% of patient Gained 1 line, 6.6% of patients not changed.

These results in agree with (11), Baseline average UCVA and BCVA were 0.07 ± 0.09 and 0.34 ± 0.21 , respectively, and they improved to 0.25 ± 0.15 and 0.54 ± 0.17 after ICRS implantation (p<0.01).

These results in agree with (18), The mean UCVA improved significantly from 0.79 ± 0.48 to 0.28 ± 0.15 logMAR (P = 0.001). The mean preoperative BCVA was 0.36 ± 0.21 improved to 0.18 ± 0.91 logMAR (P = 0.009)

Our result shows that the average K in the Flat group was reduced from 51.88 ± 1.81 to 50.19 ± 1.76 about 1.83 P value (<0.001).The k1 was reduced from 49.12 ± 1.9 to 47.68 ± 1.77 about 0.57 P value (0.009) while The k2 was reduced from 54.83 ± 1.76 to 52.72 ± 1.71 about 2.16 and P value (<0.001).SE is reduced from 5.76 ± 0.84 to 4.21 ± 1.02 about 1.37 P value (<0.001). While topographic cylinder reduced from 5.74 ± 1.07 to 5.04 ± 0.97 about 0.08 P value (<0.001).

These results disagree with (12), K1 decrease 3.26 D, *P value*0.02, K2 decrease 3.01 D, $P \le 0.01$, mean K decrease 3.24 D, *P value* (≤ 0.01). That could be explained by small number of patients & different site of insertion.

UCVA in flat group was improved in 53.3% of the studied group with None patients improved more than 2 lines in snellen chart for V.A of the studied group While 13.3% Gained 2 lines and 40% Gained 1 line. 26.6% of patients showed no improvement. while 20% patients were worsened.

These results disagree with (12) who use different devices there was improvement in total of 82.8% of patients, 36.3% of patients gained more than two lines of CDVA, while 10% of patient gained two line, and 36.5% Gained 1 line. 17.2% of patients showed no improvement.

That could be explained by different device and different site of insertion as in this group of patient we

insert (Kerraring) in the flat meridian axis against all studies as de novel technique

These results after we change the site of insertion in 9 cases after 3months from the flat axis to tradional site (steep meridian)axis, at 6 months follow up the mean central corneal curvature (average K) was reduced from 51.49±1.75 to 47.92±1.88 with highly significant P value (<0.001) so decrease keratometric reading by (3-5) diopeter. The k1 was reduced from 48.7 ± 1.8 to 46.28 ± 2.42 and that was stastically highly significant P value (<0.001) while The k2 was reduced from 54.41±1.76 to 49.87 ± 2.13 and that was stastically highly significant P value (<0.001). The preoperative spherical equivalent is reduced from 5.82 ± 0.79 to 2.72 ± 0.99 with significant P value (<0.001).

These results agree with [19] who studied Thirtyfive eyes of 28 patients. Corneal topography showed corneal flattening in all eyes. The mean minimum K value decreased from 48.99 D preoperatively to 44.45 D postoperatively and the mean maximum K value, from 54.07 D to 48.09 D, respectively the decreases were statistically significant (P value <0.001).

These results agree with [11] who studied ICRS In pediatric Fourteen eyes of 14 patients at 6 months follow up found that K minimum (K min) decreased from 48.9 ± 3.25 to 45.29 ± 3.45 D (p=0.001) and K maximum (K max) reduced from 55.92 ± 4.56 to 51.4 ± 3.33 D (p=0.002) 6–12 months after surgery.

But disagree with [15] who studied Intacs ICRS treatment of Keratoconus implantation Six months postoperatively in a prospective study and the mean keratometry value decreased just (0.75 d).

That could be explained that they use another device (Intacs) in

And also disagree with [20] also using the same device (keraRing) but with surgical technique. As regard to corneal curvature, there was significant decrease of K1, K2 and Km postoperatively, compared to corresponding preoperative values $(46.52\pm4.15,49.94\pm5.96, \text{ and } 48.23\pm4.85 \text{ vs} 48.67\pm4.46,54.03\pm5.46 \text{ and } 50.94\pm4.65 \text{ respectively})$. The mean decrease in Km was 2.7 D.

The mean decrease in the K mean was better in our study (3-5) D Vs (2.7) D in this study. That could be explained that Also using the same device but with different surgical technique.

Our results after we change the site of insertion in 9 cases after 3months from the flat axis to tradional site (steep meridian)axis. UCVA after 6 months improved in 90% of patients 50% gained more than 2 lines, 30% Gained 2 lines, 10% Gained 1 line, 10% showed no improvement. None patients were worsened at this group & BCVA was improved in 93.3% of patients,30% gained more than 2 lines, 53.3% Gained 2 lines and 10% patients Gained 1 line, 6.6% showed no improvement. None patients were worsened at this group of patients.

These results agree with [20] also using the same device (kera Ring)but with surgical technique As

regard improvement in

UCVA, there was no change in 3 cases (12.0%), improvement in 21 cases (84.0%) and deteriorated in one case (4.0%). In addition, as regard to improvement in BCVA, there was improvement in 24 cases (96.0%) and deterioration in in one case (4.0%).

These results in agree with [21] At the 6-month follow-up examination, the mean UCVA increased from 0.10 ± 0.11 to 0.32 ± 0.25 (P, 0.05),The mean BSCVA increased from 0.36 ± 0.23 to 0.57 ± 0.24 (P, 0.05). The BSCVA remained at the preoperative level in (7.3%) and increased in (87.3%). Of these, 31eyes (56.4%) gained 2 to 4 lines of VA and (5.5%) gained 5 to 8 lines of VA., (5.5%) had a 1-line decrease in BSCVA.

But disagree with [14] who compare insertion of Intacs by femto vs mechanical surgery, UCVA improved in both groups at 6 months(P,0.02) and BSCVA improved in the Femtosecond group and not improved in in the Mechanical group ($r_{-}0.63$, $P_{-}0.04$).

That could be explained that Also using the same device but with different surgical technique there were no improvement in the mechanical group.

These results disagree with [9] By 6 months after ICRS implantation, 12.5% of patients had lost 1 line, 22.5% had no change, 22.5% of eyes gained 1 line, 22.5% eyes gained 2 lines, and 20% eyes gained more than 2 Lines.

That could be explained that Also using the same device but with different mechanical technique, different type of patients with different degree of keratoconus.

5.Conclussion

Insertion of intra corneal segments in the steep axis is better than flat axis

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