

Ferrara Intra-Corneal Ring Segments for Treatment of Keratoconus

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Purpose: The aim of the present study was to evaluate the effectiveness of Ferrara intra-corneal ring segments in improving visual acuity, manifest refraction and keratometry readings in patients with keratoconus.

Material and method: 42 eyes of 33 patients (mean age 28.19 ± 6.02 years) with keratoconus were included in our retrospective study. All patients were treated with Ferrara intra-corneal ring segments implantation, during the period March 2006–May 2009, in "Optilens" Eye Clinic, Cluj Napoca. The observed parameters were: uncorrected visual acuity, best spectacle-corrected visual acuity, manifest refraction, corneal topographic keratometry values. The postoperative values were referred to the preoperative data. The mean follow up time was 21.12 ± 9.76 months.

Results: Comparative preoperative and postoperative results showed statistically significant increases of uncorrected visual acuity, best spectacle corrected visual acuity and reduction of keratometry values: maximal K, minimal K, mean K and of the manifest refractive errors: mean sphere, mean spherical equivalent, mean cylinder.

Conclusions: Ferrara Intra-corneal ring segments implantation is an effective treatment option for keratoconus. This procedure is less invasive than keratoplasty, improves significantly visual acuity, refraction, keratometry and helps to avoid or delay the need for corneal transplant procedure.

Keywords: keratoconus, intra-corneal ring segments

Introduction

Keratoconus is a non-inflammatory ectatic disease of the eye. The progressive thinning and steepening of central and/or paracentral cornea is followed by conical deformation, that leads to secondary irregular myopic astigmatism [1, 2, 3]. The onset is usually around puberty, with a moderate to marked decrease in visual acuity and with an important negative effect on the quality of life [4]. In advanced cases of keratoconus, with corneal scarring, the only surgical option is the keratoplasty. Recently new treatment options were developed for treating keratoconus and for decreasing the number of needs for corneal transplant. One of these surgical alternatives is the intra-corneal ring segments (ICRS) implantation. These intra-stromal devices are used to reshape keratoconic cornea and to improve manifest refraction, keratometry and visual acuity [5]. ICRS were developed to achieve refractive adjustment by flattening the cornea and were first used for low myopia correction [6]. The first report on the efficacy of the ICRS implantation in keratoconus treatment was made by Colin et al. in year 2000. The two main types of ICRS used for the treatment of ectatic corneal diseases are the Intacs (Addition Technology Inc., Sunnyvale, CA, USA) and the Ferrara rings (Keravision Inc., Fremont, CA, USA). Both types are made from polymethyl methacrylate (PMMA) and are different in section profile and diameter [7]. The ICRS are inserted in the deep corneal stroma, at 70–80% of the mean corneal thickness, to modify the corneal curvature [8]. The corneal tunnels can be prepared with two different methods:

through mechanical dissection and through photo disruption, using femtosecond laser technology [7]. The ICRS implantation induces a flattening of the central portion of the anterior cornea and a steepening of the peripheral zone, providing biomechanical support for the thin cornea [9]. The degree of correction effect is a function of ring diameter and the ring thickness: the diameter is negative and the ring thickness is positive correlated with the magnitude of the correction [10]. In patients with keratoconus the indication for ICRS insertion are: decreased visual acuity with best correction of glasses or contact lenses, contact lens intolerance, clear central cornea, corneal thickness at least 450 microns at the site of insertion. ICRS implantation is contraindicated in patients with corneal thickness under 450 microns, patients with autoimmune, systemic collagen or immunodeficiency diseases, patients with corneal opacities or recurrent corneal diseases (corneal dystrophies, recurrent corneal erosion), pregnancy [7, 11].

Purpose

The purpose of our study was to evaluate the results of the treatment with Ferrara ICRS implantation in patients affected by keratoconus.

Material and method

This retrospective study includes patients with keratoconus treated with Ferrara ICRS implantation in "Optilens" Eye Clinic, Cluj-Napoca, during the period March 2006–May 2009. We have studied 42 eyes of 33 patients with the fol-

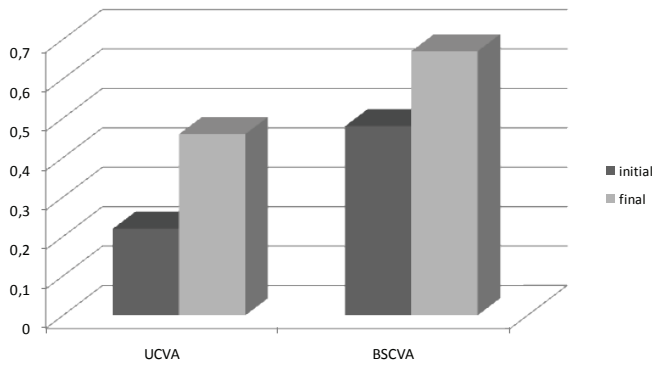


Fig. 1. UCVA and BSCVA before and after Ferrara ICRS implantation

lowing inclusion criteria: diagnosis of keratoconus, treated with Ferrara ICRS implantation, absence of other eye surgery, presence at follow-up examinations. The exclusion criteria were: other ocular surgery, absence from the follow-up examinations. Prior the surgery a complete ophthalmologic examination was performed, including: uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), slit lamp examination, refraction, keratometry, ultrasound pachymetry and corneal topography.

Surgical Technique

The ICRS implantation was performed under topical anesthesia. The center of the cornea was marked for the reference point. A 1 mm radial incision was created at 70–80% of corneal thickness with a calibrated diamond knife, under guidance of intra-operative ultrasonic pachymetry. Corneal pockets are created on each side of the radial incision, using the pocketing hooks. Two semicircular dissectors are advanced into the lamellar pocket by rotating clockwise and counterclockwise. Two semicircular tunnels are then created and the ring segments are inserted into the channels.

After the surgery, at the follow up examinations, UCVA, BSCVA, slit lamp examination, refraction, keratometry and corneal topography were recorded.

We collected all parameters from the patient's records. The postoperative values for each parameter were referred

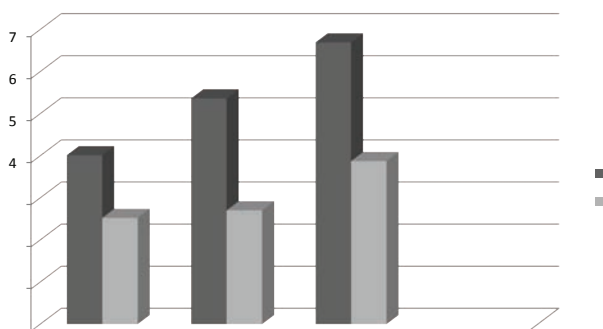


Fig. 3. Mean Sph, mean Cyl and mean SE before and after Ferrara ICRS implantation

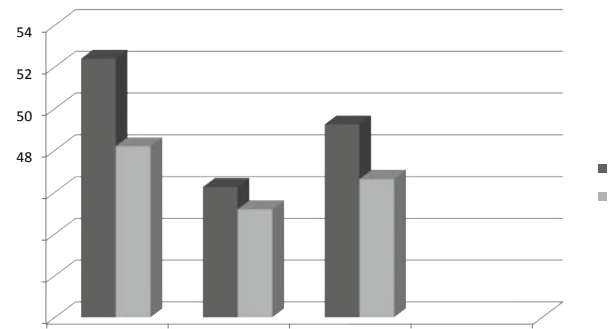


Fig. 2. Mean K values before and after Ferrara ICRS insertion

to those obtained before the intervention. The statistical analysis of data was made using Microsoft Excel and the Graph Pad Instat 3 Software. A p value < 0.05 was considered significant.

Results

In our study group 32 from 42 patients were males (76%) and 10 females (24%). The mean age was 28.19 ± 6.02 years (min.19, max. 50 years) and the mean follow-up period was 21.12 ± 9.76 months. The mean of initial (preoperative) uncorrected visual acuity (UCVA) was 0.2 ± 0.16 , ranging from 0.05 to 0.07. At the final of the observation period the recorded mean UCVA value was increased to 0.46 ± 0.19 ($p < 0.0001$). The best corrected visual acuity increase from an initial mean of 0.48 ± 0.17 to a final mean of 0.67 ± 0.17 ($p < 0.0001$) (Figure 1).

The comparative preoperative and postoperative keratometric reading (K) show a statistically significant decrease of the mean values of maximal (K max), minimal (K min) and average (K m) corneal dioptries (D) ($p < 0.0001$), suggesting a flattening of the cornea (Figure 2). The mean K max decrease with 4.2 D (from 52.4 ± 3.62 D to 48.18 ± 2.56 D), the mean K min with 1.06 D (from 46.26 ± 1.88 D to 45.2 ± 2.14 D) and the K m with 2.6 D (from 49.25 ± 2.5 D to 46.65 ± 2.22 D).

Comparing the initial and the postoperative mean values of manifest refraction we observed a statistically significant decrease of mean sphere (Sph), mean cylinder (Cyl)

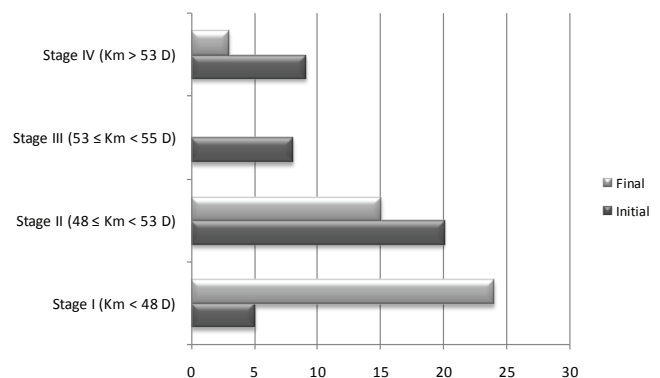


Fig. 4. Keratoconus classification after keratometry before and after treatment

and mean spherical equivalent (SE) values ($p < 0.0001$) (Figure 3).

At the final of the follow-up period the mean value of the manifest sphere refraction decreases with 1.49 D (from 4.02 ± 1.79 D to 2.53 ± 1.38 D) and the manifest cylinder value decrease with 2.66 D (from 5.37 ± 1.95 D to 2.71 ± 1.64 D). The mean value of spherical equivalent showed a decrease with 2.82 D, from the initial 6.7 ± 2.35 D to the final 3.88 ± 1.87 D. During the observation period the number of cases with keratoconus stage I increase from 5 to 24, respectively the number of cases stage II, III and IV decrease (Figure 4).

Discussions

The firsts to report the results of the ICRS implantation in reducing the refractive error and corneal steepening in keratoconus were Colin *et al.*, in year 2000 [11]. They showed a reduction of mean K with 4.85 D and of mean SE with 2.12 D (in our study 2.6 D and 2.82 D respectively). Several other studies reported statistically significant improvement of keratometric and refractive values after insertion of ICRS in keratoconus [12]. The reduction of mean K was variable from 1.57 D [13] to 3.9 D [14] and the reduction of mean SE was ranging from 1.39 [15] to 3.85 [14]. All studies showed a significant improvement on UCVA and BSCVA after ICRS implantation, which explain the favorable effect on quality of life in these patients. Ferrara rings implantation showed good results [16, 17], also in advanced cases of keratoconus [18]. The results in improving visual acuity and flattening the cornea was observed to remain stable for five years follow-up period [19].

Conclusions

Ferrara corneal ring segments implantation is an effective treatment option in keratoconus. The reduction of keratometric and refractive values shows a significant flattening of the cone shaped cornea and increase the contact lens tolerance. An important improving in best corrected visual acuity increase the quality of life of these young patients. The middle and long term observation had shown a persisting effect in most of cases, so this minimal invasive sur-

gical option can be used for prevent or for delay the need for keratoplasty.

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