Keratoconus Managed With Intacs

One-Year Results

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Objectives: To describe the visual outcome of keratoconus managed with Intacs implantation (Addition Technology Inc, Fremont, Calif) and to define criteria that predict good outcome.

Methods: This retrospective, nonrandomized, comparative, consecutive case series studied 58 eyes of 43 patients with keratoconus managed by Intacs implantation. The outcome measures were analyzed pre-Intacs and 1 year post-Intacs. Preoperative parameters were correlated with outcome.

Main Outcome Measures: Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, videokeratography, and patient questionnaires.

Results: Intacs were implanted in all eyes with no intraoperative complications. Six eyes underwent additional Intacs surgery. Post-Intacs, the mean±SD UCVA improved from less than 20/200±0.1 line to 20/50±3.1 lines, the mean±SD BSCVA was unchanged at 20/32±2.0 lines, the mean±SD spherical equivalent improved from −3.88±1.64 to −1.04±1.51 diopters (D), and the mean±SD astigmatism improved from 3.34±2.23 to 1.97±1.51 D. Twenty-five eyes had a good outcome (UCVA≥20/40). Multiple regression selected BSCVA, astigmatism, and spherical myopia as the preoperative predictors of outcome.

Conclusions: Intacs improve myopia and regular astigmatism in keratoconus. Milder keratoconus (BSCVA≥20/32−2 and astigmatism<3.50 D) and significant spherical myopia (>−1.75) predict better outcome.

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LASSICALLY, THERAPEUTIC options for keratoconus with clear corneas are limited to spectacles and contact lenses. Penetrating keratoplasty is indicated in central corneal scarring and contact lens intolerance. Because most cases of keratoconus are young adults with clear corneas and penetrating keratoplasty has significant risks, an additional treatment to improve uncorrected visual acuity (UCVA) in contact lens intolerance would be useful.

Recently, intrastromal corneal ring segments (Intacs; Addition Technology Inc, Fremont, Calif) have been reported to improve the refractive defect in keratoconus1-4 and in post–laser-assisted in situ keratomileusis keratectasia.5-9 Colin et al1-2 in 10 eyes and Boxer Wachler et al5 in 74 eyes, in an attempt to treat the inferior ectasia characteristic of keratoconus, used an asymmetric technique, implanting an inferior 0.45-mm segment and a superior 0.25-mm segment through a temporal incision. In 33 keratoconic eyes, Siganos et al4 used a symmetric technique, implanting 2 same-thickness segments in a technique similar to that used to correct low myopia.

Although these studies reported encouraging results, crucial questions remain unanswered. These include the long-term corneal stability post-Intacs and which preoperative refractive parameters predict a good outcome. In an attempt to answer these questions, we present our experience with a large number of keratoconic eyes 1 year after Intacs implantation.

METHODS

PATIENTS

We retrospectively reviewed patient records of keratoconus cases consecutively managed by Intacs surgery between March 2001 and August 2002 at our center. Keratoconus of varying severity was included. Definite keratoconus was diagnosed by slitlamp signs (localized corneal thinning, Vogt striae, Fleisher ring) or...
by videokeratography using the Rabinowitz indices\textsuperscript{10} (a keratoconic topographic pattern of inferior steepening or skewed bow-tie axes, with inferior-superior [I-S] asymmetry > 1.9 diopters [D], central corneal power > 48.7 D, or a central corneal power difference > 0.92 D between the 2 eyes). Forme fruste keratoconus was diagnosed as a keratoconic topographic pattern and at least 1 of the following: I-S asymmetry greater than 1.4 D, central corneal power greater than 47.2 D,\textsuperscript{10} or fellow eye keratoconus (as earlier). Patients were intolerant to rigid contact lenses. Exclusion criteria were central corneal scarring, additional ocular pathologic abnormalities, prior ocular surgery, and follow-up time less than 1 year. Patients with large pupils (> 7.0 mm) were not excluded. Prior to signing a detailed consent to Intacs implantation, patients received a thorough explanation of the surgical procedure emphasizing the aims, the possible adverse effects, and the paucity of experience with Intacs in keratoconus.

**SURGICAL TECHNIQUE**

Intacs surgery was performed under topical anesthesia. Two surgical techniques were used, depending on the patient's refractive problem: symmetric, that is, 2 same-thickness segments (superior or temporal incision), or asymmetric, that is, a thicker inferior segment or a single inferior segment. Our surgical nomogram depended on the manifest refraction, the patient's age (amount of presbyopia), and the site of the cone. For spherical equivalents less than −3.00 D, we used an asymmetric technique (usually a single inferior 0.45-mm-thick segment) or a symmetric technique with a temporal incision and thinner segments (0.35- or 0.40-mm-thick segments). For spherical equivalents greater than −3.75 D (most cases), we used a symmetric technique (usually 0.45-mm-thick segments) with a temporal incision (segments implanted superiorly-inferiorly) for inferior cones and a superior incision (segments implanted nasally-temporally) for central cones. We allowed our patient's age and reading habits to influence the segment thickness choice (using thinner segments in presbyopes).

Regarding inferior cone surgery, we attempted to place the Intacs segment where the cornea was steepest. To achieve this end, we marked the steepest meridian at the slitlamp because cyclotorsion of the eye in the operating room may lead to placement of the segment too nasally or too temporally. To prevent extrusion of the Intacs segment, the incision mark was made approximately 1.5 mm above the desired site of the proximal end of the Intacs segment. The corneal thickness at the planned site of Intacs implantation was measured using both Orbscan II (Bausch & Lomb Surgical, Orbtek Inc, Salt Lake City, Utah) and Ultrasound Pachymetric Analyzer pachymetry (Model P55, Paradigm Medical Industries Inc, Salt Lake City) because Orbscan pachymetry may not be reliable. Corneal thickness of at least 450 µm along the entire site was required, to enable a channel depth of at least 370 µm to prevent superficial perforation. A calibrated diamond knife with a 15°-angled blade was used to make the approximately 1.8-mm radial incision two thirds of the peripheral corneal thickness (usually ~ 400 µm). Incision depth was checked with a corneal thickness gauge. Using 2 Sinskey hooks and a stromal spreader, the corneal pocket was fashioned at the full depth of the incision. The inferior stromal hemichannel was created using a dissection glide and blade rotated under the suction of a vacuum-centering guide. Incisions were closed with a 10-0 nylon suture. Postoperatively, all eyes received antibiotic and steroid drops 4 times daily for 3 weeks, in addition to frequent use of preservative-free artificial tears. The single suture was removed 1 to 4 weeks postoperatively.

**VISUAL ACUITY**

Visual acuity was assessed at 20 feet and converted to the logarithm of the minimum angle of resolution (logMAR) for statistical analysis and was reported as logMAR or Snellen equivalents, as recommended by Holladay.\textsuperscript{11} Because our study subjects were interested in achieving good vision and tended to group all visual acuity less than 20/160 as “not seeing,” attaining reliable data in the low-vision range was difficult. Therefore, we analyzed all visual acuities less than 20/200 as 20/200.

**FOLLOW-UP**

Follow-up examinations were performed at 1 day; 1 week; and 1, 3, 6, and 12 months post-Intacs implantation. Manifest refractions, UCVs, and BSCVAs were assessed by experienced optometrists at each visit. Axial placido-based videokeratographic maps (version 4.2; EyeSys Technologies, Houston, Tex), simulated keratometry values (minimum and maximum), central corneal power, effective refractive power, and I-S asymmetry values were attained using the EyeSys software. Nine to 12 months postoperatively, patients completed a brief questionnaire that included questions on visual distortion, night vision, blurring, glare, halos, and photophobia.

**ADDITIONAL SURGERY**

Six cases underwent adjustment of their Intacs. This entailed removal, exchange, addition, or shifting of an Intacs segment. Because our aim was to assess the visual outcome of keratoconic eyes managed with Intacs, the visual outcome used in the follow-up analysis was that attained after the Intacs adjustment surgery.

**STATISTICAL ANALYSIS**

Between-group mean differences were tested for significance using the 2-tailed t test for unequal variance. We used the UCVA outcome to retrospectively classify cases into 1 of 3 outcome groups: poor-, fair-, and good-UCVA outcome (<20/63 [logMAR poorer than 0.50], ≥20/63 but <20/40 [logMAR 0.50-0.31], and ≥20/40 [logMAR better than 0.30], respectively). To define which preoperative criteria are predictive of a good visual outcome, pre-Intacs refractive parameters were correlated with the postoperative UCVA both simply (Pearson product-moment correlation coefficient) and multiply (stepwise multiple regression using the linear regression model of the SAS system 9.1, SAS Institute Inc, Cary, NC). In addition, we compared the means of the preoperative parameters of the poor- and good-outcome groups (2-tailed t test).

**RESULTS**

**PATIENT POPULATION**

Fifty-eight eyes of 43 patients were studied, 25 of whom were men. Mean±SD age was 35.9±10 years (range, 21-55 years). Fifty-one eyes were classified as definite keratoconus and 7 as forme fruste keratoconus.

**VISUAL ACUITY**

The mean±SD UCVA improved from less than 20/200±0.1 line to 20/20±0.3 line, and the mean±SD BSCVA was essentially unchanged at 20/32±2.0 lines (Table 1). Pre-Intacs UCVA was 20/200 or worse in al-
most all of the 58 eyes studied (Figure 1A). The mean±SD post-Intacs UCVA of the poor-UCVA outcome group (<20/63), comprising 21 eyes, was 20/125±1.7 lines; the mean±SD fair-UCVA outcome group (20/63 to <20/40), comprising 12 eyes, was 20/50±0.6 line; and the mean±SD good-UCVA outcome group (≥20/40), comprising 25 eyes, was 20/32±0.9 line (P<.001 for any 2 means). Most eyes with preoperative logMAR BSCVA better than 0.2 (20/32) fell into the fair- or good-outcome groups (Figure 1B).

Figure 1. Preoperative vs 1-year postoperative logarithm of the minimum angle of resolution (logMAR) uncorrected visual acuity (UCVA) (A) and best spectacle-corrected visual acuity (BSCVA) (B). Eyes were analyzed according to UCVA outcome: poor (<20/63), fair (20/63 to <20/40), and good (≥20/40). The preoperative BSCVA correlated well with the UCVA outcome group.

Figure 2A shows that 34 (60%) of 58 eyes improved their UCVA by 6 or more lines, all achieving an UCVA greater than or equal to 20/50, but the BSCVA was mostly unchanged (Figure 2B). Seven eyes, mainly of the poor-UCVA outcome group, improved their BSCVA by 2 or more lines. This gain was offset by 6 eyes, mainly of the good-UCVA outcome group, losing 2 or 3 lines.

### Table 1. Visual Acuities, Snellen Equivalents

<table>
<thead>
<tr>
<th></th>
<th>Preoperative (n = 58)</th>
<th>Postoperative (n = 58)</th>
<th>P Value</th>
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</thead>
<tbody>
<tr>
<td>Uncorrected visual acuity</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Mean ± SD</td>
<td>20/200 ± 0.1 line</td>
<td>20/50±3 ± 1.1 lines</td>
<td>&lt;.001</td>
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<tr>
<td>Median (logMAR)</td>
<td>20/200 (1.00)</td>
<td>20/50 (1.38)</td>
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<tr>
<td>Range (logMAR)</td>
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<td>20/200-20/20 (1.00-0.02)</td>
<td></td>
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<tr>
<td>Best spectacle-corrected visual acuity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>20/32±1 ± 0.23 line</td>
<td>20/32 ± 0.18 line</td>
<td>.75</td>
</tr>
<tr>
<td>Median (logMAR)</td>
<td>20/32 (0.15)</td>
<td>20/32 (0.15)</td>
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</tr>
<tr>
<td>Range (logMAR)</td>
<td>20/200-20/20 (1.00-0.00)</td>
<td>20/100-20/20 (0.70-0.00)</td>
<td></td>
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Abbreviation: logMAR, logarithm of the minimum angle of resolution.
REFRACTIVE OUTCOME

Table 2 presents that the mean manifest spherical equivalent, spherical correction, and astigmatic correction all improved significantly (P<.001). Although Intacs surgery reduced the mean spherical correction to almost 0, a significant mean astigmatic correction of 1.97 D remained. Figure 3 shows that preoperatively, the poor-outcome group had a wide range of spherical correction (Figure 3A), usually with high astigmatic correction (Figure 3B). Preoperatively, 10 poor-outcome eyes had little spherical myopia (≤−1.75 D); 9 of these had severe astigmatism (≥5.00 D). Only 3 poor-outcome eyes had less than 3.00 D of astigmatism preoperatively.

KERATOMETRY

Keratometry by videokeratography improved significantly (Table 3). The mean ± SD preoperative I-S asymmetry was 4.34±3.91 D (range, −0.91 to 19.22 D). Forty-one (80%) of 52 of the preoperative I-S values attained were greater than 1.9 D.

PATIENT QUESTIONNAIRES

Out of the 54 patient questionnaires completed, 39 reported significant improvement and 15 reported no improvement. Five cases, although satisfied with their improved UCVA, reported a slight loss of BSCVA. Many patients mildly complained of decreased near vision and intermittently “seeing the ring.”

PREOPERATIVE PARAMETERS AS PREDICTORS OF OUTCOME

Table 4 presents correlations between preoperative parameters and the UCVA outcome. The preoperative BSCVA and astigmatic correction had the strongest correlations, with keratographic parameters showing significant correlations. Table 5 summarizes the multiple regression analysis of the respective preoperative param-
The patient’s visual function worsened because of increased astigmatism after the initial Intacs implantation. This surgically induced astigmatism was managed by removing the superior segment in all 4 cases, with shifting of the lower segment in 1 case. Two of these eyes attained UCVA of 20/40 and 2 remained close to 20/160. The fifth patient had surgically induced hyperopia. This was managed by removing the superior segment, yielding UCVA of 20/50−2. The sixth patient had received a single inferior segment and remained myopic. He was treated by implanting a 0.25-mm superior segment, yielding UCVA>20/40.

**SURGICAL TECHNIQUE**

We compared the 2 techniques of symmetric Intacs implantation. In 26 eyes, the segments were implanted superio-rily-inferiorly through a temporal incision and in 18, na-sally-temporally through a superior incision. There were no significant differences in UCVA, BSCVA, refraction, corneal topography, and patient satisfaction between the 2 techniques of same-thickness Intacs implantation (Table 7).

**ADDITIONAL INTACS SURGERY**

Six eyes underwent additional Intacs surgery. In 4 cases, the patient’s visual function worsened because of in-creased astigmatism after the initial Intacs implantation. This surgically induced astigmatism was managed by removing the superior segment in all 4 cases, with shifting of the lower segment in 1 case. Two of these eyes attained UCVA of 20/40 and 2 remained close to 20/160. The fifth patient had surgically induced hyperopia. This was managed by removing the superior segment, yielding UCVA of 20/50−2. The sixth patient had received a single inferior segment and remained myopic. He was treated by implanting a 0.25-mm superior segment, yielding UCVA>20/40.

**COMMENT**

Twenty-five of 58 eyes of this study achieved an UCVA greater than or equal to 20/40, 1 year post-Intacs. We expect that selecting patients for Intacs surgery using the criteria recommended by this study will further improve this good result. A good outcome may be expected in the patient with keratoconus with a preoperative BSCVA greater than 20/32−2 and secondarily with an astigmatic correction less than 3.50 D and a spherical correction more myopic than −1.75 D. We received these values by adding 1 standard deviation to the mean of the good-UCVA outcome group in Table 6 (BSCVA) and, regarding astigmatism and spherical correction, by the watershed values on the respective scattergrams (Figure 3).

Siganos et al4 also attempted, albeit to a limited extent, to define preoperative criteria that are predictive of
Two techniques of Intacs surgery for keratoconus have been reported. Colin et al1,2 and Boxer Wachler et al3 used an asymmetric technique in which a thicker segment is implanted inferiorly. This technique aims to treat the inferior steepening seen in most keratoconic and keratectatic eyes. The same-thickness segment implantation technique used by Siganos et al4 and our study aims to reduce the myopia and astigmatism by symmetrically flattening and supporting the central cornea. We also used an asymmetric technique in certain cases where the spherical equivalent was less than −3.00 D. It seems that both techniques are effective in keratoconus. Our approach, as described in the “Methods” section, is to tailor the technique to each specific patient, the spherical equivalent being the most decisive factor. Additional study will determine the optimal surgical technique.

Because the greatest improvement was seen in the cases with astigmatism less than 3.50 D and spherical correction greater than −1.75 D, it seems that the main mechanism of Intacs improving the refractive outcome is improving the spherical error. Although astigmatism is also improved (regular astigmatism manifesting as a decrease in the manifest astigmatic correction and irregular astigmatism manifesting as an increase in the BSCVA), this effect appears more limited. Therefore, in selecting patients for Intacs implantation, the surgeon should consider that the patient with greater myopia would probably be more satisfied than the patient with high astigmatism and little spherical myopia.

Intacs implantation in keratoconus appears safe. We had no superficial corneal buttonholing because we were careful to dissect the entire length of the Intacs channel at least 370 µm deep. Likewise, we had no segment extrusion because the proximal end of the segment was implanted at least 1 mm into the channel. Ectatic corneas are thinner, less rigid, and less symmetric than normal corneas, making buttonholing and segment extrusion more likely if the preceding precautions are not taken. Eight eyes, mostly of the good-UCVA outcome group, had postoperative loss of 2 or more lines of BSCVA. Two of these eyes, having little UCVA improvement, underwent additional Intacs surgery (removal of superior segment). Both eyes greatly improved their UCVA and recovered their lost BSCVA. Others3,4 also reported loss of BSCVA post-Intacs in a small number of keratoconic eyes. Although Intacs are easily removed, which reverses the refractive effect,12,14 loss of BSCVA is a cause for concern and requires further study.

Six eyes underwent additional Intacs surgery; 3 achieved a good visual outcome and 1 a fair outcome. Additional Intacs surgery carries a negligible risk of complication, often requiring simple explantation of the superior segment. Although Siganos et al4 and our study show the visual outcome to be similar in both temporal and superior incision same-segment Intacs surgery, an advantage of the temporal incision is that it allows the option of easy removal of the superior segment, if necessary. Others3,4 respectively describe 2 cases of superior Intacs segment removal that achieved satisfactory results.

Because keratoconus differs in severity and patterns of presentation, studies on keratoconus, including ours, are limited. Boxer Wachler et al3 included cases of forme fruste keratoconus as well as advanced cases of keratoconus with corneal scarring. Although they showed the ability of Intacs to significantly improve the UCVA and BSCVA in severe keratoconus, few of the corneal-scarred cases achieved an UCVA greater than or equal to 20/40. Colin et al1,2 Siganos et al4, and we excluded cases of corneal scarring. This variation in the severity of keratoconus in the patient cohort studied makes comparing studies difficult. We stress the need for standard-
ized criteria for the different severities of keratoconus. Retrospective studies may be less reliable than prospective ones because of missing data. Besides 6 eyes lacking preoperative I-S values and 4 eyes lacking questionnaires, our study had no missing data.

To our knowledge, our study is the longest series of keratoconus patients managed with Intacs with 1-year follow-up. We show that Intacs surgery may achieve good 1-year stable UCVA in keratoconic eyes, especially if patients are selected with attention primarily to the BSCVA and secondarily to the astigmatism and the spherical error.

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REFERENCES


Correction

Error in Figure. In the Epidemiology article by The Eye Diseases Prevalence Research Group titled “The Prevalence of Refractive Errors Among Adults in the United States, Western Europe, and Australia,” published in the April 2004 issue of the Archives (2004;122:495-505), an error appeared in Figure 3 on page 498. In the creation of that figure, the black and white prevalence rates from the Baltimore Eye Survey were inadvertently reversed. The corrected figure is reprinted here with its legend.