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Efficacy of Intacs Intrastromal Corneal Ring Segments in Patients with Post-LASIK Corneal Ectasia

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Abstract

***Purpose*:** To investigate the efficacy of Intacs implantation in post-LASIK corneal ectasia (PLE)

***Methods*:** In this retrospective study, 17 eyes of 12 patients with PLE, that had been implanted Intacs, were evaluated. These parameters were assessed: uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), manifest refractive spherical equivalent (MRSE), refractive cylinder (RC), mean Keratometry (Km), and topographic cylinder (TC). Also preoperatively, thinnest point thickness (TPT) was measured with rotating Scheimpflug camera. The results of single and double-segment Intacs implantation were also reported.

***Results*:** Mean UCVA logMAR value improved from 0.93±0.41 to 0.57±0.34 (p=0.007), and BSCVA logMAR from 0.36±0.34 to 0.18±0.18 (p=0.007). MRSE reduced from 4.15±2.71 to 2.48±1.57 diopter (D) (p=0.003), and Km from 44.57±3.93 to 43.00±3.96 D (p=0.003). RC changed from 2.65±1.91 to 2.59±1.12 D (p=0.776), and TC from 2.81±1.71 to 2.44±1.41 D (p=0.365), neither change was statistically significant. BSCVA and UCVA improved in both single and double-segment groups.

***Conclusion*:** Intacs implantation can improve UCVA and BSCVA in cases of PLE, except when TPT is less than 350 microns. Both MRSE and Km reduced after surgery but astigmatism did not change.

***Keywords*:** Ectasia, Intacs, LASIK, Corneal Ectasia, Astigmatism

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Introduction

Corneal ectasia is a vision threatening complication that occurs after uncomplicated LASIK surgery with an incidence of 0.04% to 0.66%.[1-4] In this iatrogenic complication, the cornea progressively steepens and thins; this may lead to myopia and irregular astigmatism. Consequently, uncorrected visual acuity (UCVA) and best spectacle corrected visual acuity (BSCVA) progressively worsen.

Treatment options proposed for this complication include spectacle correction, rigid gas permeable contact lenses,[5-7] and more invasive procedures such as Intacs (Microthin Prescription Inserts, Addition Technology Inc, Fermont, California) and other intrastromal corneal ring segment (ICRS) implantation,[8-19] corneal collagen cross-linking,[20,21] and finally, deep anterior lamellar keratoplasty.[22]

Inatcs segments are 150 degree, semi-circular ring of polymethyl methacrylate material, that had been devised to treat low myopia [-1 to -3 diopters (D)]. Intacs are available in a variable thickness from 0.25 to 0.45 mm with 0.05 mm steps. They are designed to be implanted in deep cornea, at the 7 mm optical zone, to flatten the central cornea. However, because of more accuracy and ease of Excimer laser to treat even low myopia, Intacs segments are rarely used for this reason.

Colin[23] was the first who applied Intacs ICRS for keratoconus in 2000. After that Intacs was more frequently used for keratoconus and post-LASIK ectasia with variable results. The purpose of this study was to report the outcomes of Intacs inserts in a series of patients with post-LASIK corneal ectasia (PLE).

Methods

In this retrospective study, files of all patients with post-LASIK ectasia who had Intacs surgery between 2006 and 2008 were evaluated. Post-LASIK ectasia was diagnosed as corneal thinning on slit lamp examination, reduced distant visual acuity (VA), unstable topography (steepening of more than 1.0 D over a 6 month follow-up), progressive corneal thinning on ultrasound pachymetry (more than 20 microns over a 6 month follow-up), and unstable refraction (change of more than 0.5 D in spherical equivalent over a 6 month follow-up). From the extracted cases, we excluded those with a history of corneal or intraocular surgery other than previous LASIK and Intacs surgery.

From the patients preoperative files, these data were extracted: UCVA; BSCVA; manifest refractive spherical equivalent (MRSE); refractive cylinder (RC); steep keratometry (K1), flat keratometry (K2), mean keratometry (Km=K1+K2/2), topographic cylinder (TC=K1-K2) from EyeSys topography (EyeSys Technologies, Houston, Tex); thinnest point thickness (TPT) from rotating Scheimpflug imaging system (Pentacam; Oculus, Wetzlar, Germany). UCVA and BSCVA were recorded as Snellen acuity and converted to logMAR for statistical analysis.

Patients were assigned to Intacs ICRS surgery if their corrected distant VA was reduced and the patient was contact lens intolerant and the central cornea was clear. The study proposal was reviewed and approved by the Review Board of Farabi Eye Research Center and all patients signed written informed consents.

Intacs nomogram was based on the position of the cone as determined by topography. Inferior cone was defined if steepening area did not involve 180-degree meridian of cornea, and central cone in which steepening extended at least 1.0 mm above and beyond 180-degree meridian. In inferior cone, 1 segment 0.45 mm thick was inserted in the steep meridian; and in central cone, 2 segments 0.45 mm thick were inserted in the steep meridians. Incision position was in the flat meridian.

All surgeries were performed by a single experienced surgeon (HH). First the patient was prepped and draped, and under topical anesthesia, the geometric center of the cornea was marked with a blunt Sinskey hook. With a special painted circular marker, the 7.0 mm optical zone and incision position was marked. A 0.9 mm vertical incision was created in the flat meridian with a calibrated diamond knife to a depth of 70% of the incision site as determined by an ultrasonic pachymeter. After inspecting the depth of the incision for adequacy, two pockets were made with the help of a pocketing hook from the depth of the incision on either side taking care

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they were made on equal level. Then with a modified Suarez spreader, the pockets were lengthened. After that, under vacuum centering glide, two tunnels were made with clockwise and counter-clockwise dissectors. Next, a 0.45 mm Intacs ICRS was manually inserted into the tunnel and rotated until the end of it was about 1.5 mm from the incision. Regardless of refractive error, we implanted a single segment inferiorly if the cone was inferior, and double segments if the cone was central. Finally, the incision was closed with a 10-0 nylon suture. All surgeries were performed without any complication or LASIK flap disruption.

After surgery, all patients received antibiotic and steroid eye drops four times a day for a week. Then after six weeks the suture was removed. Patients were visited regularly, and at the last follow-up which was a minimum of 12 months, a complete ocular exam and corneal topography was done by a single physician (ARY). We recorded the final UCVA, BSCVA, MRSE and RC from these exams, and the K1, K2, Km, and TC from topography maps and compared them with preoperative values.

Statistical analysis was performed with Statistical Package for Social Sciences software for windows (version 16.0, SPSS, Inc.). The Wilcoxon rank-sum test was used to compare pre and postoperative variables (UCVA, BSCVA, MRSE, RC, K1, K2, Km, TC), and Mann-Whitney test for comparisons between groups. A p value less than 0.05 was considered to be statistically significant.

Results

Seventeen eyes from twelve patients were assessed. Six of the patients were male and six were female, and their mean age was 33.25 (range, 25 to 54) years. Five patients were treated bilaterally. Of these 17 eyes, nine (52.9%) were right and eight (47.1%) were left eyes. In 12 cases, 1 segment and in five cases 2 segments were implanted. Mean follow-up was 23.8 (range, 12 to 42) months.

Mean UCVA changed from a preoperative value of 0.93±41 to the postoperative level of 0.57±34 on the last follow-up exam with a mean change of 0.36 on the logMAR scale indicating a gain of 3.5 Snellen lines (p=0.007). BSCVA changed from 0.36±0.34 to 0.18±0.18 logMAR showing a gain of 1.5 line (p=0.007) (Table 1, Figure 1).

Preoperatively mean MRSE was -4.15±2.71 D. On the last postoperative follow-up, mean MRSE was -2.48±1.57 D, indicating an improvement of 1.67 D (p=0.003). Mean preoperative RC was -2.65±1.91 D, and postoperatively it was -2.95±1.12 D which was not statistically significant (p=0.776, table 1).

Preoperatively, the average Km was 44.57±3.93 D, and decreased to 43.00±3.96 D, with a mean change of 1.57 D (p=0.007). Mean TC changed from a preoperative value of 2.81±1.71 D to 2.44±1.41 D on the last follow-up; this change was not statistically significant (p=0.365, table 1).

In both single and double segment groups, UCVA and BCVA got better (Table 2). In our series of patients, MRSE reduced about 1.5 D in single segment group, and about 2 D in double segment group, though RC and TC changes were not so tangible.

Table 1. Comparison between preoperative and postoperative of refractive and topographic results

	Preoperative Mean±SD	Postoperative Mean±SD	Change Mean±SD	p
UCVA logMAR	0.93±0.41	0.57±0.34	0.36±0.44	0.007
BSCVA logMAR	0.36±0.34	0.18±0.18	0.18±0.26	0.007
MRSE	-4.15±2.71	-2.48±1.57	1.67±2.41	0.003
RC	-2.65±1.91	-2.59±1.12	0.06±1.62	0.776
Km	44.57±3.93	43.00±3.96	1.57±2.27	0.007
TC	2.81±1.71	2.44±1.41	0.37±1.51	0.365

UCVA: Uncorrected visual acuity, BSCVA: Best spectacle corrected visual acuity, MRSE: Manifest refractive spherical equivalent, RC: Refractive cylinder, Km: Mean keratometry, TC: Topographic cylinder

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Table 2. Comparison between mean change (preoperative to postoperative) of parameters in 1 segment and 2 segments group

	1 segment Mean change±SD	2 segments Mean change±SD	p
UCVA logMAR	0.45±0.44	0.16±0.40	0.22
BSCVA logMAR	0.24±0.28	0.04±0.10	0.049
MRSE	1.56±2.72	1.9±1.66	0.28
RC	0.18±1.18	-0.25±1.15	0. 93
Km	1.25±1.78	2.35±3.31	0.34
TC	0.57±1.71	-0.09±0.87	0.39

UCVA: Uncorrected visual acuity, BSCVA: Best spectacle corrected visual acuity, MRSE: Manifest refractive spherical equivalent, RC: Refractive cylinder, Km: Mean keratometry, TC: Topographic cylinder

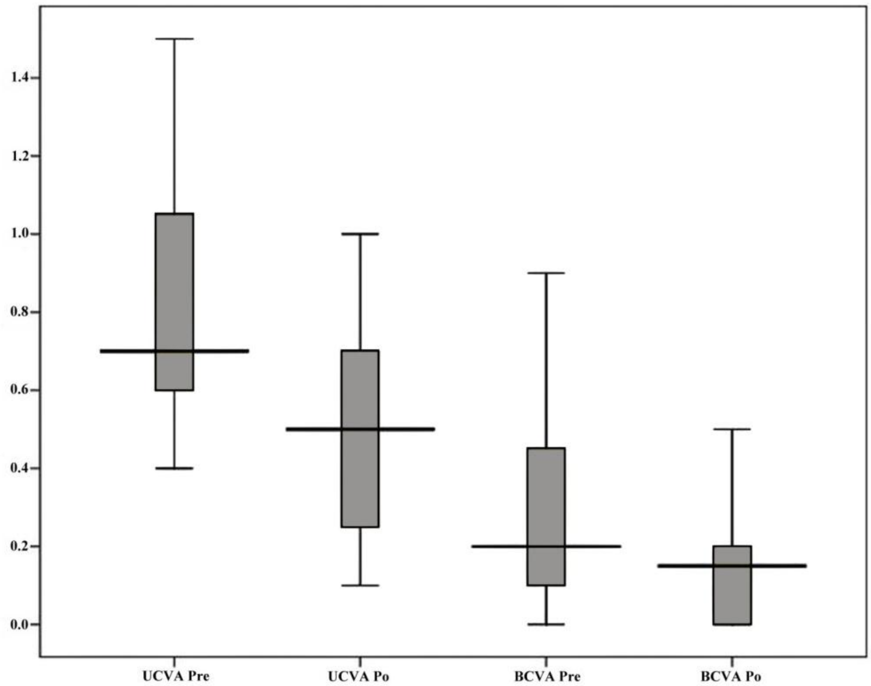

Figure 1. Box-plot of preoperative-postoperative change in uncorrected visual acuity and best corrected visual acuity on logMAR scale

UCVA change in cases with TPT less than 350 microns was -0.25±0.07 D, and in eyes with TPT more than 350 microns was 0.44±0.40 indicating that the UCVA worsened postoperatively in patients with less than 350 microns TPT (p=0.02). Mean BSCVA change in eyes with TPT less than 350 microns was 0.10±0.14 and in eyes with TPT more than 350 microns was 0.19±0.27, demonstrating a better outcome in cases with more than 350 microns, though the difference was not statistically significant. Therefore; preoperative corneal thickness may be an independent factor for the result of surgery.

Discussion

Several studies were done on the outcome of Intacs inserts in patients with post-LASIK ectasia and improvement of UCVA and BSCVA was noted in about 70% of cases.[8-19] In our study, UCVA got worse in four cases (23.5%), did not change in one case (5.8%), and improved in 12 cases (70.5%). The range of UCVA change in the logMAR scale was

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from -0.30 (loss of 3 lines) to 1.10 (gain of 11 line), and on average a UCVA improvement of 0.36 (3.5 lines increase) was observed.

In this study, BSCVA decreased in two cases (11.7%), not changed in three cases (17.6%), and improved in 12 cases (70.5%). The range of BSCVA change in the logMAR scale was from -0.10 to 0.80 (loss of 1 line to a gain of 8 Snellen lines) and on average BSCVA increased about 0.18 logMAR (nearly 2 lines).

The cause of more improvement in UCVA relative to BSCVA is the effect of Intacs. Intacs has two effects: reducing the spherocylindrical component, and decreasing high order aberrations of the cornea. Both effects are important in improving UCVA, but BSCVA gets better only because of decreasing high order aberrations.[19,24]

Mean change of MRSE and Km were 1.66±2.41 D and 1.5±2.27 D respectively; however, mean change RC and TC were 0.06±1.62 and 0.37±1.51. Thus, in our series of patients with post-LASIK ectasia, Intacs implantation did not improve astigmatism despite reducing MRSE and Km. Decreased MRSE was shown in most studies on patients with post-LASIK ectasia,[(8-10,12,14,19)] but in terms of the cylindrical component, some showed reduced astigmatism,[(8,18)] and some others demonstrated no change.[(12,19)] Intacs ICRS may appear to have a smaller effect in correcting astigmatism in patients with post-LASIK ectasia than in keratoconic patients. Most studies on Intacs in patients with keratoconus showed decreased astigmatism,[25-30] than no change.[31,32]

Alio et al showed with a similar nomogram, that single segment and double segments are both effective in terms of reducing cylinder and maximum and minimum keratometric values.[33] But in our series, as depicted in table 2, in single segment group, MRSE reduced about 1.5 D and in double segment group, about 2 D. However TC and RC changes were negligible in both groups.

We proposed that preoperative corneal thickness may be an independent factor for the outcome of surgery. We showed that in patients with very thin corneas (TPT less than 350 microns), Intacs implantation had an adverse effect on UCVA (loss of 2.5 lines) compared to cases with more than 350 microns (average gain of 4.5 lines). Therefore, it could be wise to avoid Intacs implantation in these very thin corneas.

Conclusion

Intacs implantation in patients with post-LASIK ectasia has a promising effect on improving vision in about 70% of cases. Visual outcome with single-segment implantation in inferior cone, and double-segment implantation in central cone has good results, but surgeons should proceed with caution when the TPT is less than 350 microns.

References

1. Reinstein DZ, Srivannaboon S, Archer TJ, Silverman RH, Sutton H, Coleman DJ. Probability model of the inaccuracy of residual stromal thickness prediction to reduce the risk of ectasia after LASIK Part II: quantifying population risk. J Refract Surg 2006;22(9):861-70.
2. Pallikaris IG, Kymionis GD, Astyrakakis NI. Corneal ectasia induced by laser in situ keratomileusis. J Cataract Refract Surg 2001;27(11):1796-802.
3. Condon PI, O'Keefe M, Binder PS. Long-term results of laser in situ keratomileusis for high myopia: risk for ectasia. J Cataract Refract Surg 2007;33(4):583-90.
4. Randleman JB, Stulting RD. Corneal ectasia. In Alió JL, Azar DT, eds. Management of Complications in Refractive Surgery. Berlin: Springer; 2008:89-96.
5. Randleman JB. Post-laser in-situ keratomileusis ectasia: current understanding and future directions. Curr Opin Ophthalmol 2006;17(4):406-12.
6. Woodward MA, Randleman JB, Russell B, Lynn MJ, Ward MA, Stulting RD. Visual rehabilitation and outcomes for ectasia after corneal refractive surgery. J Cataract Refract Surg 2008;34(3):383-8.
7. Eggink FA, Beekhuis WH. Contact lens fitting in a patient with keratectasia after laser in situ keratomileusis. J Cataract Refract Surg 2001;27(7):1119-23.
8. Carrasquillo KG, Rand J, Talamo JH. Intacs for keratoconus and post-LASIK ectasia: mechanical versus femtosecond laser-assisted channel creation. Cornea 2007;26(8):956-62.

9. Uceda-Montanes A, Tomás JD, Alió JL. Correction of severe ectasia after LASIK with intracorneal ring segments. J Refract Surg 2008;24(4):408-11.
10. Kymionis GD, Tsiklis NS, Pallikaris AI, Kounis G, Diakonis VF, Astyrakakis N, et al. Long-term follow-up of Intacs for post-LASIK corneal ectasia. Ophthalmology 2006;113(11):1909-17.
11. Sharma M, Boxer Wachler BS. Comparison of single-segment and double-segment Intacs for keratoconus and post-LASIK ectasia. Am J Ophthalmol 2006;141(5):891-5.
12. Polkroy R, Levinger S, Hirsh A. Single Intacs segment for post-laser in situ keratomileusis keratectasia. J Cataract Refract Surg 2004;30(8):1685-95.
13. Güell JL, Velasco F, Sánchez SI, Gris O, Garcia-Rojas M. Intracorneal ring segments after laser in situ keratomileusis. J Refract Surg 2004;20(4):349-55.
14. Kymionis GD, Siganos CS, Kounis G, Astyrakakis N, Kalyvianaki MI, Pallikaris IG. Management of post-LASIK corneal ectasia with Intacs inserts: one-year results. Arch Ophthalmol 2003;121(3):322-6.
15. Siganos CS, Kymionis GD, Astyrakakis N, Pallikaris IG. Management of corneal ectasia after laser in situ keratomileusis with INTACS. J Refract Surg 2002;18(1):43-6.
16. Lovisolo CF, Fleming JF. Intracorneal ring segments for iatrogenic keratectasia after laser in situ keratomileusis or photorefractive keratectomy. J Refract Surg 2002;18(5):535-41.
17. Alió JL, Salem T, Artola A, Osman A. Intracorneal rings to correct corneal ectasia after laser in situ keratomileusis. J Cataract Refract Surg 2002;28(9):1568-74.
18. Piñero DP, Alio JL, Uceda-Montanes A, El Kady B, Pascual I. Intracorneal ring segment implantation in corneas with post-aser In situ keratomileusis keratectasia. Ophthalmology 2009;116(9):1665-74.
19. Piñero DP, Alio JL, El Kady B, Pascual I. Corneal aberrometric and refractive performance of 2 intrastromal corneal ring segment models in early and moderate ectatic disease. J Cataract Refract Surg 2010;36(1):102-9.
20. Kymionis GD, Diakonis VF, Kalyvianaki M, Portaliou D, Siganos C, Kozobolis VP, et al. One-year follow-up of corneal confocal microscopy after corneal cross-linking in patients with post laser in situ keratomileusis ectasia and keratoconus. Am J Ophthalmol 2009;147(5):774-8.
21. Tan DT, Por YM. Current treatment options for corneal ectasia. Curr Opin Ophthalmol 2007;18(4):284-9.
22. McAllum PJ, Segev F, Herzig S, Rootman DS. Deep anterior lamellar keratoplasty for post-LASIK ectasia. Cornea 2007;26(4):507-11.
23. Colin J, Cochener B, Savary G, Malet F. Correcting keratoconus with intracorneal rings. J Cataract Refract Surg 2000;26(8):1117-22.
24. Piñero DP, Alio JL, El Kady B, Coskunseven E, Morbelli H, Uceda-Montanes A, et al. Refractive and aberrometric outcomes of intracorneal ring segments for keratoconus: mechanical versus femtosecond-assisted procedures. Ophthalmology 2009;116(9):1675-87.
25. Shetty R, Kurian M, Anand D, Mhaske P, Narayana KM, Shetty BK. Intacs in advanced keratoconus. Cornea 2008;27(9):1022-9.
26. Alió JL, Shabayek MH, Belda JI, Correas P, Feijoo ED. Analysis of results related to good and bad outcomes of Intacs implantation for keratoconus correction. J Cataract Refract Surg 2006; 32(5):756-61.
27. Ertan A, Kamburoğlu G, Bahadir M. Intacs insertion with the femtosecond laser for the management of keratoconus; one-year results. J Cataract Refract Surg 2006;32(12):2039-42.
28. Colin J. European clinical evaluation: use of Intacs for the treatment of keratoconus. J Cataract Refract Surg 2006;32(5):747-55.
29. Kanellopoulos AJ, Pe LH, Perry HD, Donnenfeld ED. Modified intracorneal ring segment implantations (INTACS) for the management of moderate to advanced keratoconus: efficacy and complications. Cornea 2006;25(1):29-33.
30. Colin J, Cochener B, Savary G, Malet F, Holmes-Higgin D. INTACS inserts for treating keratoconus: one-year results. Ophthalmology 2001;108(8):1409-14.
31. Ertan A, Kamburoğlu G. Intacs implantation using femtosecond laser for management of keratoconus: comparison of 306 cases in different stages. J Cataract Refract Surg 2008;34(9):1521-6.
32. Zare MA, Hashemi H, Salari MR. Intracorneal ring segment implantation for the management of keratoconus: safety and efficacy. J Cataract Refract Surg 2007;33(11):1886-91.
33. Alió JL, Artola A, Hassanein A, Haroun H, MD, Galal A. One or 2 Intact segments for the correction of keratoconus. J Cataract Refract Surg 2005;31(5):943-53.

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