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CLINICAL STUDY

Keraring implantation using the Zeiss Visumax femtosecond laser in the management of patients with keratoconus

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Abstract

Purpose **To evaluate the safety and efficacy of implanted Kerarings in patients with mild, moderate, and severe keratoconus.**

Patients and methods **A 12-month retrospective case series of 70 eyes of 70 patients who underwent Keraring implantation with the Zeiss Visumax femtosecond laser. Patients were stratified into three groups according to their topography as mild (mean K <48 D) moderate (48–55 D) or severe (>55 D). Main outcome measures were visual acuity, manifest refraction, and corneal topography. Complications were recorded.**

Results **A total of 66 patients completed the 12-month follow-up. In all, 4 rings were explanted, 3 due to no improvement in visual function and 1 due to corneal neovascularization. Also, 4 rings were repositioned. In mild disease ($n=28$), BCVA increased to 0.10 logMAR, sphere decreased to -1.54 D, cylinder decreased to 2.54 D, Kmax decreased to 46.25 D, and keratometric astigmatism to 3.88 D ($P<0.01$ for each compared with preoperative values). No patients lost vision. In moderate disease ($n=27$), sphere decreased to -4.06 D, cylinder decreased to 3.47 D, Kmax decreased to 51.69 D, and keratometric astigmatism to 4.56 D ($P<0.05$ for each compared with preoperative values). In severe disease ($n=11$), BCVA increased to 0.34 logMAR, Kmax decreased to 57.65 D, and keratometric astigmatism to 5.07 D ($P<0.05$ for each compared with preoperative values).**

Conclusion **Femtosecond laser-assisted Keraring implantation is a safe and minimally invasive treatment option to improve the refraction and visual function in patients with keratoconus. Patients with mild keratoconus are more likely to have a favourable outcome following Keraring implantation.**

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Introduction

Keratoconus is the most common form of corneal ectasia in which progressive corneal steepening causes increasing myopia and astigmatism. Until relatively recently, disease progression in keratoconus was managed with spectacles until irregular astigmatism necessitated rigid contact lens fitting, and then corneal transplantation where contact lenses failed.[1,2]

The mainstay of treatment to prevent disease progression is corneal crosslinking. For some patients corneal crosslinking can result in disease regression, but for the majority of patients the refraction does not improve sufficiently to avoid the use of contact lenses or improve contact lens tolerance.[3] As a result of this, there has been renewed interest in techniques such as intrastromal corneal ring segment (ICRS) implantation that aim to significantly improve the patient's refraction and or contact lens fit/tolerance.

ICRS are polymethylmethacrylate segments inserted at a precise depth in the corneal stroma. Initially developed to correct myopia, the use of ICRSs was first described by Fleming *et al*[4] in the late 1970s initially as almost 360-degree 'complete' rings. Modern ICRSs are incomplete rings and were shown to be effective in keratoconus by the work of Colin *et al*.[5] The two most widely available are Intacs (Addition Technologies, Fremont, CA, USA) and Kerarings

(Mediphacos, Belo Horizonte, Brazil). Kerarings are the direct descendent of the Ferrara ring (Mediphacos), only differing in the number of available segment lengths and being designed specifically for keratoconus rather than myopia.[6] ICRS implantation can be mechanical or femtosecond laser-assisted, with both techniques providing equivalent visual and refractive outcomes, but with femtosecond laser-assisted implantation providing improved safety.[7]

There continues to be controversy over the role of ICRS in the management of keratoconus. It has been argued that ICRS is most effective in advanced disease and that its role is therefore as a procedure of last resort in order to avoid corneal transplantation.[8]

We present a series of 70 patients undergoing Zeiss Visumax femtosecond laser-assisted Keraring implantation for keratoconus (Carl Zeiss Meditech, Jena, Germany). Our primary aim was to evaluate the overall safety and efficacy of ICRS implantation. Patients were stratified by disease severity in order to achieve our secondary aim of evaluating the efficacy of ICRS in mild, moderate, and severe keratoconus.

Patients and methods

A retrospective case series was performed of 70 eyes, of 70 patients (58 males and 12 females) who underwent Keraring implantation with a femtosecond laser. The mean patient age was 29.96 ± 9.96 years (range, 18–65 years). All procedures were performed at St James's University Hospital, Leeds, UK. If a patient had a Keraring implanted in both eyes, only the first eye was included in the analysis. The Keraring was removed in four patients. A total of 66 patients completed 12 months of follow-up.

Ethics statement

This study was approved by the hospital research governance committee.

Examination protocol

A complete ophthalmic evaluation was performed preoperatively and at 12 months postoperatively. This included uncorrected Snellen visual acuity (UCVA), best-corrected Snellen visual acuity (BCVA), subjective refraction, slit-lamp biomicroscopy, fundus examination, corneal topography (Galilei, Ziemer Ophthalmic Systems, Port, Switzerland), and anterior segment optical coherence tomography (Visante, Carl Zeiss Meditech). Corneal topography allowed Kmax and keratometric astigmatism to be evaluated and recorded.

Kmax is the corneal dioptric power in the steepest meridian for the 3 mm central zone. Keratometric astigmatism was defined as the difference between the corneal dioptric power in the steepest and flattest meridian for the 3 mm central zone.

Grading system

Patients were stratified into three groups according to their topography as described by Watson *et al*.[9] Eyes with a mean K of <48 D were classed as having mild keratoconus, 48–55 D as moderate keratoconus, and >55 D as severe keratoconus.

Surgical procedure

The appropriate Keraring implant was chosen according to the nomogram supplied by the manufacturer (Mediphacos). All procedures were performed under topical anaesthesia by one of two consultant corneal surgeons or the departmental fellow.

Preoperative medication comprised Proxymetacaine 0.5% and Tetracaine 0.5%. The intrastromal tunnels were created by a Visumax femtosecond laser (Carl Zeiss Meditech). Tunnel depth was calculated as 80% of the minimum corneal thickness at the 5–7 mm optical zone as measured on the Visante. A minimum distance of 100 μm from the endothelium was maintained for eyes in which the corneal thickness was <500 μm microns at the 5–7 mm optical zone. Tunnel dimensions were 4.8 mm (inner diameter) and 6.6 mm (outer diameter) for SI5 implants and 5.8 and 7.95 mm, respectively, for SI6 implants. The axis of the incision was made on the steepest topographic axis, unless the patient's visual acuity corrected to 6/12 Snellen acuity or better. In this instance, the axis of incision was made at the cylinder axis as measured by subjective refraction. Tunnel creation lasted $\sim$15 s, after which the Kerarings were implanted immediately using the forceps and tunnel dissectors provided by the manufacturer. The segments were manipulated into their final position using the manufacturer-provided hook designed to fit through the dialing hole situated at each end of a ring segment. Postoperatively, patients were prescribed Ofloxacin 0.3% q.d.s. for 1 week and Prednisolone 0.5% minims q.d.s. for 2 weeks. Slit-lamp examination occurred at 1 week postoperatively where ring position and corneal incision healing were assessed.

Collagen crosslinking (CXL)

Patients who underwent CXL preoperatively or in the 12-month follow-up period were recorded. All corneal CXL was undertaken using an 'epithelium off' approach.

Following de-epithelialization with a Beaver blade, central corneal thickness was measured and an isotonic or hypotonic Riboflavin solution was chosen, as appropriate. An accelerated Dresden protocol was used, involving 30 min of drop administration and 10 min of UVA radiation at 9 mW/cm^2.

Main outcome measures

Main outcome measures were visual acuity (BCVA, UCVA), manifest refraction, and corneal topography.

Complications

Complications were recorded if patients presented to the emergency eye clinic or at postoperative clinic appointments.

Statistical analysis

Statistical analysis was undertaken using Numbers (Apple Inc., Cupertino, CA, USA). Results are presented as mean ± SD. Snellen visual acuity was converted into logMAR for statistical analysis. Differences between preoperative and 12-months postoperative continuous variables were tested using the paired Student's *t*-test. A *P*-value of <0.05 was regarded as significant.

Results

This study comprised a total of 70 eyes of 70 patients treated with Keraring implantation. Four eyes required explantation of the Keraring within the 12-month follow-up period. Three eyes had moderate keratoconus and one classified as severe keratoconus. In the severely keratoconic eye and two of the three eyes with moderate keratoconus, the rings were removed because there was no improvement in visual function. Lastly, the one remaining patient with moderate keratoconus suffered a flare-up of associated atopic keratoconjunctivitis with subsequent corneal neovascularization. The ring was removed despite an early improvement in both refraction and BCVA. The 66 remaining eyes were graded according to their topography: 28 eyes (42.42%) were classed as mild, 27 eyes (40.90%) as moderate, and 11 (16.67%) as severe.

Visual outcomes

Of the remaining 66 patients, 7 eyes (10.6%) had an UCVA of 6/12 or better preoperatively compared with 17 (25.76%) at 12 months. Of the 66 eyes, 33 (50.00%) had a BCVA of 6/12 or better preoperatively, increasing to 57 eyes (86.36%) at 12 months. On BCVA testing, 39 eyes (59.09%) gained lines on the Snellen chart, whereas 23 eyes (34.84%) stayed the same and 4 eyes (6.06%) lost lines on the chart.

Overall, there was a significant increase in BCVA. BCVA increased from mean logMAR 0.30 ± 0.25 logMAR (range, 0 to 1 logMAR) preoperatively to 0.14 ± 0.21 logMAR (range, −0.2 to 0.8 logMAR; $P<0.0001$) at 12-months follow-up. Upon stratification into keratoconus severity all groups showed improvement in BCVA, but this reached statistical significance only for the mild and severe groups. Patients with mild keratoconus showed an increase in BCVA from a preoperative mean value of 0.26 ± 0.21 logMAR (range, 0 to 0.6) to a mean postoperative value of 0.10 ± 0.18 (range, −0.2 to 0.5; $P<0.001$)). No patients in this group lost vision. Patients with moderate keratoconus experienced an increase in BCVA from mean 0.25 ± 0.26 (range, 0 to 0.1) to 0.11 ± 0.21 logMAR (range, −0.2 to 0.8; $P=0.05$) but this just failed to achieve statistical significance. Three patients in this group (11.11%, 3/27) lost BCVA that included a loss of one line, three lines and five lines of vision. One eye with moderate keratoconus achieved an improvement in unaided vision despite a loss of five lines of BCVA. The preoperative BCVA was 0.0 logMAR but required a 13 D astigmatic correction. This was not useful to the patient and he felt that the overall unaided visual function of the eye was improved by the procedure. BCVA of patients with severe keratoconus significantly increased from 0.52 ± 0.23 logMAR (range, 0.2–1.0) preoperatively to 0.34 ± 0.21 logMAR (range, 0.2–0.8; $P<0.05$). One patient in this group (9.09%, 1/11) lost two lines of vision and he went on to have a deep anterior lamellar keratoplasty. These results are displayed in Table 1.

Table 1 Visual outcomes of patients 12 months postoperatively

	Preoperative BCVA (logMAR)			*Postoperative BCVA (logMAR)*			P-*value*
	Mean	*SD*	*Range*	*Mean*	*SD*	*Range*	
Mild	0.26	0.21	0 to 0.6	0.1	0.18	−0.2 to 0.5	<0.0001
Moderate	0.25	0.26	0 to 1.0	0.11	0.21	−0.2 to 0.8	0.05
Severe	0.52	0.23	0.2 to 1.0	0.34	0.21	0.2 to 0.8	<0.05
All	0.3	0.25	0 to 1.0	0.14	0.21	−0.2 to 0.8	<0.0001

Refractive outcomes

Analysis of the patient cohort as a whole showed a statistically significant reduction in sphere, cylinder, Kmax, and keratometric astigmatism at 12-month follow-up ($P<0.0001$). These results are displayed in Table 2. Sphere reduced from -5.67 ± 4.15 D (range, -16 to 4 D) to -3.40 ± 4.14 D (range, -24 to 5 D; $P<0.0001$) and cylinder from 6.00 ± 2.95 D (range, 0.8 to 15.5 D) to 3.39 ± 2.34 D (range, 0 to 10.5 D; $P<0.0001$). Mean Kmax decreased from 52.56 ± 5.29 D (range, 43.6 to 69.3 D) preoperatively to 50.37 ± 5.35 D (range, 43.1 to 64.3 D; $P<0.0001$) postoperatively at 12 months. Mean keratometric astigmatism decreased from 6.34 ± 3.70 D (range, 0.9 to 22.9 D) to 4.36 ± 3.23 (range, 0.4 to 16.5 D; $P<0.0001$) at 12 months.

Upon stratification into grades of keratoconus severity, only patients with mild and moderate disease achieved a significant reduction in sphere. Mean sphere in mild keratoconus decreased from -3.43 ± 3.31 D (range, -9.0 to 4.0 D) to -1.54 ± 3.07 D (range, -9.5 to 5.0 D; $P<0.01$) and in moderate from -6.81 ± 3.97 D (range, -15.0 to -0.75 D) to -4.06 ± 2.89 D (range, -8.5 to 0.8 D; $P<0.0005$) at 12 months. Patients with severe keratoconus demonstrated a reduction from a preoperative mean value of -8.61 ± 3.82 D (range, -16.0 to -4.0 D) to a postoperative mean of -6.85 ± 6.67 D (range, -24.0 to 0.5 D; $P=0.41$).

Analysis of cylinder also showed that only patients with mild and moderate disease achieved a significant reduction. In mild keratoconus, mean cylinder decreased from 4.85 ± 2.15 D (range, 0.8 to 9.5 D) to 2.54 ± 1.90 D (range, 0.3 to 7.5 D; $P<0.0001$) and in moderate from 6.48 ± 2.48 D (range, 2.0 to 13.0 D) to 3.47 ± 2.35 D (range, 0 to 10.5 D; $P<0.0001$). Patients with severe keratoconus failed to achieve significance.

There was a significant reduction in Kmax across all groups with the smallest *P*-value achieved by patients with mild disease. There was a reduction in Kmax in mild keratoconus from 48.15 ± 2.17 D (range, 43.6 to 52.4 D) to 46.25 ± 2.31 D (range, 43.1 to 51.8 D; $P<0.0001$) and in moderate from 53.95 ± 2.76 D (range, 50.3 to 62.0 D) to 51.69 ± 3.55 D (range, 44.0 to 58.1 D; $P<0.001$). Patients with severe disease underwent a reduction from 61.66 ± 2.94 D (range, 58.8 to 69.3 D) to 57.65 ± 5.35 D (range, 48.6 to 64.3 D; $P<0.05$).

Keratometric astigmatism measured by topography underwent statistically significant reduction across all disease severities. Patients with mild disease demonstrated a reduction from 5.50 ± 2.73 D (range, 0.9 to 13.3 D) to 3.88 ± 2.23 D (range, 0.4 to 9.8 D; $P<0.005$) and with moderate disease from 6.00 ± 3.92 D (range, 2.5 to 22.9 D) to 4.56 ± 3.93 D (range, 0.5 to 16.5 D; $P<0.0001$). In severe disease, mean keratometric astigmatism reduced from 9.07 ± 4.24 D (range, 5.9 to 21.1 D) to 5.07 ± 3.23 D (range, 0.4 to 16.5 D; $P<0.0001$).

Table 2 Refractive outcomes of patients 12 months postoperatively

	Preoperative			*Postoperative*			P-*value*
	Mean	*SD*	*Range*	*Mean*	*SD*	*Range*	
Sphere (D)							
Mild	−3.43	3.31	−9.0 to 4.0	−1.54	3.07	−9.5 to 5.0	<0.01
Moderate	−6.81	3.97	−15.0 to −0.75	−4.06	2.89	−8.5 to 0.8	<0.0005
Severe	−8.61	3.82	−16.0 to −4.0	−6.85	6.67	−24.0 to 0.5	0.41
All	−5.67	4.15	−16 to 4	−3.40	4.14	−24.0 to 5.0	<0.0001
Cylinder (D)							
Mild	4.85	2.15	0.8 to 9.5	2.54	1.9	0.3 to 7.5	<0.0001
Moderate	6.48	2.48	2.0 to 13.0	3.47	2.35	0 to 10.5	<0.0001
Severe	7.77	4.52	3.5 to 15.5	5.37	2.25	2.0 to 10.0	0.16
All	6.00	2.95	0.8 to 15.5	3.39	2.34	0 to 10.5	<0.0001
Kmax (D)							
Mild	48.15	2.17	43.6 to 52.4	46.25	2.31	43.1 to 51.8	<0.0001
Moderate	53.95	2.76	50.3 to 62.0	51.69	3.55	44.0 to 58.1	<0.001
Severe	61.66	2.94	58.8 to 69.3	57.65	5.35	48.6 to 64.3	<0.05
All	52.77	5.43	43.6 to 69.3	50.37	5.35	43.1 to 64.3	<0.0001
Keratometric astigmatism (D)							
Mild	5.50	2.73	0.9 to 13.3	3.88	2.23	0.4 to 9.8	<0.005
Moderate	6.00	3.92	2.5 to 22.9	4.56	3.93	0.5 to 16.5	<0.05
Severe	9.07	4.24	5.9 to 21.1	5.07	3.60	1.0 to 13.6	<0.05
All	6.30	3.69	0.9 to 22.9	4.36	3.23	0.4 to 16.5	<0.0001

Collagen crosslinking

Five (7.58%) patients had collagen crosslinking before implantation of the Keraring. In the 12 months following Keraring implantation, 51 (77.27%) patients underwent CXL. Also, 10 (15.15%) patients did not undergo CXL preoperatively or during the 12-month period of follow-up. Table 3 shows the number of patients in each group who all underwent CXL.

The 51 patients who underwent CXL in the 12 months following keraring implantation were stratified into mild, moderate, and severe disease. Table 4 shows these results.

Results of patients with mild disease ($n=19$) were comparable to the results from the total cohort with statistically significant improvements in BCVA ($P<0.001$), cylinder ($P<0.005$), Kmax ($P<0.001$), and keratometric astigmatism ($P<0.01$). A significant reduction in sphere ($P=0.06$), however, was not achieved compared with a significant reduction in the total cohort ($P<0.001$).

Patients with moderate keratoconus ($n=23$) had significant improvements in the same parameters as the total cohort. A significant improvement was achieved in sphere ($P<0.005$), cylinder ($P<0.001$), Kmax ($P<0.005$), and keratometric astigmatism ($P<0.05$) with no significant improvement in BCVA ($P=0.14$).

Table 3 Proportion of patients undergoing CXL preoperatively, postoperatively or Keraring implantation only

	Preoperative CXL		*Postoperative CXL*		*Keraring implantation only*	
	Number	*Percentage (%)*	*Number*	*Percentage (%)*	*Number*	*Percentage (%)*
Mild	2	7.14	19	67.86	7	25
Moderate	1	3.7	23	85.16	3	11.11
Severe	2	18.18	9	81.81	0	0
All	5	7.58	51	77.27	10	15.15

Table 4 Visual and refractive outcomes of patients who underwent CXL in the 12 months following Keraring implantation

	Preoperative			*Postoperative*			P-*value*
	Mean	*SD*	*Range*	*Mean*	*SD*	*Range*	
BCVA							
Mild	0.27	0.22	0.0 to 0.6	0.08	0.16	−0.2 to 0.5	<0.001
Moderate	0.23	0.26	0.0 to 1.0	0.11	0.22	−0.2 to 0.8	0.14
Severe	0.54	0.22	0.2 to 1.0	0.37	0.22	0.2 to 0.8	0.09
All	0.3	0.26	0.0 to 1.0	0.14	0.22	−0.2 to 0.8	<0.0005
Sphere (D)							
Mild	−3.04	3.61	−9.0 to 4.0	−1.25	3.21	−9.5 to 5.0	0.06
Moderate	−6.07	3.59	−15.0 to −0.8	−3.77	2.91	−8.0 to 0.8	<0.005
Severe	−9.11	4.03	−16.0 to −4.0	−7	7.52	−24.0 to 0.5	0.42
All	−5.48	4.22	−16.0 to 4.0	−3.33	4.43	−24.0 to 5.0	<0.001
Cylinder (D)							
Mild	4.86	2.36	0.8 to 9.5	2.42	1.86	0.3 to 5.5	<0.005
Moderate	6.43	2.65	2.0 to 13.0	3.46	2.43	0.0 to 10.5	<0.001
Severe	7.72	4.95	3.5 to 15.5	5.65	2.41	2.0 to 10.0	0.31
All	6.07	3.18	0.8 to 15.5	3.46	2.46	0.0 to 10.5	<0.0001
Kmax (D)							
Mild	48.2	2.32	43.6 to 52.4	46.36	2.46	43.1 to 51.8	<0.001
Moderate	54.16	2.91	50.3 to 62.0	51.88	3.31	46.6 to 58.1	<0.005
Severe	62.18	3.01	59.5 to 69.3	58.5	5.41	48.6 to 64.3	0.06
All	53.35	5.62	43.6 to 69.3	50.99	5.51	43.1 to 64.3	<0.0001
Keratometric astigmatism (D)							
Mild	5.72	2.34	1.3 to 10.2	3.88	2.26	0.4 to 9.8	<0.01
Moderate	6.21	4.22	2.5 to 22.9	4.53	3.88	0.5 to 16.5	<0.05
Severe	9.77	4.41	4.4 to 21.1	5.56	3.84	1.0 to 13.6	0.09
All	6.66	3.88	1.3 to 22.9	4.47	3.34	0.4 to 16.5	<0.0005

Patients with severe disease ($n=11$) showed no significant improvements despite the severe group in the total cohort recording significant improvements in BCVA, Kmax, and keratometric astigmatism.

Adverse events and complications

Implant repositioning was required in four patients. There were no reported intraoperative complications. Complications included significant glare ($n=2$) and dry eye ($n=2$). These symptoms were treated conservatively and did not result in ICRS explantation.

Discussion

This is the largest series of Kerarings in the United Kingdom and our 12-month results indicate that implantation is a safe and effective treatment for keratoconus. Taking the patient cohort as a whole, we have demonstrated a statistically significant in reduction in sphere and cylinder magnitudes, Kmax, and keratometric astigmatism. Moreover, we observed a statistically significant increase in BCVA following ICRS implantation.

We report a 2.27 D decrease in mean sphere following Keraring implantation, and this is remarkably similar to the 2.23 D decrease reported by Shabayek and Alio.[10] Similarly, the mean reduction in cylinder (2.61 D *vs* 2.67 D) and change in Kmax (2.19 D *vs* 2.24 D) were comparable. Regarding visual outcomes, 59.09% of patients gained lines of BCVA as compared with 70% of patients in the series reported by Shabayek and Alio[10] and 68% of patients by Coskunseven *et al.*[11] Furthermore, Coskunseven *et al*[11] reported two patients (4%) losing two lines of BCVA at their last follow-up. Both cases had advanced keratoconus and concomitantly demonstrated an increase in UCVA. We report 4 (6.06%) patients losing lines of vision.

In our series, upon stratification into different severities of keratoconus, statistical significance was not achieved by each individual group in each primary outcome measure. This in part may be explained by the reduced numbers in each strata. Eyes with mild keratoconus had the best outcomes as they were the only group with a statistical significant improvement in all primary outcome measures; BCVA, sphere, cylinder, keratometric astigmatism, and Kmax. No patients in this group lost any lines of vision and no rings were explanted. Alio *et al*[12] reported a greater gain in visual acuity and reduction in spherical equivalent in patients with less advanced keratoconus, after Intacs implantation.

Moderate keratoconus achieved significance in all parameters except BCVA. Three patients in this group lost vision. Three patients in this group underwent ring explantation, two of these because of no improvement in visual function.

Patients with severe keratoconus failed to achieve significance in sphere or cylinder, but did in BCVA, keratometric astigmatism, and Kmax. This group experienced the greatest reductions in keratometry that echoes the findings of Ertan and Kamburoglu.[13] This contradicts the findings of Boxer Wachler *et al*[14] who reported a greater reduction in spherical equivalent in those with more advanced keratoconus. Of the patients with advanced keratoconus, 63.6% (7/11) showed an improvement in BCVA, avoiding the need for a corneal graft. Keraring implantation is, therefore, still worthwhile in those patients with advanced keratoconus where the only alternative option would be a corneal graft, providing the patients have been appropriately counselled regarding the likelihood of a successful outcome.

A multicentre, retrospective study of 611 eyes of 361 keratoconic patients analysed the outcomes of ICRS using a RETICS grading system based on preoperative visual impairment.[15] This reported significant improvements in UCVA, spherical equivalent, and keratometry readings across all grades of preoperative visual impairment. Patients with grade I disease (no visual impairment) had a statistically significant reduction in BCVA despite improvements in mean preoperative spherical equivalent, UCVA, and significant reductions in keratometry with no changes in the corneal high-order aberrations. Vega-Estrada *et al*[15] hypothesized that this may be because of induced biomechanics changes or unpredictable changes in the refractive index in the cornea. This is in contrast to our findings where patients with mild disease had the best outcomes, although our patients with mild disease had preoperative visual impairment. Disease progression in this group could also explain these contradictory findings. Furthermore, Vega Estrada *et al*[15] did not use a femtosecond laser in all cases and therefore the same precision and predictability of results may not have been achieved. They concluded that ICRS implantation should be reserved for the management of keratoconus where there is clear visual impairment.

Published literature is conflicting regarding outcomes following ICRS implantation in different severities of disease. The variable findings reported in the literature may be explained by fundamental differences including the type of ICRS used, whether mechanical or femtosecond laser-assisted implantation was performed and the nomogram used for segment selection.

The femtosecond laser has revolutionized modern ophthalmic practice and is now the gold standard for ICRS implantation. The femtosecond laser can deliver energy precisely for accurate intrastromal tunnel creation.

This allows predictable outcomes that have been modelled with finite element analysis.[16] Use of the femtosecond laser decreases the risk of inflammation or infection and reduces procedure time.[17] In contrast, manual implantation requires the surgeon to estimate the depth of the tunnel and perform mechanical stromal dissection. This has been associated with a number of possible complications including epithelial defects, anterior or posterior corneal perforations, infectious keratitis, and asymmetric segment placement.[17] A study of 51 eyes of 47 patients in which the ICRS were mechanically inserted reported a 19.6% rate of ICRS extrusion.[18] Explantation rates reported in the literature for mechanical implantations can be as high as 30% as observed by Pinero and Alio.[6]

Of our original 70 patient cohort, 3 patients (4.2%) underwent ICRS explantation because of no significant subjective improvement in visual function being achieved and one because of induced corneal vascularization. There were no ICRS extrusions or infections. Four patients required ICRS repositioning because of a suboptimal ring position being achieved at the time of surgery that was subsequently rectified by a second procedure. A small number of patients complained of glare and dry eye. This closely echoes the repositioning rate reported by Coskunseven *et al*[11] from their 50 eye, femtosecond laser-assisted series where there were no cases of ICRS ring extrusion, keratitis, or explantation.

Collagen crosslinking is a well-established treatment option for keratoconus and in combination with ICRS is potentially synergistic.[19] Several studies have reported that combining these two complementary interventions is safe and effective.[20,21] El-Raggal[22] evaluated the efficacy of sequential CXL and Keraring implantation or combined surgery and found no significant difference between the two groups. In our study, 51 (77.27%) patients underwent CXL in the 12 months following Keraring implantation. Upon stratification into different severities of disease, the results of patients with mild and moderate disease were comparable to the total cohort. Patients with severe disease failed to reach significance in any parameter but this may be explained by the small sample size.

This article has several potential limitations including the retrospective nature of the study and the relatively short period of follow-up. Pinero and Alio highlight[6] the fact that longer-term studies show that regression from the initially achieved postoperative spherical equivalent does occur, possibly because of cone progression.[23–25] There are no comparative control group and no data regarding contrast sensitivity, contact lens intolerance, or qualitative outcomes. Confounding was reduced by only including the first treated eye of each patient.

Conclusions

Femtosecond laser-assisted Keraring implantation is a safe and minimally invasive treatment option to improve the refraction and visual function in patients with mild, moderate, and severe keratoconus. Current studies are conflicting about predicting which patients have the best outcome from this intervention. Our series suggests that patients with mild keratoconus are more likely to have a favourable outcome following Keraring implantation.

Summary

What was known before

- Keratoconus is the most common form of corneal ectasia in which progressive corneal steepening causes increasing myopia and astigmatism.
- Kerarings are intrastromal corneal ring segments that aim to improve the patient's corneal topography and vision.

What this study adds

- Femtosecond laser-assisted Keraring implantation is a safe and minimally invasive treatment option to improve the refraction and visual function in patients with mild, moderate, and severe keratoconus.
- Patients with mild keratoconus are more likely to have a favourable outcome following Keraring implantation.

Conflict of interest

The authors declare no conflict of interest.

disclaimer

This is original research which has not previously been submitted for publication.

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