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INTACS for KERATOCONUS and Ectasia after LASIK

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BACKGROUND

INTACS are two, arc like, PMMA segments which were designed to be surgically inserted into the deep corneal stroma to flatten the central cornea. Their original application was for the refractive correction of mild myopia (–1 to –3D). However, because of the superior accuracy and familiarity with the excimer laser by refractive surgeons, they are rarely used for this indication, except in patients with forme fruste keratoconus or extremely thin corneas with less than 3D of myopia (1,2).

Dr. Joseph Colin in France first conceived of the concept of using INTACS to treat patients with keratoconus and published his first report on the safety and efficacy for this indication in 2001(3). At 1 year, all 10 patients he operated became contact lens tolerant and demonstrated an improvement in both uncorrected and best-corrected acuity (4).

Since his pioneering work, corneal surgeons throughout the world have adopted this technology to treat patients with mild to moderate keratoconus who are contact lens intolerant and/or who desire a modest improvement in uncorrected and best-corrected visual acuity (5–14).

In the United States 0.25mm, 0.275mm, 0.30mm, 0.325mm, 0.35mm, 0.4mm and 0.45mm segments are available for use. They are approved in the United States by the FDA under a human device exemption (HDE) for compassionate therapeutic use. Competitive devices such as the Ferrara ring and the Keraring are also sold and marketed outside of the United States since they do not have FDA approval in the United States. The main difference between these two devices is that with INTACS the optical zone is approximately 7mm while the Ferrara and Kerarings have an optical zone of the order of 4.5 to 5mm(15). The smaller optical zone allows for more efficacy in flattening of the cornea at the expense of increased visual aberrations, particularly at night when the pupil dilates.

Recently Intacs SK was introduced outside of the United States. They have an optical zone of 6 mm and have a round design to minimize glare. They may be used to correct larger myopic and astigmatic refractive errors than INTACS because of their design and closer proximity to the visual axis(16,17)

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INDICATIONS

Most published studies suggest that the best indications for INTACS are patients with mild to moderate keratoconus with a clear optical zone and who are contact lens intolerant. INTACS can then be offered as an alternative to penetrating or lamellar keratoplasty for visual rehabilitation. The upper limit of the steepest K reading should not exceed 58D, the patient should not have any scarring in the visual axis and the cornea should be at least 450um thick by ultrasonic pachymetry at the 7mm optical zone or over the area in which the INTACS are to be placed. (4,9).

Preliminary data with the INTACS SK suggest they can correct larger refractive errors and as such may be offered to individuals with corneas steeper than 58D, however long term data to support this are not yet available (15). Asymmetric INTACS SK might also be more effective in correcting larger amounts of astigmatism than single segments (18). INTACS can also be offered as a refractive option to improve a patient's uncorrected or best-corrected acuity with either contact lenses or glasses. This indication would however not meet the FDA's guideline for HDE approval in the United States, and such patients should be offered this option on an off label basis only.

Poor candidates for INTACS are: individuals with central or paracentral scarring, patients whose corneas are thinner than 450um at the site of placement of the INTACS, patients who are in the rapidly progressive phase of the disease and have not had collagen cross-linking and patients who expect excellent uncorrected acuity following surgery.

If the goal is to make a contact lens intolerant patient contact lens tolerant, by operating on patients whose K readings are in excess of 58D, you are unlikely to achieve your goal with regular INTACS, since you will only achieve on average approximately 3D of flattening and typically patients with K readings in excess of 55D have difficulty tolerating contact lenses (19). Even if you achieve your goal of making patients with steeper corneas or corneas with scarring contact lens tolerant, it is highly likely that the quality of their vision will be so poor that they would have been better off undergoing a corneal or lamellar transplant.

RESULTS

Most studies to date show an average of two to three diopters of flattening accompanied by 2 to 3 lines of gain in best-corrected vision. However the range is large and variable ranging from 2 lines of loss of best-corrected vision to a gain in 8 lines of best-corrected vision (5–14)

Improvement in best corrected vision is due to the decrease in higher order aberrations produced by the INTACS. This was first demonstrated by our group and subsequently by several other groups (9,17,18). In general 70 – 80% of patients treated in all studies noted an improvement in best-corrected and uncorrected vision (5–14). A comparative study of INTACS SK and Kerarings showed similar outcomes at 1-year postoperatively.(20)

Long-term studies of up to 9 years for keratoconus and 6 years for post lasik ectasia have demonstrated safety and stability with maintenance of the initial refractive effect. (21–27) Bedi et al recently reported five year follow up data on 105 eyes that had undergone consecutive INTACS implantation. 91.3% of eye demonstrated no progression between 1 and 5 year follow up and in a subgroup analysis of patients who had preoperative progression of 1D twelve months prior to surgery, 92.9% (52/56) eyes demonstrated no progression, additionally there were no statistically significant differences between the mean steep, flat, and average keratometry; manifest refraction spherical equivalent; and uncorrected and corrected distance visual acuity($p>.05$) between 1 and 5 year follow up.

These findings suggest that INTACS implantation might be considered as a therapeutic option to halt progressive keratoconus.(21)

INTACS COMBINED WITH OTHER SURGERIES

Because INTACS improves the best-corrected acuity by reducing higher order aberrations, they can be used to sphericize the cornea in patients who desire Phakic IOL's to improve their uncorrected myopic refractive error or in patients with cataracts prior to their cataract surgery.

Good outcomes have been reported when used in combination both with the Visian ICL and the Verisyse Phakic IOL(9,22,23,28–30). We insert INTACS in eyes of such patients 3 months prior to inserting the phakic IOL's since it takes this long for the final effect and reasonable stability to be achieved. However, a recent study by Moshirfar et al suggests that the results of simultaneous implantation of INTACS and the verisyse phakic IOL in a single surgery was similar to the results achieved with sequential implantation using 2 surgeries (31)

INTACS can be used in combination with collagen cross-linking either prior to the cross-linking or three months prior to the cross linking(32–35). This improves both the refractive error and decreases the possibility of continued progression of the ectasia.

Since the optimal time of doing cross-linking has not as yet been determined nor has the cumulative effect of the two treatments been quantified, our group is conducting a randomized clinical trial for patients with keratoconus to answer these questions. One group is receiving cross-linking only and the other INTACS followed by cross-linking 3 months later (go to www.clinicaltrials.gov for more information about this study).

PRK can also be performed after INTACS to reduce the residual refractive error (36,37) or reduce the astigmatism enough to make patient's contact lens tolerant. Great caution should be used in such instances since there can be residual scarring and the corneal thinning could be enhanced by this procedure. If this is to be done, it is our recommendation to always have a careful informed consent outlining the potential dangers of PRK in such patients, always to use mitomycin at the time of surgery and never to leave the cornea with less than 400 um thickness.

Recently there have been two reports illustrating the use of INTACS, PRK and cross-linking in the same eye. In the first report, Kremmer et al studied patients with moderate keratoconus who had had INTACS 6 months previously. They performed simultaneous wavefront PRK and collagen cross-linking on these patients. At 12 months following surgery they noted improved uncorrected acuity, best corrected acuity and decreased central K values with no complications, only mild haze in 11% of eyes (38). In a second study, Iovenia et al reported on 4 patients who had same day INTACS, PRK and collagen cross-linking. At 6 months they noted significant improvement in uncorrected acuity, best corrected acuity and keratometry (39). No patient lost lines of best-corrected acuity. Larger sample sizes with longer follow up are needed before either of these two techniques will be universally adopted.

SURGICAL TECHNIQUE

MECHANICAL SPREADER

The following is a brief description of how to perform INTACS implantation using the mechanical technique recommended by the manufacturer.

Central and peripheral ultrasonic pachymetry measurements are made at the 7mm optical zone or if a practice has an OCT either a Visante or Optovue this would be preferable since it gives a more accurate representations of the 3 dimensional corneal thickness profile for planning the procedure and may identify thin areas that would otherwise be missed by regional ultrasonic pachymetry. It is essential to ensure that the cornea is at least 450um thick in the area of the proposed implantation of the INTACS

The eye is prepped with iodine and draped. Topical anesthesia is applied to the eye and the central cornea is marked with a felt-tipped pen. A marker is then used to mark the 7mm optical zone as well as the entry site into the cornea, which in keratoconus is typically temporal.

A diamond knife is set at 70% of the thickness of the cornea at the incision site and a vertical incision is made into the cornea. From the base of the incision, a corneal pocket is created on each side of the incision. Pockets should be at the same depth across the full width of incision within the same stromal plane and as long as the stromal spreader. Pockets are created at the full depth of the incision to avoid shallow implant depth. The pocket depth is estimated and deeper pockets are cut if necessary.

The VCG & IPM are located on the center mark and a vacuum of 400 – 500 mBar is applied. The placement is confirmed and the vacuum is increased to 600 – 667 mBar. The continuous VCG time should be limited to 3 minutes or less and applied vacuum to 750 mBar. The glide is inserted into the first pocket and the dissector blade tip rotated under glide. The dissector is rotated to create a tunnel. An intrastromal tunnel is created on the second side. The vacuum is released and the VCG is removed.

Dissecting should be stopped if excessive resistance or “tissue wave” is encountered. If this happens, consider creating a deeper pocket and tunnel. The procedure should be aborted in the event of perforation into the anterior chamber or anterior corneal surface perforation. The incision area should be irrigated and one intrastromal corneal ring segment should be inserted into each intrastromal tunnel with the positioning hole left 1 to 2mm from the incision site.

Place one or two interrupted sutures, evenly spaced to make sure the wound is closed tight. Suture depth should be to the level of the stromal pocket, this prevents segment migration. Suture knots should be buried. An antibiotic-corticosteroid eye drop is administered postoperatively for at least a week and more if necessary. We routinely cycloplege our patients and give them a bandage contact lens to be worn for the first day. This significantly increases patient comfort in the immediate postoperative period.

FEMTOSECOND LASER

Since our group first described the insertion of INTACS using tunnels created with a Femtosecond Laser (Intralase), this technique has rapidly been adopted by surgeons who throughout the world with access to this technology (9–14).

This procedure is very quick and extremely surgeon and patient friendly. Many corneal surgeons who had abandoned the surgical technique with the mechanical spreader because of technical difficulties experienced with the device supplied by the manufacturer, have now once again started doing this procedure using the intralase to create the channels to insert the INTACS.

Besides being extremely quick and easy, there are other advantages of the intranasal. These are: there is a high degree of certainty of the depth of placement, so superficial placement

and erosion of the INTACS can be avoided. The channels can be recut at a shallower depth for the INTACS to be reinserted if the initial outcome is unsatisfactory. More effect can be achieved by making the stromal channels narrower than the INTACS and lastly visual recovery tends to be quicker.

The following is a suggested technique for inserting INTACS using a femtosecond laser to create the channels: Preoperative Videokeratography and pachymetry or OCT is performed. The eye is prepped and draped. The center of the pupil is marked with a felt tipped pen. The initial intralase settings for INTACS should be as follows: depth 400um, incision site temporal, Incision length 1.4mm, incision width 1 mm, channel size should be 6.6×7.4mm for .35mm INTACS which gives you an 0.4mm channel which is 0.05mm larger than the INTACS. As surgeons gain more experience, the size of the outer channel can be reduced to increase effect if necessary. For the INTACS SK the channel diameters should be 6.0×6.8mm, the other laser parameters are the same as with regular INTACS.

Since the entry cut is vertical it can often initially be a bit tricky to advance the INTAC through the channel. To facilitate this it is important to hydrate the cornea, identify the lip of the circular incision with a sinsky hook and then while putting upward pressure on the sinsky hook to keep the lip open place the INTACS under and advance it under the sinsky hook all the while keeping the lip elevated this will prevent the INTAC from being hung up on the lip of the incision. Sometimes, there can be difficulty in advancing the INTACS because of uncut stromal fibers in the channels. To overcome this problem, the blades of the mechanical spreader can be used to open up the tunnels.

Both INTACS should be advanced at least 1mm away from the lip of the incision but should not touch each other on the other side. The wound should be closed with a single 10/0 through and through nylon suture, which should be buried. A soft contact lens with an approximate correction can be put on the eye and the patient is given an antibiotic, steroid drop and cycloplegic drop postoperatively.

INCISION PLACEMENT AND INTACS SELECTION

Colin in his original article placed his incisions temporally and still got significant reduction in astigmatism because of the asymmetric sizes of the INTACS i.e. .25mm above and .45 mm below. The best place to place the vertical incision is on the steepest keratometric axis, make sure however that the INTACS will bisect the thinnest part of the cornea so that it will physiologically make the cornea normal by thickening the thin area. (See figures 1 to 3)

In almost all cases of oval and central cones this turns out to be temporal. It is only mild cones where thinning is in an unusual location where placing the incision could make a significant difference. More astigmatic effect is probably achieved from asymmetry of the INTACS than the location of the entry incision.

Because INTACS come in many different sizes there are potentially many different combinations of INTACS can be used to achieve both flattening of the central cornea and reduce the astigmatism. Most studies show that irrespective of what combination you use, you get some effect. In centrally located cones where you just want to get the maximum flattening effect it is best to use two symmetrical INTACS. Two .45mm segments would be best for corrections of greater than 3D two symmetrical or where available two .45mm INTACS SK are best for getting the greatest reduction in myopia. If the patient is not severely myopic, lesser size symmetrical INTACS could be used so as not to overcorrect and induce hyperopia.

In typical oval type cones, most surgeons follow Colin's original concept of putting in asymmetric INTACS: .25mm above and .45mm below. In very mild cones that don't cross the horizontal meridian, a single INTAC often suffices (9,40,41).

Recently there is a trend towards just putting in a single INTAC inferiorly in oval cones because it is felt this is the most asymmetrical way to perform this procedure and will maximize reduction of the astigmatic effect (40,41). It certainly has been our experience that in patients in whom we have put in two INTACS with an unsatisfactory result, the patients often see better and are happier once we remove the superior INTAC. The issue of where to place the incision and what size INTAC to use is evolving and could be considered to be dictated by the 'Art of medicine'.

POST LASIK ECTASIA

Several studies have demonstrated that inserting a single inferior INTAC in patients with post LASIK ectasia improves the BCVA and UCVA (41–45). We have had a similar experience. In an unpublished series of approximately 50 eyes treated by our group for this condition we have found a 60% success rate in improving both uncorrected and best corrected visual acuity using a single inferior INTAC. The advantage of this procedure is it reduces the anisometropia between the two eyes and also improves contact lens tolerance in these patients. This offers them an alternative to penetrating or lamellar keratoplasty, while comfortably using the two eyes together.(see example figures 1 and 2)

Unfortunately patients are unable to achieve good unaided acuity, which was their original goal. Performing INTACS in such patients can be tricky and should only be done by experienced surgeons, since it is very easy to create "a false channel" in the plane of the LASIK flap thereby dislocating the flap and getting minimal effect from the procedure. The key is to go deep and make sure the INTACS is well below the plane of the flap (46).

If patients with this complication want good vision without any visual aids, their best option is to consider a lamellar or penetrating keratoplasty to remove their ectasia followed by either LASIK or PRK to correct their residual refractive error. INTACS can easily be removed at the time of keratoplasty and slightly larger grafts are needed to go beyond the margins of the INTACS channels. The use of the femtosecond laser for penetrating grafts (I.E.K. – Intralase Enabled Keratoplasty) makes this a much more attractive option for many such patients (47)

PELLUCID MARGINAL DEGENERATION

INTACS is a good option for reducing the astigmatism in patients with pellucid marginal degeneration who have clear corneas but are contact lens intolerant (48,49). Again there is no uniform agreement as to where to place the INTACS but our experience has been that placing the INTACS to bisect the steepest part of the cornea yields the maximum astigmatic effect. In contrast to this a study published this year suggests that excellent results are achieved with a temporal incision and placing two INTACS: one above and one below the horizontal meridian.

CONTACT LENS WEAR

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

Rigid contact lens fitting is delayed for at least 3 months when the cornea is relatively stable, the sutures have been removed and the entry incision has healed. Fitting contact lenses over these patients is an art, which is evolving. Working with a good and experienced contact lens fitter will significantly enhance the success rate of any good INTACS surgeon since contact lens intolerance is most often the primary reason patients choose to undergo the INTACS procedure. Published studies suggest good outcomes for contact lens wear following conservative INTACS implantation (50–52). In more advanced cases, following INTACS implantation, MSD(mini scleral design) contact lenses have been shown to be very useful(53).

COMPLICATIONS

Though rare, both intra operative and postoperative complications do occur (54–64). Intraoperative complications include: perforation of the anterior chamber (63,64) and superficial placement of the INTACS, both of these complications are less likely to occur with the intralase than the mechanical technique.

Another intraoperative complication, which can occur with either technique, is either leaving the INTACS too close to the lip of the wound or rotating the INTACS too much so that the ends of the two INTACS end up touching each other. The first complication will result in wound gape with potential for infection while the latter problem might result in rotation of the INTACS with ultimate erosion through the corneal stroma. Rarely in cases of Post Lasik ectasia the Intacs can erode into the plane of the flap. In such cases the INTACS should be removed and reinserted deeper. The flap can then be sutured with good long-term results.

Infection most commonly occurs as a result of a loose stitch or as a result of wound gape from migration of the INTACS to the site of the wound(54–57). If the infection creeps along the channels, it is best to remove the INTACS and treat the patients with fortified antibiotics. Culturing the INTACS might be helpful in isolating the organism.

Erosion of the INTACS occurs most commonly due to superficial placement, but can also occur as a result of infections dermatitis (58). If this occurs the INTACS should be removed, the dermatitis treated if present and the eye allowed healing. The INTACS can always be reinserted creating a new channel at a greater depth at a later time.

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

Other complications include: persistent inflammation, persistent fluctuation of vision, intraocular inflammation, photophobia, loss of uncorrected visual acuity and loss of best corrected visual acuity and vascularization of the wound (59). Patients who are soft or rigid contact lens wearers need to be monitored for corneal neovascularization which may occur peripherally or centrally and sometimes many years after the initial surgery(60,61). If central revascularization is persistent contact lens wear needs to be discontinued or the INTACS removed. Rarely there can be persistent pain with no signs of infection this might be a sign of neuritis due to the INTAC irritating a corneal nerve(62).

If INTACS implantation fails and the patient elects to undergo a corneal transplant, INTACS can safely be removed at the time of the corneal transplant or several months prior to the transplant without affecting the ultimate outcome of the transplant.

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Post LASIK Ectasia

Preop: UCVA OS 20/400 CL intolerant

MR -4.00 – 2.75 x 03 = 20/80: Pach 460 microns

Inf. INTAC (0.35mm) OS with Intralase on 3/3/05

Figure 1.
Patient with Ectasia after LASIK before INTACS

4 years postop
very happy less anisometropia

UCVA 20/40 -2, Ref Pl -1.25 x 46 =
20/40+

Figure 2.

Same patient post INTACS after placement of a single inferior ring in the area of the ectasia