• Original Article •

Clinical effectiveness of intrastromal corneal ring segments among keratoconus patients

Abdullhamid Alghamdi

Faculty of Medicine, Department of Ophthalmology, Ophthalmology Unit, Taif University, Taif 21974, Kingdom of Saudi Arabia

Correspondence to: Abdullhamid Alghamdi. Faculty of Medicine, Department of Ophthalmology, Ophthalmology Unit, Taif University, Taif 21974, Kingdom of Saudi Arabia. drghamdieye@hotmail.com

Received: 2019-09-20 Accepted: 2020-06-15

Abstract

• AIM: To evaluate the clinical effectiveness of intrastromal corneal ring segments (ICRS) among the patients suffering from keratoconus.

• METHODS: A retrospective and non-comparative interventional design had been utilized on the basis of postoperative follow-up among 56 keratoconus patients. Visual acuity was significantly assessed during complete ophthalmic examination of the patients. The femtosecond laser had been used to create the corneal tunnels in 15 eyes; whereas, the corneal tunnels were created in 72 eyes mechanically.

• RESULTS: The ranges and standard deviations had been used to obtain results. It had been revealed through ophthalmic assessment that the mean preoperative uncorrected visual acuity observed was 1.38±0.37 logarithm of Minimal Angle of Resolution. Moreover, a significant improvement was observed postoperatively in visual acuity by 0.58±0.32 during the 4th month. The improvement was also witnessed in the 16th month by 0.48±0.30.

• CONCLUSION: The implantation of ICRS is an efficient and effective surgical intervention for the treatment of keratoconus. Thus, identified intervention seems to be associated with appropriate visual outcomes and safety after the development of femtosecond as well as mechanical tunnels.

• KEYWORDS: keratoconus; intrastromal corneal ring segments; keraring implantation; femtosecond tunnels; mechanical tunnels

DOI:10.18240/ier.2020.03.02

Citation: Alghamdi A. Evaluation of clinical effectiveness of intrastromal corneal ring segments among keratoconus patients. *Int Eye Res* 2020;1(3):140-144

INTRODUCTION

A decline in corrected as well as uncorrected visual acuity is considered as a severe ophthalmic clinical issue, which is based upon diverse diseases of corneal ectatic. Such diseases mainly include pellucid marginal degeneration, keratoconus, and post LASIK ectasia, which usually results in impaired vision. Cornea is observed to be a highly affected ophthalmic structure in majority of the patients from mild to severe intensity. A significant number of clinical and surgical alternatives are available for visual correction of the patients. For the treatment of differential corneal ectatic disorders from mild to moderate grades, a new modality has been generated that is known as intrastromal corneal ring segments (ICRS)[1].

The implantation of ICRS is a minimally invasive and tissue saving surgical procedure, which is generally used for the treatment of keratoconic corneas. The efficiency of ICRS has been evidenced from various past literatures in accordance with the treatment of different corneal complications. These complications include myopia, post-LASIK ectasia, and astigmatism[2-3]. Pinero *et al*[4] has examined the aberrometric alterations in corneas through post-LASIK keratectasia, which is treated by implanting ICRS. The implantation of ICRS has been performed with an objective to reduce the spherocylindrical error as well as to enhance the quality of vision. It has been evaluated through postoperative outcomes that intensively lower improvement has been observed in regards to uncorrected visual acuity during initial days after surgery. However, a non-significant reduction in sphere has been determined at 6mo, and the manifest cylinder has been significantly declined during the postoperative follow-up. Thus, the implantation of ICRS has been assessed as a valuable intervention to treat astigmatism and coma-like aberrations in post-LASIK corneal ectasia[4].

An evolution in the usage of ICRS for the treatment of corneal ectasia has been scrutinized by Park and Gritz[5]. It has been evaluated through post surgical outcomes that ICRS has resulted in the improvement of refractive, visual, and keratometric parameters among patients being diagnosed with post laser *in situ* keratomileusis ectasia and keratoconus disorders. Femtosecond lasers have been used to make ICRS quicker, safer, and more accurate for the insertion of rings.

Table 1 Manufacturer's normogram of thickness and segment distribution according to se and ectasia

S.E	0/100	25/75	33/66	50/50
	All ectasia is limited to one half of the cornea.	75% of the ectasia in one half of the cornea and 25% situated in the other half.	Two-thirds of the ectasia area in one half of the cornea and one third in the other half.	The ectasia is distributed evenly in both corneal halves.
>-10 D	26/35	26/35	31/35	35/35
-8 to -10 D	21/30	21/30	26/30	30/30
-6 to -8 D	16/25	16/25	21/25	25/25
-2 to -6 D	0/20	0/20	16/20	20/20
<-2 D	0/15	0/15	15/15	15/15

Moreover, the results demonstrated that better visual outcomes can be developed by ICRS among patients having poor preoperative corrected distance visual acuity. Thus, it has been determined that visual acuity can be improved variably through the usage of ICRS[5].

Keratoconus is a progressive corneal ectasia, which is likely to be controlled through conservative measures, chiefly include contact lenses or glasses in non-progressive situations. Furthermore, it can also be managed through surgical procedures such as collagen cross linking (CXL), with or without adjuvant measures. The surgical procedure of implantation seems to be easier, faster, and comfortable by using femtosecond laser in the development of corneal tunnel. From the past research, it is evidenced that the safety of implantation procedure becomes higher through femtosecond laser[6]. Therefore, it can be said that ICRS is a safe and an appropriate option to avoid corneal complications and visual problems among patients, suffering from keratoconus disease. Besides this, the treatment through ICRS provides excellent outcomes, regarding the acuity of vision, change in topography, and tolerance to the contact lenses. It has been recommended that it is mandatory to consider different factors, which can impact the response to treatment before planning the procedure of surgery. Such valuable factors include the biomechanics of eye, location of cone, and the severity of keratoconus[7].

Israel *et al*[8] scrutinized the optical value of ICR among the patients of keratoconus. The objective was to evaluate the quantification of subsequent changes in corneal asphericity and topography. The patients with primary keratoconus or keratectasia after laser *in situ* keratomileusis have been considered as the study sample. Rings have been generated by using a femtosecond laser or manually, and tunnels have been used for implantation of rings. At an incision site, all eyes had a clear visual axis, and the thickness of corneal was over 450 μm. Thus, it has been examined that visual improvement and topography in post-LASIK keratectasia and keratoconus is provided by ICRS through the outcomes[8].

Numerous ICRS are commercially available that varies on the basis of its width, curvature, and implantation zone. Keraring is a form of ICRS, which is a small, arc-like segment, and is made up of polymethyl methacrylate. Keraring is generally distinguished by a unique prismatic design, which compresses the cornea for better visual outcomes. Similarly, it has also reduced the incidence of halos and glare. The central curvature of cornea is flattened due to Keraring by providing an addition of tissue to stabilize the progression of ectasia[9]. Thus, the primary objective is to examine the effectiveness and safety regarding the implantation of Keraring for treatment of different stages of keratoconus with the usage of mechanical and femtosecond assisted tunnel creation.

SUBJECTS AND METHODS

Ethical Approval The study was conducted in accordance with the principles of the Declaration of Helsinki and the informed consent was obtained from the subjects.

The patients with intolerance of contact lenses and clear central corneas have been considered as the study participants. Totally 87 eyes of 56 patients suffering from keratoconus have been taken as the sample size. All eyes have been categorized into four stages, depending on its severity to keratoconus, as proposed by Amsler-Krumeich[10]. In stage I, 12 eyes have been considered, stage II was consisted of 34 eyes, stage III was comprised of 20 eyes, and 21 eyes have been used in stage IV. The femtosecond laser has been implied to make the corneal tunnels in 24 eyes. For 63 eyes, the corneal tunnels have been made mechanically. In each eye, the Keraring has been implanted, which was comprised of an arc length of 160 degree and 5 mm diameter, as shown in Table 1. The informed consent form has been provided to each participant to ensure the confidentiality of the data collected. All the procedures were explained regarding the participation and surgical techniques. The research approval has been granted from the ethics committee for the selection of individuals demonstrating every single measure to ensure confidentiality of data. In Table 1, SE illustrates the level of steepness, 0/100 demonstrates ectasia limited to one half of the cornea. 25/75 shows 25% of the ectasia situated in one half of the cornea and 75% situated in the other half. Similarly, 33/66 displays one-third of the ectasia situated in one half of the cornea and two-thirds situated in the other half. Finally, 50/50 indicates that the ectasia is evenly distributed in both corneal halves.

The surgical procedures have been carried out under topical anesthesia. As the central point, purkinje reflex has been selected. An ultrasonic pachymetry has also been used for the measurement of corneal thickness at the corneal diameter of 5 mm. On the cornea, target localization of ICR has been marked as well as the stromal tunnel generated accordingly. In the case if tunnel has been created outside this particular area, it accepted the decentration. In order to minimize decentration, a disposable suction ring has been placed after marking the location area of ring. The depth of tunnel has been set at 70% of thinnest corneal thickness for tunnels, which have been created manually. For femtosecond tunnels, the depth set at 70% and the inner diameter has been set at 4.4 mm. Moreover, the outside diameter has been set at 5.6 mm. The energy of 1.30 μJ has also been used for femtosecond tunnel generation and entry incision. An approximate of 15s duration has been set for the entire procedure with femtosecond laser. Once the tunnel has been created, special forceps have been incorporated for the implantation of Keraring segments. Single intrastromal ring segment has been inserted in 15 eyes, whereas, 2 segments inserted in 72 eyes.

During every session of surgery, the Keraring has been implanted in one eye of every patient, in first 28 eyes. Each eye has been implanted in a different session in the case if ring segments implanted in both eyes of the patients. The bilateral surgery has been performed in remaining 59 eyes of patients. The steroid eye drops and antibiotic have been prescribed to the patients daily for 2wk postoperatively.

Follow-up Preoperatively and postoperatively, a complete ophthalmic assessment has been performed. This assessment was comprised of best spectacle-corrected visual activity (BSCVA), uncorrected visual acuity (UCVA), manifest cylindrical and spherical refraction, and readings taken through keratometric by using OrbscanII. For all patients, the follow-up period of at least 4mo to 16mo considered. For the statistical analysis, the visual acuity has been measured in Decimal Snellen, which has been converted to logarithm of Minimum Angle of Resolution (logMAR).

Statistical Analysis SPSS version 20 has been incorporated for statistical analysis. The standard deviations and ranges have been considered to generate the outcomes. Moreover, 2-tailed probability of 5% or less than 5% has been considered as statistically significant.

RESULTS

From the outcomes, it has been examined that the age of all patients lies between the ranges of 16-42y, and the patients included 29 males and 27 females. A follow-up of at least 4mo have been completed for 87 eyes. Without any major intraoperative decentration or complications, the implantations of Keraring segment and tunnel incisions have been performed.

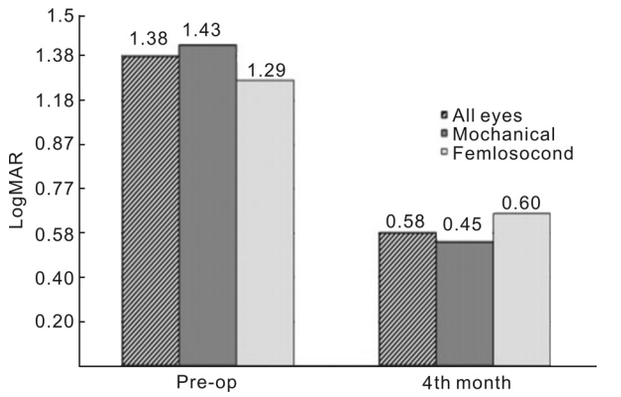

Figure 1 Uncorrected visual acuity changes preoperatively and at 4mo after keraring implantation.

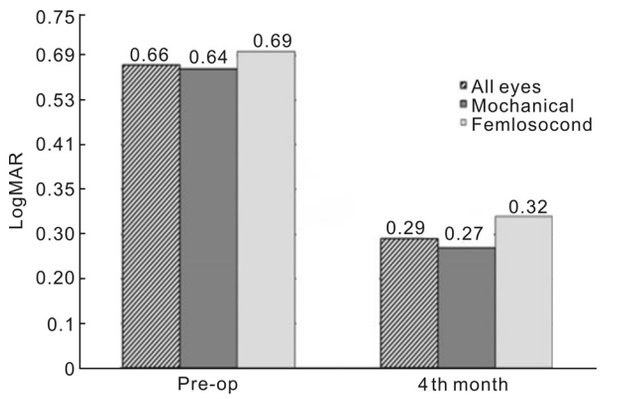

Figure 2 Best spectacle-corrected visual acuity changes preoperatively and at 4mo after keraring implantation.

Visual Acuity For all eyes (n=87), the mean preoperative uncorrected visual acuity determined was 1.38±0.37, and its range lies between 0.1 to 1.40. A mean of 0.58±0.32, with a range of 0-1.1 had been examined postoperatively, at the fourth month. Besides this, the mean was 0.53±0.31, which was comprised of 60 eyes (range=0-1.1, with a P-value of less than 0.001) at first year. Moreover, an improvement had been observed in the mean of visual acuity (0.48±0.30) with 45 eyes and comprised of a range of 0-1.1, with a P<0.001 at the 16th month. For 87 eyes, the mean of preoperative best spectacle-corrected visual acuity had been observed as 0.66±0.34 (with a range of 0.1-1.1). At fourth month, the observed mean was 0.27±0.19, which was comprised of 87 eyes and the range is between 0-1, showing a P-value of less than 0.001. The mean value was 0.26±0.18 (n=60, range was between 0-1 logMAR, and P<0.001) at the first year. At the 16th month, the mean had been improved to 0.24±0.18 for 45 eyes (range: 0-1 logMAR, P<0.001; Figures 1 and 2).

In contrast with preoperative levels, an improvement in uncorrected visual acuity had been observed in 76 eyes (90.2%). On the other hand, uncorrected visual acuity remained same in 6 eyes (5.1%), whereas, it had been declined in 5 eyes (3.9%). The differences among the mean values of uncorrected visual activity demonstrated a gain of Snellen lines (2.04±1.79). The similar outcomes had been observed

for best spectacle-corrected visual acuity; however, there was a distinction among the values of mean difference. For BSCVA, the mean difference was a gain of 2.60±2.15 lines. Hence, it had been examined that in stage IV of keratoconus, 5 eyes (3.9%) had declined uncorrected visual acuity and best spectacle-corrected visual acuity.

It has been examined through results that there were limited epithelial effects in 19 eyes (28%) at the incision site on first postoperative day within the mechanical group. It had been observed that these epithelial effects spontaneously resolved in few days. In 3 eyes, the implantation of superficial Keraring segment had been observed. Moreover, an appropriate depth had been considered for the creation of intrastromal corneal tunnel and the segments had been reimplanted at the first week after first operation into the new corneal tunnel. Taking into consideration the femtosecond group, segment migration had been observed to the incision site in 3 eyes at the first postoperative month. Away from the incision site, migrated segment had been placed in a different position, enabling the segment to remain stable.

DISCUSSION

It has been demonstrated from results that keraring implantation was resulted in efficient and safe therapeutic keratoconus treatment in all eyes. A significant improvement has been determined in visual acuity, with a greater improvement in UCVA in contrast with BSCVA[11-12]. Moreover, it has been observed through visual results that the range of mean UCVA was from 0.40 to 1.20 logMAR. On the other hand, the results of BSCVA demonstrated a mean of 0.27 to 0.66 logMAR, after 4mo follow-up. A recent study has been carried out, in which the keratoconus patients followed up for 6mo after the implantation of Keraring. The Keraring was implanted through the usage of femtosecond laser. It has been revealed through outcomes that there was an increase in the mean UCVA from 0.06 to 0.3. Besides this, the results also demonstrated that BSCVA increased from 0.54 to 0.71. It has been recommended that the implantation of intrastromal corneal ring segment is an efficient procedure by using femtosecond laser[13].

Among the femtosecond tunnel (15 eyes) and mechanical intracorneal tunnel (72 eyes), a comparison has been made between the visual changes. No statistical significant difference has been observed at 4mo after surgery in any of the group; despite the fact that the visual outcomes of mechanical group are far better in contrast with the femtosecond group. With respect to the implantation of intrastromal corneal ring segment by mechanical spreaders, a few complications have been notified. Some of these complications include posterior or anterior perforation of cornea with spreaders, epithelial defects, movement of segment, superficial placement of rings, infectious keratitis[14-15]. In mechanical group, majority of the complications have been observed, in contrast with the femtosecond group. Almost 28% of eyes have been observed with epithelial defects at incision site in mechanical group. Besides this, the placement of superficial Keraring has been observed in 3 eyes. Moreover, in 3.6% of eyes, the migration of segment to incision site has been observed in femtosecond group.

The two main techniques entailed in the tunnel creation are the femtosecond laser and mechanical dissection, which are utilized throughout the ICRS. Epithelial defects are the major complications caused from the conventional mechanical technique for tunnel construction. These complications can be examined at the anterior and posterior perforations, persistent incisional gaping, and asymmetric placement. The mechanical tunnel section method showed the prevalence rate of 35% for postoperative complications including segment movement and corneal melt[16]. The traditional technique of femtosecond laser has been effective in providing considerable higher extent when utilizing the manual technique. The occurrence of complications is slightly lower when implementing the femtosecond laser to acquire equivalent refractive SE and VA results. The procedure of tunnel construction is easier and more effective for the surgery by using the femtosecond laser[17].

It has been adhered that the objective of ICRS implication is to withstand and strengthen the ectatic cornea. The effects of ICRS are revealed on the cornea after 6mo; therefore, it enhanced the visual perception due to the viscoelastic nature of the cornea. A significant augment is revealed from the corneal thickness among all groups. The augment in the corneal pachymetry is reported with possible interference of corneal collagen turnover. Furthermore, the ICRS implantation revealed the significant reduction in the asphericity values [18]. The negative consequences have been adhered from the modifications in the spherical similarity through astigmatism. The study group was found statistically significant through the enhancement in astigmatism and spherical equivalence. The improvement in the spherical astigmatism was not revealed among control group. The spherical equivalent for all cones was suggested from the implementation of asymmetric rings. Furthermore, numerous studies have revealed that there was no statistical relationship between astigmatism and spherical equivalence[19-20].

Keratoconus has been identified as an essential cause of visual loss, which severely affects young and apparently healthy individuals. The surgical treatment of keratoconus comprised of the transplantation of cornea with its elongated period of healing, infection, and the rupture of cornea. From the outcomes, the efficacy of ICRS has been assessed. It has been evaluated that an efficient and safe therapeutic treatment has been offered by the implantation of Keraring segments in the

patients, suffering from keratoconus disorder. As the usage of contact lenses is not effective always, the procedures of surgery such as deep lamellar keratoplasty or penetrating keratoplasty have been recommended for the patients suffering from advanced keratoconus. These surgical procedures encompass relatively low amount of complication risk. Hence, it has been assessed that the implantation of Keraring is more suitable and effective alternative, which provides excellent visual outcomes and safety, once the femtosecond and mechanical tunnels have been created.

ACKNOWLEDGEMENTS

Conflicts of Interest: Alghamdi A, None.

Peer Review File: Available at: http://ier.ijo.cn/gjykier/ch/reader/download_attache_file.aspx?seq_id=20210325152823001&flag=1&journal_id=gjykier&year_id=2020&issue=3

REFERENCES

1 Bakshi R, Khurana C, Sachdev R, Sachdev M. Intra-stromal corneal ring segments. *The Official Scientific Journal of Delhi Ophthalmological Society* 2013; 24:16-22

2 Ferrara G, Torquetti L, Ferrara P, Merayo-Lloves J. Intrastromal corneal ring segments: visual outcomes from a large case series. *Clin Exp Ophthalmol* 2012;40(5):433-439.

3 Ertan A, Kamburoğlu G. Intacs implantation using a femtosecond laser for management of keratoconus: Comparison of 306 cases in different stages. *J Cataract Refract Surg* 2008;34(9):1521-1526.

4 Piñero DP, Alio JL, Uceda-Montanes A, El Kady B, Pascual I. Intracorneal ring segment implantation in corneas with post-laser *in situ* keratomileusis keratectasia. *Ophthalmology* 2009;116(9):1665-1674.

5 Park J, Gritz DC. Evolution in the use of intrastromal corneal ring segments for corneal ectasia. *Curr Opin Ophthalmol* 2013;24(4):296-301.

6 Ratkay-Traub I, Ferincz IE, Juhasz T, Kurtz RM, Krueger RR. First clinical results with the femtosecond neodynium-glass laser in refractive surgery. *J Refract Surg* 2003;19(2):94-103.

7 Ganesh S, Shetty R, D'Souza S, Ramachandran S, Kurian M. Intrastromal corneal ring segments for management of keratoconus. *Indian J Ophthalmol* 2013;61(8):451-455.

8 Israel M, Yousif MO, Osman NA, Nashed M, Abdelfattah NS. Keratoconus correction using a new model of intrastromal corneal ring segments. *J Cataract Refract Surg* 2016;42(3):444-454.

9 Mohamad M, Amin N, Kurosh S, Nazli T, Samira M. Clinical and topographical corneal changes after keraring implantation in keratoconus patients. *Adv Biosci Clin Med* 2015;3(1):40-45.

10 Vinciguerra P, Albè E, Trazza S, Rosetta P, Vinciguerra R, Seiler T, Epstein D. Refractive, topographic, tomographic, and aberrometric analysis of keratoconic eyes undergoing corneal cross-linking. *Ophthalmology* 2009;116(3):369-378.

11 Kaiser PK. Prospective evaluation of visual acuity assessment: a comparison of snellen versus ETDRS charts in clinical practice (An AOS Thesis). *Trans Am Ophthalmol Soc* 2009;107:311-324.

12 Hernandezbogantes E, Wu L, Flikier D. Long term follow-up of corneal topographic indices following collagen crosslinking in eyes with keratoconus. *Invest Ophthalmol Vis Sci* 2013;54(15):1617.

13 Shabayek MH, Alió JL. Intrastromal corneal ring segment implantation by femtosecond laser for keratoconus correction. *Ophthalmology* 2007;114(9):1643-1652.

14 Kymionis GD. Actual indications for intracorneal ring segment implantation in keratoconus. *Cornea* ESASO Course Series. Basel, Karger, 2015;66-73.

15 Tunc Z, Helvacioglu F, Sencan S. Evaluation of intrastromal corneal ring segments for treatment of keratoconus with a mechanical implantation technique. *Indian J Ophthalmol* 2013;61(5):218-225.

16 Jadidi K, Mosavi SA, Nejat F, *et al*. Intrastromal corneal ring segment implantation (keraring 355°) in patients with central keratoconus: 6-month follow-up. *J Ophthalmol* 2015;2015:916385.

17 Ferenczy PA, Dalcegio M, Koehler M, Pereira TS, Moreira H, Luciane Bugmann M. Femtosecond-assisted intrastromal corneal ring implantation for keratoconus treatment: a comparison with crosslinking combination. *Arq Bras Oftalmol* 2015;78(2):76-81.

18 Torquetti L. Predictors of clinical outcomes after intrastromal corneal ring segments implantation. *Int J Keratoconus Ectatic Corneal Dis* 2012;1(1):26-30.

19 Shetty R, D'Souza S, Ramachandran S, Kurian M, Nuijts RM. Decision making nomogram for intrastromal corneal ring segments in keratoconus. *Indian J Ophthalmol* 2014;62(1):23-28.

20 Vega-Estrada A, Alio JL. The use of intracorneal ring segments in keratoconus. *Eye Vis (Lond)* 2016;3:8.