



INTACS for Keratoconus

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■ Background

INTACS are 2, arclike, polymethylmethacrylate segments which are designed to be surgically inserted into the deep corneal stroma to flatten the central cornea. They were designed and approved by the FDA for the correction of mild myopia [-1 to -3 Diopter(D)].¹ However, with the approval of the excimer laser around about the same time, the competition from laser-assisted subepithelial keratomileusis (LASIK) which could more accurately and simply correct these refractive errors in the same range proved too much for Keravision, the company who originally manufactured this device, resulting in their demise and the discontinuation of its use for myopia.²

Dr Joseph Colin in France first conceived of the concept of using INTACS to treat patients with keratoconus, even though it was initially considered a contraindication for this disorder.³ In 2001, he published, 1-year follow-up data, on 10 patients he treated with moderate disease who were contact lens intolerant and demonstrated an improvement in both uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) in almost all patients with very few complications.⁴ Recently, he presented 5-year data on this same group of patients and demonstrated refractive stability and no long-term complications (ESCRS winter meeting, Monte Carlo, 2006, unpublished data). Since his pioneering work, at least 5 other groups have been able to duplicate his work and have demonstrated that this device has a role in the armamentarium for the treatment of keratoconus.⁵⁻⁹ Recently, INTACS was approved for the treatment of keratoconus in the United States under a human device exemption which allows for its use under the surveillance of an institutional review board. In the United States, 0.25, 0.275, 0.30, 0.325, and 0.35 mm segments are available for the use. Outside the United States, 40 and 0.45 mm-sized segments are also available. A competitive device, the Ferrara ring is also sold and marketed outside the United States because it does not have FDA approval in the United States. The main difference between these 2 devices is that with INTACS

the optical zone is approximately 7 mm, whereas the Ferrara ring has an optical zone of the order of 4.5 to 5 mm.

INTACS, which is now manufactured and sold by Addition

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1 without being exposed to the risk of developing progressive post-LASIK
2 ectasia.

3 ■ **Surgical Technique**

5 ***Mechanical Spreader***

7 The following is a brief description of the surgical technique using
8 the mechanical spreader and instruments provided by the manufacturer
9 for inserting INTACS for keratoconus.

11 Central and peripheral ultrasonic pachymetry measurements are
12 made at the 7 mm optical zone. The eye is prepped with iodine and
13 draped. Topical anesthesia is applied to the eye and the central cornea is
14 marked with a felt-tipped pen. A marker is then used to mark the 7 mm
15 optical zone and the entry site into the cornea, which in keratoconus is
16 typically temporal.

17 A diamond knife is set at 70% of the thickness of the cornea at the
18 incision site and a vertical incision is made into the cornea. From the base
19 of the incision, a corneal pocket is created on each side of the incision.
20 Pockets should be at the same depth across the full width of incision
21 within the same stromal plane and as long as the Stromal Spreader
22 blade. Pockets are created at the full depth of the incision to avoid
23 shallow implant depth. The pocket depth is estimated and deeper
24 pockets are cut if necessary. The VCG and IPM are located on the center
25 mark and a vacuum of 400 to 500 mBar is applied. The placement is
26 confirmed and the vacuum is increased to 600 to 667 mBar. The
27 continuous VCG time should be limited to 3 minutes or less and applied
28 vacuum to 750 mBar. The glide is inserted into the first pocket and the
29 dissector blade tip rotated under Glide. The dissector is rotated to create
30 a tunnel. An intrastromal tunnel is created on the second side. The
31 vacuum is released and the VCG is removed. Dissecting should be
32 stopped if excessive resistance or “tissue wave” is encountered, consider
33 creating a deeper pocket and tunnel. The procedure should be aborted
34 in the event of a posterior chamber perforation or anterior corneal
35 surface perforation. The incision area should be irrigated and 1
36 intrastromal corneal ring segment should be inserted into each
37 intrastromal tunnel with the positioning hole adjacent to the incision.
38 Place 1 or 2 interrupted sutures, evenly spaced. Suture depth should be
39 to the level of the stromal pocket. Suture knots should be buried. An
40 antibiotic-corticosteroid eye drop are administered postoperatively.^{1,3}

41 ***Femtosecond Laser***

43 Recently, a femtosecond laser (the Intralase) was introduced into
44 clinical practice. This device creates channels at a predetermined depth
45 and allows for easy insertion of the INTACS at a predictable depth. This

1 procedure is very quick and extremely surgeon and patient friendly.
2 Many corneal surgeons who had abandoned the surgical technique with
3 the mechanical spreader because of technical difficulties experienced
4 with the device supplied by the manufacturer, are now taking a new look
5 at this procedure using the intralase to create the channels to insert the
6 INTACS. Besides being extremely quick and easy, there are other
7 advantages of the intralase, these are: there is a high degree of certainty
8 of the depth of placement so superficial placement and erosion of the
9 INTACS can be avoided, the channels can be recut a shallower depth for
10 the INTACS to be reinserted if the initial outcome is unsatisfactory, more
11 effect can be achieved by making the stromal channels narrower than the
12 INTACS and lastly visual recovery tends to be quicker.

13 The following is a suggested technique for inserting INTACS using
14 the Intralase: Preoperative pachymetry is performed. The eye is
15 prepped and draped. The center of the pupil is marked with a felt-
16 tipped pen. The initial intralase settings should be as follows: depth
17 400 μ m, incision site temporal, incision length 1.4 mm, incision width
18 1 mm, channel size should be 6.6 \times 7.4 mm which gives you an 0.4-mm
19 channel which is 0.05 mm larger than the INTACS. As surgeons gain
20 more experience, the outer channel size can be reduced to 7.2 mm
21 which effectively gives you a 0.3-mm channel which is 0.05 mm narrower
22 than the INTACS.⁹ Since the entry cut is vertical, it can often initially be a
23 bit tricky to advance the INTAC through the channel.

24 To facilitate this it is important to hydrate the cornea, identify the lip
25 of the circular incision with a sinskey hook and then while putting
26 upward pressure on the sinskey hook to keep the lip open place the
27 INTACS under and advance it under the sinskey hook all the while
28 keeping the lip elevated this will prevent the INTAC from being hung
29 up on the lip of the incision. Both INTACS should be advanced at least
30 1 mm away from the lip of the incision but should not touch each other
31 on the other side. The wound should be closed with a single 10 0
32 through and through nylon suture, which should be buried. A soft
33 contact lens with an approximate correction can be put on the eye and
34 the patient is given an antibiotic and steroid drop postoperatively.

35 ***Incision Placement and INTACS Selection***

36 There is no uniform agreement as to where to place the entry
37 incision. Some recommend putting it on the steepest axis claiming it
38 reduces the astigmatism. Colin in his original article placed his incisions
39 temporally and still got significant reduction in astigmatism because of
40 the asymmetric sizes of the INTACS, that is, 0.25 mm above and
41 0.45 mm below.

42 I believe the best place to make the incision is where you are assured
43 the INTACS will bisect the thinnest part of the cornea so that it will
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1 physiologically make the cornea normal by thickening the thin area. In
2 almost all cases of oval and central cones, this turns out to be temporal. It
3 is only mild cones where thinning is in an unusual location where placing
4 the incision could make a significant difference. More astigmatic effect is
5 probably achieved from asymmetry of the INTACS than the location of
6 the entry incision. Research is however ongoing as to where the optimal
7 entry incision should be.

8 Because INTACS come in many different sizes, there are potentially
9 many different combinations of INTACS can be used to achieve both
10 flattening of the central cornea and reduce the astigmatism. Most studies
11 show that irrespective of what combination you use, you get some effect.
12 In pure nipple cones where you just want to get the maximum flattening
13 effect, it is best to use 2 symmetrical INTACS. In the United States, two
14 0.35 mm INTACS are best and in Europe, two 0.45 mm segments would
15 be best. If the patient is not severely myopic, lesser size symmetrical
16 INTACS could be used so as not to overcorrect and induce hyperopia.

17 In typical oval type cones, most surgeons follow Colin's original
18 concept of putting in asymmetric INTACS: 0.25 mm above and 0.45 mm
19 below outside the United States and 0.25 mm above and 0.35 mm below
20 in the United States. In very mild cones which do not cross the
21 horizontal meridian often suffices.¹⁰ Recently, there is a trend towards
22 just putting in a single INTAC inferiorly in oval cones because it is felt
23 this is the most asymmetrical way to perform this procedure and will
24 maximize reduction of the astigmatic effect.¹¹ It certainly has been our
25 experience that in patients in whom we have put in 2 INTACS with an
26 unsatisfactory result, the patients often see better and are happier once
27 we remove the superior INTAC.

28 Although the issue of where to place the incision and what size
29 INTAC to use is evolving and could be considered to be dictated by the
30 "Art of medicine," a summary of data in published studies using
31 different combination of techniques outlined below can help the
32 beginning surgeon transition from art to science.

33 ■ Outcomes of Published Studies

34 Colin et al in 2001 published the first series of 10 patients with 1-year
35 follow-up. All patients had keratoconus with clear central corneas and
36 were contact lens intolerant. INTACS inserts of 0.45-mm thickness were
37 placed in the inferior cornea to lift the cone and INTACS of 0.25-mm
38 thickness were inserted superiorly to counterbalance and flatten the
39 overall anterior corneal surface. In his study, there were no intraopera-
40 tive complications. Spherical equivalent error and refractive astigmatism
41 were reduced with INTACS inserts treatment. Postoperative month 12
42 UCVA [logarithm of the minimum angle of resolution (logMAR) mean,
43 0.35, standard deviation (SD), 0.16 (approximately 20/50, approximately
44 45

1 2 lines)] was significantly better than preoperative [logMAR mean, 1.05; SD, 0.33 (approximately 20/200, approximately 3 lines); $P \leq 0.05$].
3 Average best spectacle-corrected visual acuity at postoperative month 12
5 was improved by approximately 2 lines compared with baseline [logMAR
7 mean, 0.22; SD, 0.12 (approximately 20/32, approximately 1 line);
9 logMAR mean, 0.38; SD, 0.13 (approximately 20/50, approximately 1
11 line), respectively]. Topographic corneal shape (size and height of the
13 cone) was improved for all subjects after insert placement. The corneal
15 steepening and astigmatism associated with keratoconus was reduced, and
17 visual acuity was improved with treatment in almost all eyes.⁴

19 Siganos in 2003 published the results of a prospective randomized
21 trial on 33 eyes with keratoconus in Greece. All patients had clear central
23 corneas and contact lens intolerance. Two INTACS segments of 0.45-
25 mm thickness were inserted in the cornea of each eye, aiming at
27 embracing the keratoconus area to try to achieve maximal flattening. He
29 noted that INTACS were successfully implanted in all eyes. In 1 eye,
31 INTACS were removed after 3 months because of their improper
(superficial) placement. The follow-up ranged from 1 to 24 months
(mean: 11.3 mo). The mean UCVA significantly improved from
0.13 \pm 0.14 [range, counting fingers (CF)-0.5] to 0.39 \pm 0.27 (range,
CF-1.0) ($P < 0.01$). Of 33 eyes, 2 eyes lost 1 line of UCVA, and 3 eyes
maintained the preoperative UCVA, whereas the rest (28 eyes) experi-
enced a 1-line to 10-line gain. The mean BCVA also improved from
0.47 \pm 0.31 (range, CF-1.0) to 0.64 \pm 0.26 (range, 0.1 to 1.0) ($P < 0.01$).
Of 33 eyes, 4 eyes experienced 1-line to 2-line loss of BCVA, 4 eyes
maintained the preoperative BCVA, whereas the rest (25 eyes),
experienced a 1-line to 6-line gain. Of 3 patients (3 eyes) with
unsatisfactory results, 1 patient improved with 1 segment removal and
in 2 patients, the segments were permanently removed. One of these
eyes underwent successful PKP. He concluded that intracorneal ring
segments implantation improved UCVA and BCVA in the majority of
the keratoconus patients.⁵

33 In 2003, Boxer Wachler in Los Angeles California reported the
35 results on 74 eyes of patients with keratoconus. All patients with
37 keratoconus were treated, he did not exclude patients with central
39 scarring as suggested by Colin. A thicker ring segment was typically
41 placed inferiorly, and a thinner segment was placed superiorly. He
43 found that the preoperative mean best-corrected LogMAR visual acuity
45 was 0.41 (20/50-1) (SD, \pm 0.48), which improved to a postoperative
mean of 0.24 (20/32-2) (SD, \pm 0.31) (2 lines of improvement).
Preoperative mean uncorrected LogMAR visual acuity was 1.05 (20/
200-2 1) (SD, \pm 0.48), which improved to a mean of 0.61 (20/80-)
(SD, \pm 0.52) (4 lines of improvement) at postoperative follow-up. Preopera-
tive mean best-corrected LogMAR acuity in the corneal scarring group
was 0.96 (20/200+2) (SD, \pm 0.72), which improved to a mean of 0.54

1 (SD, ± 0.43) (20/63-2) (5 lines of improvement). Uncorrected mean
2 LogMAR acuity in the eyes with corneal scarring was 1.42 (20/400-4)
3 (SD, ± 0.27), which improved to a mean of 1.03 (20/200-1) (SD, ± 73) (3
4 lines of improvement). The mean spherical equivalent before surgery
5 was -3.89 D (SD, ± 5.16), which was reduced to a mean of -1.46 D
6 (± 4.11) at the postoperative follow-up. He concluded that asymmetric
7 INTACS implantation can improve both uncorrected and best spectacle-
8 corrected visual acuity and can reduce irregular astigmatism in corneas
9 with and without corneal scarring.⁸

10 In 2005, Levinger et al reported 1-year data on a series of 54 eyes
11 with keratoconus treated in Israel with INTACS. The goal of his
12 retrospective study was to describe the visual outcome and define
13 criteria that were predictive of a good outcome. He found that the mean
14 improvement in UCVA was from less than 20/200 (± 1 line) to 20/50-3
15 (± 3.1 lines), the mean BSCVA was unchanged at $20/32 \pm 2.0$ lines, the
16 mean spherical equivalent improved from -3.88 ± 1.64 D to
17 -1.04 ± 1.51 D, and the mean astigmatism improved from 3.34 ± 2.23 D
18 to 1.97 ± 1.51 D. Twenty-five eyes had a good outcome (UCVA $>$ or
19 $= 20/40$). Multiple regression selected BSCVA, astigmatism, and spher-
20 ical myopia as the preoperative predictors of outcome. His study
21 concluded that milder keratoconus (BSCVA $> 20/32(-2)$, astigmatism
22 < 3.50 D) and significant spherical myopia (> -1.75) are predictive of
23 better outcomes.⁶

24 In 2005, Hallstead et al in a study in Finland performed a
25 nonrandomized prospective clinical trial on 50 eyes of patients with mild
26 to moderate keratoconus treated with a pair of asymmetrical INTACS, the
27 mean follow-up was 6.3 ± 3.2 months. Of the 50 operations performed,
28 92% were successful. In 4 (8%) eyes, both INTACS segments were
29 removed. In addition, 7 refractive adjustments in 7 eyes were performed
30 successfully to improve visual and surgical outcome. Both BSCVA and
31 UCVA improved throughout follow-up. Visual functioning index im-
32 proved from 61.6 ± 21.1 to 80.8 ± 22.5 , and the percentage of satisfaction
33 with vision improved from 24.3% to 87.5% at 12 months. Vector analysis
34 of astigmatism correction showed that the mean change in corneal
35 astigmatism was 2.9 ± 2.9 D at 6 months postoperatively. By selecting
36 patients in whom astigmatism correction was best (index of success > 0.5),
37 an analysis was performed to determine individual factors important in
38 successful surgery. Preoperatively, these 11 (22%) eyes did not differ
39 significantly from the remaining eyes and the only significant value was
40 low K readings in the flat axis. They concluded that INTACS placement is
41 safe and effective procedure, improves BSCVA and UCVA and reduces
42 astigmatism in patients with mild to moderate keratoconus, however the
43 astigmatic change was unpredictable.⁷

44 In 2005, Alio et al performed a prospective study to evaluate the
45 effect of implanting 1 versus 2 intracranial rings in patients with

1 keratoconus in Spain. He studied 26 eyes and divided them into 2
2 groups depending on their topography: group 1, the topographic
3 pattern did not cross the 180-degree meridian, whereas in group 2,
4 the topographic pattern crossed the 180-degree meridian. In group 1, a
5 single INTAC (0.45 mm) was placed inferiorly, whereas in group 2, 2
6 INTACS were placed (0.25 mm superiorly and 0.45 mm inferiorly). All
7 INTACS were placed through a horizontal lateral incision. At 1-year
8 spherical equivalent error, mean keratometric values and refractive
9 astigmatism were significantly reduced in both groups: In group 1, the
10 mean UCVA improved from 20/100 to 20/32, whereas the mean BSCVA
11 improved from 20/50 to 20/32. In group 2, the mean UCVA improved
12 from 20/400 to 20/63, whereas the mean BSCVA improved from 20/50
13 to 20/32. In 4 eyes, the inferior segment was removed because of partial
14 extrusion during the postoperative follow-up.¹⁰

15 At the Refractive Surgery Subspecialty day of the American Academy
16 of Ophthalmology in Chicago October 2005, Rabinowitz et al presented
17 the results of the first comparative study comparing the femtosecond
18 laser (INTRALASE) with that of the mechanical spreader for inserting
19 INTACS in patients with keratoconus. INTACS was performed on 10
20 patients using the mechanical spreader to create the channels and
21 subsequently on another 20 patients using the femtosecond laser. UCVA
22 and BCVA, manifest refraction and corneal topography were measured
23 before surgery, at 6 months (femtosecond group) and 1 year (mechanical
24 group), respectively. Preoperative data and postoperative data were
25 analyzed to determine changes in the above parameters. Both groups
26 showed significant reduction in average keratometry (K), spherical
27 equivalent, BCVA, UCVA, SRI, and SAI. The laser group performed
28 better in all parameters except change in SRI: Results of the Intralase
29 versus mechanical were as follows: reduction in spherical equivalent
30 (3.98 vs. 2.96); change average K (2.91 vs. 2.52); improvement in UCVA
31 (4.13 vs. 3.63); improvement in BCVA 3.92 vs. 1.63), change in SRI (0.37
32 vs 0.64), and change in SAI (1.00 vs 0.70). Statistical analysis, however,
33 did not reveal any statistically significant differences between the 2
34 groups for any single parameter studied. The biggest improvement in
35 the laser group versus the mechanical group was the BCVA (*P* value
36 0.09). Overall success defined as contact lens or glasses tolerance was
37 85% in the laser group and 70% in the mechanical group. His group
38 concluded that inserting INTACS using the femtosecond laser to create
39 the channels is as effective as using the mechanical spreader.⁹

41 ■ **Post Lasik Ectasia**

42 There are now several published studies which suggest that inserting
43 a single inferior INTAC in patients with post-LASIK ectasia improves the
44 BCVA and UCVA.¹²⁻¹⁵ We have had a similar experience. In an
45

1 unpublished series of approximately 20 eyes treated by our group for
3 this condition, we have found a 60% success rate in improving both
5 UCVA and BCVA using a single inferior INTAC. The advantage of this
7 procedure is that it reduces the anisometropia between the 2 eyes and
9 also improves contact lens tolerance in these patients. It offers them an
11 alternative to penetrating keratoplasty, unfortunately patients are unable
13 to achieve good unaided acuity which was their original goal. Performing
15 INTACS in such patients can be tricky and should only be done by
17 experienced surgeons, because it is very easy to create your channel in
19 the plane of the LASIK flap thereby dislocating the flap and getting
21 minimal effect. The key is to go deep and make sure your INTACS is
23 well below the plane of the flap. If patients with this complication want
25 good vision without any visual aids, their best option is to consider a
27 lamellar or penetrating keratoplasty to remove their ectasia followed by
29 either LASIK or photorefractive keratectomy (PRK) to correct their
31 residual refractive error.

■ Pellucid Marginal Degeneration

19 INTACS is a good option for reducing the astigmatism in patients
21 with pellucid marginal degeneration who have clear corneas but are
23 contact lens intolerant. At least 2 published reports have demonstrated
25 its efficacy.^{16,17} Again there is no uniform agreement as to where to place
27 the INTACS but our experience has been that placing the INTACS to
29 bisect the steepest part of the cornea yields the maximum antiastigmatic
31 effect. In contrast to this, a study published this year suggests that
excellent results are achieved with a temporal incision and placing 2
INTACS: one above and one below the horizontal meridian.¹⁶

■ Contact Lens Wear

31 Immediately postoperatively, a soft disposable contact lens can safely
33 be worn after INTACS placement. We commonly provide patients with a
35 contact lens approximately 3 D less than their preoperative spherical
37 equivalent immediately after surgery because this will improve their
39 comfort and provide them with some immediate postoperative vision.

37 Rigid contact lens fitting is delayed for at least 3 months when the
39 cornea is relatively stable, the sutures have been removed and the entry
41 incision has healed. Fitting contact lenses over these patients is an art
43 which is evolving. By working with a good and experienced contact lens
45 fitter will significantly enhance the success rate of any good INTACS
surgeon because contact lens tolerance is most often the primary reason
patients choose to undergo the INTACS procedure. Recently, there have
been 2 published studies demonstrating success with specialized contact
lenses after INTACS placement.^{18,19}

1 ■ **Complications**

3 Though unusual, both intraoperative and postoperative complications do occur.^{20,21} Intraoperative complications include: perforation of
5 the anterior chamber and superficial placement of the INTACS, both of these complications are less likely to occur with the intralase than the
7 mechanical technique. Another intraoperative complication which can occur with either technique is either leaving the INTACS too close to the
9 lip of the wound or rotating the INTACS too much so that they end up touching each other. The first complication will result in wound gape
11 with potential for infection, whereas the latter problem might result in rotation of the INTACS with ultimate erosion through the corneal
13 stroma.

 Infection most commonly occurs as a result of a loose stitch or as a
15 result of wound gape from migration of the INTACS to the site of the wound. If the infection creeps along the channels it is best to remove the
17 INTACS and treat the patients with fortified antibiotics. Culturing the INTACS might be helpful in isolating the organism.

19 Erosion of the INTACS occurs most commonly because of superficial placement. If this occurs, the INTACS should be removed, the eye
21 allowed to heal and the INTACS can always be reinserted at a greater depth at a later time.

23 Since many patients receiving this treatment are young and have large pupils which might extend beyond the 7mm optical zone,
25 complaints of halo and glare are not uncommon. This can often be managed with a single drop of Alphagan .

27 Other rare complications include: persistent inflammation, persistent fluctuation of vision, intraocular inflammation, photophobia, loss of
29 UCVA, and loss of BCVA. If INTACS implantation fails and the patient elects to undergo a corneal transplant, INTACS can safely be removed at
31 the time of the corneal transplant without affecting the ultimate outcome of the transplant.

33 ■ **Future Applications and Unanswered Questions**

35 Future applications could include performing PRK, either topo-
37 graphic-guided PRK or wavefront-guided PRK on patients who have undergone INTACS placement with thick corneas and whose disease is
39 nonprogressive. This could improve the uncorrected acuity in many of these patients significantly. Preliminary work in this direction is
41 currently underway.²²

 It is not known, at this time, if there is an increased risk of
43 endothelial cell loss after the insertion of an intrastromal corneal ring segment in keratoconic corneas. Additionally, a risk that may be
45 associated with the removal of the intrastromal corneal ring segments

1 from keratoconus corneas may be the induction of an additional
 3 refractive error.

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