Comparison of Single-Segment and Double-Segment Intacs for Keratoconus and Post-LASIK Ectasia

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• PURPOSE: To evaluate the efficacy of single-segment Intacs and compare with double-segment Intacs in subjects with post-LASIK ectasia and keratoconus.

• DESIGN: Retrospective comparative analysis.

• METHODS: SETTING: Boxer Wachler Vision Institute, Beverly Hills, California, USA. STUDY POPULATION: Thirty-seven eyes of 28 patients with keratoconus and post-LASIK ectasia classified into two groups: single-segment group (17 eyes, 11 patients) and double-segment group (20 eyes, 17 patients). Both groups were matched for age, visual acuity (uncorrected, UCVA; best spectacle-corrected, BSCVA), refractive error (sphere, cylinder, spherical equivalent), and keratometry (K) value (flat, steep, average) by *t* test for equality of means. INTERVENTION: Single- or double-segment Intacs procedure with axis of incision for insertion in the steep axis of manifest refraction. MAIN OUTCOME MEASURE: Improvement of acuity, refractive error, K values, and inferior-superior (I-S) ratio.

• RESULTS: There was more improvement in UCVA in the single-segment group (nine lines) than the double-segment group (2.5 lines), $P < .01$; in BSCVA in the single-segment group (2.5 lines) than the double-segment group (<1 line), $P < .01$; in steep K values in the single-segment group (2.76 diopters ± 2.68) than the double-segment group (0.93 diopters ± 2.01), $P = .02$; and in I-S ratio in the single-segment group (9.51 ± 7.49) than the double-segment group (4.22 ± 4.82), $P = .01$; and greater cylinder decrease after Holladay vector analysis in the single-segment group (5.69 diopters ± 3.10) than the double-segment group (1.58 diopters ± 3.09), $P < .01$.

• CONCLUSIONS: Single-segment Intacs improved both UCVA and BSCVA by differential flattening of inferior meridian and steepening of superior meridian as reflected by change in I-S ratio.

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KERATOCONUS IS A BILATERAL, ASYMMETRIC, CHRONIC, initially progressive ectasia of the cornea characterized by steepening, distortion and thinning of the apical cornea, corneal scarring, and treatment-related sequelae, such as abrasions from contact lenses and surgical complications.[1] In most patients, keratoconus is diagnosed at an early age, when spectacles are not able to provide sufficient vision, or at an older age, when the patients are evaluated for laser vision correction. Rigid gas permeable lenses are able to correct the vision in many, but not all, patients. Intacs (Addition Technology Inc, Sunnyvale, California, USA) is one treatment option available for these patients, especially those with contact lens intolerance. Most of the earlier studies have advocated the use of two segments during the surgery.[2–6] Post-LASIK ectasia is a similar progressive tectonic deterioration of corneal anatomy due to structural instability in the cornea. Intacs has been shown to improve the quality of vision in cases of iatrogenic post-LASIK ectasia after laser in situ keratomileusis or photorefractive keratectomy.[7] Most cases have been treated with two segments of Intacs. Recent studies report on the use of single-segment Intacs,[8,9] but no study has compared outcomes of single-segment Intacs with double-segment Intacs. The purpose of the present study was to compare single-segment Intacs with double-segment Intacs in treatment of keratoconus and post-LASIK ectasia.

METHODS

ALL THE SURGERIES WERE PERFORMED AT BOXER WACHLER Vision Institute, Beverly Hills, California, USA, by a single surgeon (B.B.W.). Retrospective analysis of all patients who underwent Intacs surgery for ectasia with noncentral (peripheral) cones from January 2004 through

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TABLE 1. Comparison of Preoperative Parameters in the Single-Segment and Double-Segment Intacs Groups

Variable	Single-Segment Group (mean ± SD)	Double-Segment Group (mean ± SD)	*P* Value
Age (y)	44.23 ± 14.51	43.90 ± 9.41	.93
Preoperative UCVA (logMAR)	1.36 ± 0.77	0.94 ± 0.40	.06
Preoperative BCVA (logMAR)	0.33 ± 0.22	0.34 ± 0.46	.93
Preoperative sphere	−1.25 ± 3.22	−1.67 ± 5.27	.79
Preoperative cylinder	−4.19 ± 1.99	−4.17 ± 1.76	.98
Preoperative SE	−3.34 ± 3.01	−3.76 ± 5.69	.79
Preoperative steep K	49.89 ± 5.37	48.60 ± 4.37	.43
Preoperative flat K	45.01 ± 3.68	42.50 ± 5.59	.12
Preoperative average K	47.45 ± 4.39	45.55 ± 3.95	.18

BCVA = best-corrected visual acuity; K = keratometry; logMAR = logarithm of minimal angle of resolution; UCVA = uncorrected visual acuity.

November 2004 was done for the single-segment group and from one year before 2003 for the double-segment group. The other technique difference was a second incision was often made approximately 180 degrees opposite the entry incision in single-segment group. The two groups were matched for age, preoperative uncorrected visual acuity (UCVA), refractive error (sphere, cylinder, and spherical equivalent), best spectacle-corrected visual acuity (BSCVA), steep topography keratometry (K) value, flat K value, and average K value by independent sample *t* test for equality of means (Table 1). Thirty-seven eyes of 28 patients with keratoconus or post-LASIK ectasia were included in analysis; 32 eyes were in patients with keratoconus, and five eyes experienced post-LASIK ectasia. All patients were referred cases for evaluation. During the process of consent for surgery, consent was taken to later include clinical information in scientific studies.

Patients were evaluated for preoperative and postoperative UCVA, BSCVA, manifest refraction, corneal topography, and ultrasonic pachymetry. During manifest refraction, patients were allowed to choose the axis of cylinder by manually rotating the knob on the phoropter if BSCVA was worse than 20/40. Patients were followed at day one, one month, three months, six months, and one year postoperatively. All patients underwent Intacs surgery with the axis of incision in the steepest axis of manifest refraction, and Intacs was inserted at 66% corneal thickness at the site of incision determined by intraoperative pachymetry. Patients were classified into two groups: inferior single-segment group (17 eyes of 11 patients) and double-segment group (20 eyes of 17 patients). There were three eyes from patients with post-LASIK ectasia in the single-segment group and two eyes in the double-segment group. Mean duration of follow-up was 94.45 days (range 30 to 380 days). All patients in both groups had at least a one-month follow-up visit, 94.1% in the single-segment group and 95% in the double-segment group had a three-month visit, 35.29% in the single-segment group and 40% in the double-segment group had a six-month visit, and 17.64% in the single-segment group and 20% in the double-segment group had a one-year visit.

The SPSS software (SPSS Inc, Chicago, Illinois, USA) was used for data entry and analysis. Both groups were compared with each other for the change in UCVA, BSCVA, K values in diopters (steep, flat, and average), and manifest refraction by independent sample *t* test for equality of means. For α at .05 and power of 0.80, 13 eyes were the minimum sample size per group for a minimum detectable difference of 0.17 logarithm of minimal angle of resolution (logMAR) lines (SD 0.17), K difference of 1.3 diopters (SD 1.6), and vector cylinder difference of 4.3 diopters (SD 3.0).

The inferior-superior (I-S) ratio[5,10] was also used for comparing outcomes between single- and double-segment groups, because this ratio quantifies the degree of irregular corneal shape. I-S was calculated as the difference in the sum of inferior and superior keratometry values with the horizontal axes as reference meridians. Steepest, flattest, average, and central keratometry values were evaluated with the values at meridians of 0 degrees, 30 degrees, 60 degrees, 90 degrees, 120 degrees, 150 degrees, 180 degrees, 210 degrees, 240 degrees, 270 degrees, 300 degrees, 330 degrees, and 360 degrees. To evaluate the change in I-S ratio from the available data, 29 eyes were used with 14 eyes from the single-segment and 15 eyes from the double-segment group. They were chosen and matched for preoperative values of mean I-S ratio. For α at .05 and power of 0.80, 13 eyes were the minimum sample size per group for a minimum detectable I-S difference of 5.3 and a SD of 6.4.

We used the Holladay[11] vector analysis method to assess preoperative and postoperative change in cylinder from the surgery. Comparative analysis of the same factors was

TABLE 2. Types of Intacs Used in Patients

Segment Size	Number of Treated Eyes	Percentage of Eyes Treated
0.25 (single)	2	5.40
0.30 (single)	6	16.20
0.35 (single)	9	24.30
0.25/0.30	7	18.9
0.25/0.35	11	29.7
0.30/0.35	1	2.70
0.35/0.35	1	2.70
Total	37	100

also done with respective preoperative values in the single-segment group using paired sample *t* test for means.

RESULTS

PREOPERATIVELY, NO EYES HAD CENTRAL SCARRING, seven eyes (18.9%) had peripheral scarring, and two eyes (5.4%) had a ferrous line. In the single-segment group, the 0.35-mm segment was used most frequently, and in the double-segment group, the 0.25-mm and 0.35-mm Intacs combination was most frequently used (Table 2).

In the single-segment group, mean preoperative UCVA of <20/400 (1.37 ± 0.77) improved to better than 20/60 (0.47 ± 0.24), representing a gain of 9 lines ($P < .01$), and BSCVA improved from 20/40 (0.33 ± 0.22) preoperatively to 20/25 (0.09 ± 0.14) postoperatively ($P < .01$), representing a gain of 2.5 lines. In the double-segment group, mean preoperative UCVA was approximately 20/200 (0.94 ± 0.40), which improved to better than 20/100 (0.70 ± 0.34), representing 2.5 gained lines ($P = .25$), and BSCVA was 20/40 − 2 (0.34 ± 0.46) preoperatively and increased to 20/40 + 1 (0.27 ± 0.14) postoperatively, representing a gain of less than one line ($P = .10$). The improvement in UCVA and BSCVA was greater in the single-segment group than in the double-segment group ($P < .01$; Table 3).

There was a significant improvement in the steep K after surgery in the single-segment group, with a preoperative mean steep K of 49.90 diopters ± 5.37 decreasing to a postoperative mean steep K of 47.12 diopters ± 4.23 ($P < .01$). The preoperative mean steep K in the double-segment group was 48.60 diopters ± 4.37, which improved to 47.66 diopters ± 2.57 ($P = .05$). This change in the single-segment group (2.76 diopters ± 2.68) was more than in the double-segment group (0.93 diopters ± 2.01), $P = .02$. Similarly, flat K and average K were less postoperatively, but decrease was more in the single-segment group than in the double-segment group for average K, $P < .01$ (Table 4).

Mean manifest cylinder decreased after the surgery in both the single- and double-segment groups (Table 5), but the decrease in the single-segment group (1.62 diopters ± 1.15) was greater than in the double-segment group (0.51 diopters ± 1.70), $P = .02$. After vector analysis using the Holladay method, surgically induced decrease of cylinder was greater in the single-segment group (5.69 diopters ± 3.10) than in the double-segment group (1.58 diopters ± 3.09), $P < .01$. The change of sphere was more in the double-segment group (2.01 diopters ± 3.10) than in the single-segment group (0.65 diopters ± 1.77), although it was not statistically significant, $P = .38$.

Both groups showed improved I-S ratios postoperatively ($P < .01$). However, the postoperative I-S improvement was greater in the single-segment group (9.51 ± 7.49) compared with the double-segment group (4.22 ± 4.82), $P = .01$ (Table 6). This indicated that the single segment led to a more physiologic improvement in the irregular corneal shape.

TABLE 3. Comparison of LogMAR and Snellen Acuities in Single-Segment and Double-Segment Intacs Groups

	Preoperative-Postoperative Change		
Variable	Single-Segment Group	Double-Segment Group	*P* Value*
UCVA			
logMAR mean ± SD	0.89 ± 0.75	0.24 ± 0.54	<.01
Snellen	9 lines	2.5 lines	
BSCVA			
logMAR mean ± SD	0.24 ± 0.17	0.07 ± 0.17	<.01
Snellen	2.5 lines	<1 line	

BSCVA = best spectacle-corrected visual acuity; UCVA = uncorrected visual acuity.
*Change in single-segment vs double-segment group.

TABLE 4. Comparison of Flattening of Keratometry in Single-Segment and Double-Segment Intacs Groups

	Preoperative to Postoperative Change (D)		
Variable	Single-Segment Group (mean ± SD)	Double-Segment Group (mean ± SD)	*P* Value*
K steep	2.76 ± 2.68	0.93 ± 2.01	.02
K flat	0.92 ± 1.72	0.13 ± 4.60	.50
Average K	1.84 ± 1.93	0.53 ± 2.55	<.01

*Change in single-segment vs double-segment group.

DISCUSSION

INSERTION OF SINGLE-SEGMENT INTACS HAS BEEN REported to be effective in decreasing the corneal steepening and astigmatism and improving BSCVA in patients with keratoconus[8] and to improve progressive myopia and astigmatism (regular and irregular) in eyes with post-

TABLE 5. Comparison of Refractive Changes in Single-Segment and Double-Segment Intacs Groups

Variable	Preoperative to Postoperative Change (D) Single-Segment Group (mean ± SD)	Double-Segment Group (mean ± SD)	*P* Value*
Sphere	0.65 ± 1.77	2.01 ± 3.10	.38
Cylinder	1.62 ± 1.15	0.51 ± 1.70	.02
Spherical equivalent	1.45 ± 1.60	2.26 ± 3.66	.59
Vector change in cylinder	5.69 ± 3.10	1.58 ± 3.09	<.01

*Change in single-segment vs double-segment group.

TABLE 6. Comparison of Inferior-Superior (I-S) Values in Single-Segment and Double-Segment Intacs Groups

Variable	K Values (D) Single-Segment Group	Double-Segment Group	*P* Value*
Preoperative I-S value	20.49 ± 14.33	27.78 ± 13.07	.16
Postoperative I-S	10.98 ± 10.24	23.56 ± 11.04	<.01
Change I-S	9.51 ± 7.49	4.22 ± 4.82	.01

*Change in single-segment vs double-segment group.

LASIK ectasia.[9] In particular, Alio and associates[8] reported outcomes of single and double segments, but there was neither comparison nor matching of the two groups. Our present study directly compared the results of single-segment Intacs with those of double-segment Intacs and represents the first direct comparison of the two techniques. Using matched groups preoperatively, we found that single-segment Intacs resulted in improved outcomes compared with double-segment Intacs for cases of peripheral keratoconus. The reasons for the better results with single segments are based on the anatomic and topographic change that occurs in keratoconic corneas. In most cases of keratoconus, there is an inferior cone with concomitant steepening, but there is also flattening in the superior aspect of topography (Figure 1). Double segments flatten the cornea inferiorly as well as superiorly. This global flattening of cornea and greater reduction of myopic spherical error were observed in our results. However, global flattening with double segments did not have as much effect on the asymmetry in shape of cornea (I-S ratio) or astigmatism in cornea as from single segments.

Single segments induced localized flattening inferiorly much like the inferior segment in a double-segment procedure. The difference between the two techniques lies in the superior aspect of the cornea. The single segment often leads to superior steepening in the upper cornea (Figure 2), not flattening as seen with double segments. We believe this is the reason that the single-segment group

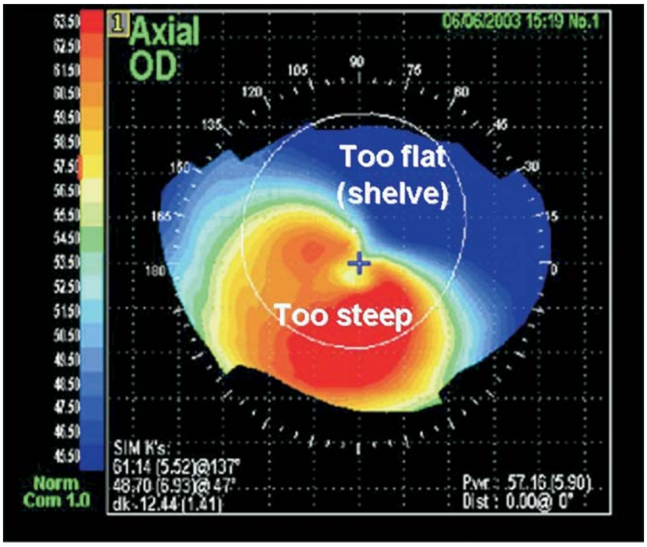

FIGURE 1. Typical keratoconus cone is associated with inferior steepening and superior flattening.

resulted in greater decrease of I-S ratio than the double-segment group. This finding likely translates into better optics with single-segment Intacs and accounted for the greater improvement in BSCVA in the single-segment group. The second incision may explain the greater astigmatism correction with single segments. We currently use single segments for keratoconus with peripheral cones (Figure 1). For centrally located cones, we still use double segments. Centrally located cones do not have a delineated inferior-steeper and superior-flatter topographic pattern because they are more symmetric. Therefore we employ double symmetric segments in such cases, as reported in our previous study.[5]

In a group with preoperative BSCVA of 20/78, Hellstedt and associates[12] found three lines of BSCVA improvement with double segments. In our previous study with double-segment Intacs,[5] the group with central or paracentral corneal scarring had five lines of improvement in BSCVA compared with three lines of improvement in the group without corneal scarring. Corneal scarring indicates a more advanced stage of keratoconus (as reflected in worse

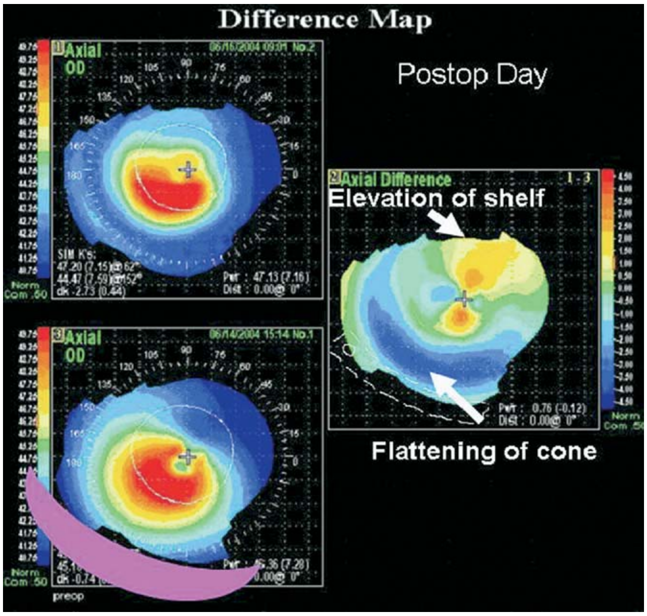

FIGURE 2. Preoperative (lower left) and postoperative (upper left) topography maps following single-segment Intacs insertion (pink). The difference map (right) shows the inferior flattening and superior steepening induced by single-segment Intacs.

BSCVA preoperatively in the corneal scarring group, 20/200 + 2, vs nonscarring group, 20/40 + 2). In general, these more advanced cases have more potential for improvement in BSCVA even though their final postoperative BSCVA may not be as good as less advanced cases.[5] In the present study, we found less than one line of BSCVA improvement in the double-segment group (with preoperative BSCVA of 20/40 − 2), which is somewhat less than the three lines gained in the above-cited studies with double segments and preoperative BSCVA of 20/40. This difference likely reflects the selection process used to preoperatively match single-segment and double-segment groups in our study.

Our study has limitations. Although we observed corneal asymmetry to be more improved in single segments using I-S ratio as the metric for comparison, there are other potential means to assess changes in asymmetry and optical characteristics. Corneal irregularly can be characterized by coma with wavefront analysis. Future studies may consider incorporating coma analysis to quantify corneal irregularity. When employing wavefront analysis, it is prudent to use the same analysis diameter for all eyes preoperatively and postoperatively, which may require dilation. Without controlling analysis diameters, wavefront measurements can be skewed too high or too low. Changes in coma could mistakenly be attributable to a certain treatment that is being evaluated, when in reality such coma changes were from uncontrolled analysis diameters. In our study, we did not distinguish between patients with keratoconus and post-LASIK ectasia, because there were no results differences between them within each Intacs group. Mean postoperative change in steep K value in three patients with post-LASIK ectasia in the single-segment group was 2.47 ± 0.87, and in two patients in the double-segment group was 0.98 ± 0.23, which is similar to the whole group (Table 4).

Our study demonstrated that single-segment Intacs induce more physiologic corneal shape changes and improved postoperative results in keratoconus than double-segment Intacs. Further evaluation of single-segment Intacs is warranted.

REFERENCES

1. Szczotka LB, Barr JT, Zadnik K, the CLEK Study Group. A summary of the findings from the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study. Optometry 2001;72:574–587.
2. Colin J, Cochener B, Savary G, et al. Correcting keratoconus with intracorneal rings. J Cataract Refract Surg 2000;26:1117–1122.
3. Colin J, Cochener B, Savary G, et al. INTACS inserts for treating keratoconus: one-year results. Ophthalmology 2001;108:1409–1414.
4. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. Am J Ophthalmol 2003;135:64–70.
5. Boxer Wachler BS, Christie JP, Chandra NS, et al. Intacs for keratoconus. Ophthalmology 2003;110:1031–1040.
6. Tunc Z, Deveci N, Sener B, et al. Corneal ring segments (INTACS) for the treatment of asymmetrical astigmatism of the keratoconus. Follow-up after 2 years. J Fr Ophthalmol 2003;26:824–830.
7. Lovisolo CF, Fleming JF. Intracorneal ring segments for iatrogenic keratectasia after laser in situ keratomileusis or photorefractive keratectomy. J Refract Surg 2002;18:535–541.
8. Alio JL, Artola A, Hassanein A, et al. One or 2 Intacs segments for the correction of keratoconus. J Cataract Refract Surg 2005;31:943–953.
9. Pokroy R, Levinger S, Hirsh A. Single Intacs segment for post-laser in situ keratomileusis keratectasia. J Cataract Refract Surg 2004;30:1685–1695.
10. Rabinowitz YS. Videokeratographic indices to aid in screening for keratoconus. J Refract Surg 1995;11:371–379.
11. Holladay JT, Cravy TV, Koch DD. Calculating the surgically induced refractive change following ocular surgery. J Cataract Refract Surg 1992;18:429–443.
12. Hellstedt T, Makela J, Uusitalo R, et al. Treating keratoconus with Intacs corneal ring segments. J Refract Surg 2005;21:236–246.