

# Preliminary Results of Femtosecond Laser Assisted Corneal Ring Segment Implantation for Keratoconus

Kemal Ozulken, Florence Cabot, Vardhaman P Kankariya, Sonia H Yoo

## ABSTRACT

**Purpose:** To present refractive, visual and topographic outcomes of femtosecond laser assisted intrastromal ring segments (ISRS) implantation.

**Settings:** Bascom Palmer Eye Institute, Miami, FL, USA.

**Materials and methods:** Nineteen eyes of 15 patients with keratoconus, clear central corneas, and contact lens intolerance had implantation of a symmetrical 0.45 mm INTACS segment (Addition Technology Inc, California, USA) using 200 kHz femtosecond laser (WaveLight GmbH, Erlangen, Germany). The outcomes of the procedure were evaluated in terms of uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), average keratometry value (K-value) and spheric equivalent (SE).

**Results:** Femtosecond laser assisted ISRS implantation could be performed with ease, while no intra- or postoperative complications were encountered. Mean UCVA improved from  $0.95 \pm 0.39$  to  $0.66 \pm 0.28$  logMAR, mean BSCVA improved from  $0.46 \pm 0.13$  to  $0.29 \pm 0.21$  logMAR, mean spherical equivalent considerably reduced from  $-7.15 \pm 4.57$  to  $-4.38 \pm 4.07$  and K value reduced from  $52.39 \pm 5.79$  to  $49.78 \pm 6.84$  D at the last follow-up.

**Conclusion:** Using a 200 kHz femtosecond laser is a safe procedure providing optimal refractive, visual and topographic outcomes in our preliminary study.

**Keywords:** Keratoconus, Intrastromal ring segment, Femtosecond laser.

**How to cite this article:** Ozulken K, Cabot F, Kankariya VP, Yoo SH. Preliminary Results of Femtosecond Laser Assisted Corneal Ring Segment Implantation for Keratoconus. *Int J Kerat Ect Cor Dis* 2013;2(2):47-50.

**Source of support:** Nil

**Conflict of interest:** None

## INTRODUCTION

Keratoconus is a progressive, noninflammatory, asymmetric, bilateral, corneal ectatic disorder most commonly presenting in second decade of life. This disease can result in irregular astigmatism, progressive myopia, or visual impairment.<sup>1,2</sup> Because of optical aberrations caused by distortion and bowing of the cornea in keratoconus, spectacle correction frequently does not result in acceptable quality of vision, therefore, patients usually require rigid gas permeable contact lenses to achieve good functional vision.<sup>3,4</sup> Furthermore, approximately 20% of keratoconus patients become intolerant to contact lenses overtime and thus require a corneal transplantation for visual rehabilitation.

Intrastromal corneal ring segments (ISRS) have been recently proposed as an alternative treatment to more invasive corneal transplantation procedures (lamellar or penetrating keratoplasties).<sup>5-7</sup> ISRS are implanted in the corneal mid peripheral tunnels (created either manually or with the help of femtosecond lasers), resulting in an arc shortening effect and redistribution of corneal peripheral lamellae to produce flattening of the central cornea. In this study, we present the preliminary visual, refractive and topographic outcomes of femtosecond laser (WaveLight GmbH, Erlangen, Germany) assisted implantation of ISRS in patients with keratoconus.

## MATERIALS AND METHODS

### Study Population

This retrospective single center, single surgeon (SY), study was performed at Bascom Palmer Eye Institute, Miami, FL from January 2011 through January 2012. Retrospective chart review was performed after obtaining approval from Institutional Review Board of University of Miami. Inclusion criteria were: patients with keratoconus, clear central corneas, and contact lens intolerance who had ISRS implantation assisted by 200 kHz femtosecond laser (WaveLight GmbH, Erlangen, Germany). Nineteen eyes of 15 patients were included in this study.

### Surgical Technique

In this study, all ISRS implanted were United States Food and Drug Administration (FDA) approved INTACS (Addition Technology Inc, California, USA). These ring segments are made of polymethyl methacrylate (PMMA) and have a 7.0 mm optical zone, a crescent arc length of 150°, and a transverse hexagonal shape.

Intrastromal tunnels were created using the 200 kHz femtosecond laser (WaveLight GmbH, Erlangen, Germany) in all cases. The entry incision to insert the ring segments into the cornea was programmed on the steepest corneal topographic axis so as to center the segments on the flat meridian. The disposable glass lens of the laser system was first applanated to the cornea to fixate the eye and help maintain a precise distance from the laser head to the focal point. Then, a continuous circular stromal tunnel was created at approximately 70% of the corneal thickness (if this depth was <350 μm; if not, a channel was dissected exactly at

350 μm). Inner and outer diameter of the tunnel was programmed at 6.8 and 8.1 mm utilizing 1.3 μJ energy for both entry cut and tunnel creation.

The Addition Technology provided nomogram was used to determine the appropriate segment thickness in each case. At the end of the procedure, the entry incision was closed with a carefully applied 10/0 nylon suture to avoid corneal ring segment extrusion. Postoperatively, prednisolone acetate, moxifloxacin and ketorolac were prescribed 4 times a day for 1 week. Suture removal was performed after 4 weeks.

Postoperative visits were scheduled for the first postoperative day and for months 1 and 3 postoperatively. On the first postoperative day, only UDVA measurement and slit-lamp examination was performed. Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) measurement, manifest refraction, slit-lamp examination, and corneal topography were performed preoperatively and at each postoperative examination.

The outcome of the procedure was evaluated in terms of UDVA, CDVA, manifest refraction, average keratometry value (K-value) and spheric equivalent (SE) at 3 months postoperatively.

### Statistical Analysis

Statistics were performed with SPSS version 20.0 (SPSS Inc, IBM, Chicago, Illinois, USA). Normality of all data samples was first checked by means of the Kolmogorov-Smirnov test. When parametric analysis was possible, the Student t-test for paired data was performed for all parameter comparisons between preoperative and postoperative examinations. When parametric analysis was not possible, the Wilcoxon rank-sum test was applied to assess the significance of differences between preoperative and postoperative data.

### RESULTS

A total of 19 eyes of 15 patients with a mean age of 32.31 years (ranging from 18 to 50 years) were included. Ten patients were male (66%), and five patients were female (33%) in which nine right eyes and 10 left eyes were operated upon. No intra- or postoperative complications were encountered.

Mean preoperative UDVA was  $0.95 \pm 0.39$  logarithm of minimum angle of resolution (LogMAR) (range, 0.4-1.6 logMAR), CDVA was  $0.46 \pm 0.13$  logMAR (range, 0.3 - 0.69 logMAR), spherical equivalent (SE) was  $-7.15 \pm 4.57$  D (range,  $-0.5-16$  D), and K-value was  $52.39 \pm 5.79$  D (range, 42.46 – 61.43 D). At postoperative 3-month follow-up, statistically significant improvement was observed in mean UDVA which improved to  $0.66 \pm 0.28$  logMAR ( $p < 0.001$ ), mean CDVA improved to  $0.29 \pm 0.21$  logMAR ( $p = 0.001$ ), mean SE considerably reduced to  $-4.38 \pm 4.07$  ( $p = 0.03$ ) and K value reduced to  $49.78 \pm 6.84$  ( $p = 0.001$ ). Table 1 summarizes the visual, refractive, and keratometric outcomes in eyes implanted with INTACS using femtosecond laser technology.

### DISCUSSION

Intrastromal corneal ring segments are crescent-shaped PMMA implants originally designed to correct low to moderate myopia.<sup>8</sup> Currently, they are used to treat postoperative LASIK corneal ectasia, pellucid marginal degeneration, and keratoconus.<sup>5,9,10</sup> Intrastromal corneal ring segments are inserted in intrastromal channels (created either manually or using a femtosecond laser) at 75% depth of the thinnest pachymetry. This results in an arc shortening effect and redistribution of corneal peripheral lamellae to produce flattening of the central cornea.<sup>11</sup> INTACS (Addition Technology, Sunnyvale, California, USA), Kerarings (Mediphacos, Belo Horizonte, Brazil), and Ferrara rings (Mediphacos, Belo Horizonte, Brazil) are the 3 available designs of ISRS. INTACS are the only currently FDA approved ring segments, but Kerarings and Ferrara rings are widely used outside of the USA.

ISRS can be implanted in the corneal mid-periphery after creation of a manual or femtosecond laser-assisted intrastromal tunnel. The traditional mechanical technique for tunnel creation may demonstrated several and potentially severe complications. These include epithelial defects at the keratotomy site, anterior and posterior perforations during tunnel creation, extension of the incision toward the central visual axis or limbus, shallow placement and/or uneven placement of the INTACS segments, infectious keratitis, introduction of the epithelial cells into the tunnel during

**Table 1:** Summary of visual, refractive and keratometric outcomes

	Preoperative	3 months	p-value
UDVA	$0.95 \pm 0.39$ (0.4-1.6)	$0.66 \pm 0.28$ (0.17-1)	<0.001
CDVA	$0.46 \pm 0.13$ (0.3-0.69)	$0.29 \pm 0.21$ (0-0.96)	0.001
SE (D)	$-7.15 \pm 4.57$ ( $-0.5-16$ )	$-4.38 \pm 4.07$ (2.75-11.5)	0.003
K-value (D)	$52.39 \pm 5.79$ (42.46-61.43)	$49.78 \pm 6.84$ (40.06-62.02)	<0.001

UDVA: Uncorrected distance visual acuity in logarithm of minimum angle resolution (LogMAR); CDVA: Corrected distance visual acuity in LogMAR; SE: Spherical equivalent; K-value: Average keratometry value; D: Diopters. All values are displayed as means ± standard deviation (range)

the tunnel dissection, asymmetric placement, persistent incisional gaping, decentration, stromal thinning, and corneal stromal edema around the incision and tunnel from surgical manipulation.<sup>12-15</sup> Kanellopoulos et al reported a 35% rate of postoperative complications with the mechanical tunnel dissection method.<sup>16</sup>

The femtosecond laser has several advantages over the mechanical method for INTACS tunnel creation. Because laser energy is delivered optically to a precise depth, tunnel resections and entry incisions are highly reproducible, with little risk of corneal perforation. Also, the tunnel size and depth as well as the side-cut position may be changed as desired.<sup>17</sup> We prefer to place the INTACS segments in the 70% depth of the cornea whenever possible. Ratkay-Traub et al reported the first clinical results using the femtosecond laser in INTACS treatment.<sup>18</sup> The investigators found that of 16 eyes receiving intracorneal ring segments, the same refractive results were achieved compared with previous conventional treatments. Moreover, Ertan and Colin showed that the femtosecond laser, compared with mechanical channel dissection, boasted greater refractive improvement.<sup>19</sup>

The design of the patient interface of the femtosecond laser (200 kHz) system used in this study, combines high optical quality of the plane appplanation plate with an increase in the IOP similar to other femtosecond lasers. The optimized scanning algorithms allow the minimization of opaque bubble layer formation. The three-dimensional tissue cutting provides a broad spectrum of applications in refractive surgery as well as in corneal surgery. Furthermore, this laser system creates one continuous circular channel for the two-ring segments implantation and the software of this femtosecond laser allows for the creation of a small rectangular pocket tangential to the radial incision that makes it easier to introduce the leading end of the INTACS segment. Furthermore, with a rapid laser firing speed it reduces surgery duration with the least amount of energy necessary without sacrificing speed, accuracy or stromal smoothness.

Mohamed H Shabayek et al in their study reported superficial corneal opacification in eight eyes coinciding with the incision site, which did not affect the visual outcome.<sup>20</sup> They stated that this result is most probably due to the high energy used for the incision (5 mJ) and concluded that this complication can be eliminated by using faster femtosecond laser utilizing lower energy. We did not observe this complication in our study with comparatively faster femtosecond laser (200 kHz). Michael Mrochen et al, in their study, cut 30 porcine eyes with the same 200 kHz femtosecond laser for the tunnel creation and compared the deviations of the attempted vs the achieved mean tunnel dimensions for the corneal ring segments by using

OCT.<sup>21</sup> Their results demonstrated optimal accuracy for tunnel creation.

In our series, three patients had a history of crosslinking (CXL) procedure prior to referral to our institution. Due to nonavailability of their medical records before and after crosslinking procedure, it is not possible to draw conclusion about outcomes regarding sequence of procedures. Coskunseven et al in their study, stated that although each treatment step improves the cornea, a stiffer cornea that has been treated by CXL decreases the flattening effect of ICRS implantation, thus restricting its effect and decreasing the maximum flattening potential.<sup>22</sup> Thus, to achieve the maximum overall effect, ICRS implantation should be performed first so the segments can reshape the cornea without restriction.

Limitations of our study are that we could not provide homogeneity in our study; there were numerous variables in order to obtain exact results and 3 months of follow-up period was not long enough to evaluate the long-term results of the study.

Despite the small number of cases in our study, we can conclude that using a high speed 200 kHz femtosecond laser in the tunnel creation for INTACS implantation reduces surgery period compared to slower femtosecond laser systems without increasing the risk of operative and postoperative complications and provides good visual and refractive outcomes. Future larger, comparative studies with other femtosecond lasers focusing on the possible intra- and postoperative complications of channel creation with longer follow-up period are needed.

## REFERENCES

1. Pearson RM. Kalt, keratoconus and contact lens. *Optom Vis Sci* 1989;66:643-646.
2. Rabinowitz YS. Keratoconus. *Surv Ophthalmol* 1998;42:297-319.
3. Alió JL, Shabayek MH. Corneal higher order aberrations: a method to grade keratoconus. *J Refract Surg* 2006;22:539-545.
4. Gobbe M, Guillon M. Corneal wavefront aberration measurements to detect keratoconus patients. *Con Lens Anterior Eye* 2005;28:57-66.
5. Alió JL, Shabayek MH, Belda JI, et al. Analysis of results related to good and bad outcomes of INTACS implantation for keratoconus correction. *J Cataract Refract Surg* 2006; 32:756-761.
6. Alió JL, Shabayek MH. Intracorneal asymmetrical rings for keratoconus: where should the thicker segment be implanted? *J Refract Surg* 2006; 22:307-309.
7. Alió JL, Shabayek MH, Artola A. Intracorneal ring segments for keratoconus correction: long-term follow-up. *J Cataract Refract Surg* 2006;32:978-985.
8. Schanzlin DJ, Asbell PA, Burris TE, Durrie DS. The intrastromal corneal ring segments: phase II results for the correction of myopia. *Ophthalmology* 1997;104:1067-1078.

9. Pinero DP, Alio JL, Uceda-Montanes A, El Kady B, Pascual I. Intracorneal ring segment implantation in corneas with postlaser in situ keratomileusis keratectasia. *Ophthalmology* 2009;116:1665-1674.
10. Pinero DP, Alio JL, Morbelli H, et al. Refractive and corneal aberrometric changes after intracorneal ring implantation in corneas with pellucid marginal degeneration. *Ophthalmology*. 2009;116:1656-1664.
11. Alio JL, Artola A, Ruiz-Moreno JM, Hassanein A, Galal A, Awadalla MA. Changes in keratoconic corneas after intracorneal ring segment explantation and reimplantation. *Ophthalmology*. 2004;111:747-751.
12. Alió AJ, Artola A, Hassanein A, et al. One or two INTACS segments for the correction of keratoconus. *J Cataract Refract Surg* 2005; 31:943-953.
13. Colin J, Cochener B, Savary G, et al. INTACS inserts for treating keratoconus: one-year results. *Ophthalmology* 2001;108:1409-1414.
14. Boxer Wachler BS, Christie JP, Chandra NS, et al. INTACS for keratoconus. *Ophthalmology* 2003;110:1031-1040.
15. Ruckhofer J, Stoiber J, Alzner E, Grabner G. Multicenter European Corneal Correction Assessment Study Group. One-year results of European multicenter study of intrastromal corneal ring segments. *J Cataract Refract Surg* 2001;27:287-296.
16. Kanellopoulos AJ, Lawrence H, Perry HD, Donnenfeld ED. Modified intracorneal ring segment implantations (INTACS) for the management of moderate to advanced keratoconus: efficacy and complications. *Cornea* 2006;25:29-33.
17. Rabinowitz YS, Li X, Ignacio TS, Maguen E. INTACS inserts using the femtosecond laser compared to the mechanical spreader in the treatment of keratoconus. *J Refract Surg* 2006;30:74-78.
18. Ratkay-Traub I, Ferincz IE, Juhasz T, et al. First clinical results with the femtosecond neodymium-glass laser in refractive surgery. *J Refract Surg* 2003;19:94-103.
19. Ertan A. INTACS for keratoconus: comparison of mechanical versus femtolaser channel dissection. Paper presented at: American Academy of Ophthalmology Annual Meeting; October 10-14, 2007; Las Vegas.
20. Shabayek MH, Alió JL. Intrastromal corneal ring segment implantation by femtosecond laser for keratoconus correction. *Ophthalmology* 2007;114:1643-1652.
21. Mrochen M, Wüllner C, Krause J, Klafke M, Donitzky C, Seiler T. Technical Aspects of the WaveLight FS200 femtosecond laser. *J Refract Surg* 2010;26: 833-840.
22. Coskunseven E, Jankov MR 2nd, Hafezi F, Atun S, Arslan E, Kymionis GD. Effect of treatment sequence in combined intrastromal corneal rings and corneal collagen crosslinking for keratoconus. *J Cataract Refract Surg* 2009;35:2084-2091.

## ABOUT THE AUTHORS

### Kemal Ozulken

Fellow, Department of Cornea, Cataract and Refractive Surgery Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, FL, USA

### Florence Cabot

Fellow, Department of Cornea, Cataract and Refractive Surgery Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, FL, USA

### Vardhaman P Kankariya

Fellow, Department of Cornea, Cataract and Refractive Surgery Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, FL, USA

### Sonia H Yoo (Corresponding Author)

Professor of Ophthalmology, Department of Cornea, Cataract and Refractive Surgery, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, 900 NW, 17th ST, Miami, FL-33136 USA, Phone: 305-326-6000, Fax: 305-326-6337, e-mail: syoo@med.miami.edu