

Peer-Reviewed Literature:

Intacs for Keratoconus



Editor: Ming Wang, MD, PhD, Research Associate Professor of Biomedical Engineering at Vanderbilt University and Director of the Wang Vision Institute in Nashville, Tennessee



Co-Editor and Reviewer: Tracy Swartz, OD, MS, Educational Director at the Wang Vision Institute in Nashville, Tennessee

Panel Members: Helen Abdelmalak, OD; Y. Ralph Chu, MD; Arun Gulani, MD; Walid Haddad, MD; Paul Karpecki, OD; Jay Pepose, MD, PhD; and Kemming Yu, MD, PhD

Keratoconus and pellucid marginal degeneration are both noninflammatory, progressive diseases in which bilateral thinning of the cornea results in corneal distortion and reduced vision. Historically, management of the disease was limited to gas permeable contact lenses and penetrating keratoplasty procedures. Penetrating keratoplasty is associated with significant risks, including graft rejection, a prolonged use of steroids, endothelial cell loss, anisometropia, and irregular astigmatism.

Ablative procedures such as phototherapeutic keratectomy (to remove stromal haze and round the tip of the cone) and PRK (to address astigmatism and nearsightedness) may allow patients who have become contact-lens intolerant to successfully wear lenses. However, additive procedures that reinforce the cornea rather than weaken it are more logical choices. The implantation of intracorneal ring segments (Intacs; Addition Technology, Inc., Des Plaines, IL), which reshape the cornea in eyes with keratoconus, was first performed in 1997.¹ In July 2004, the FDA granted limited approval with a Humanitarian Device Exemption for the placement of Intacs in patients with keratoconus.

The following articles were reviewed:

1. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. *Am J Ophthalmol.* 2003;135:64-70.
2. Colin J, Velou S. Implantation of Intacs and a refractive intraocular lens to correct keratoconus. *J Cataract Refract Surg.* 2003;29:832-834.
3. Colin J, Cochener B, Savary G, et al. Intacs inserts for treating keratoconus: one-year results. *Ophthalmology.* 2001;108:1409-1414.
4. Boxer Wachler BS, Christie JP, Chandra NS, et al. Intacs for keratoconus. *Ophthalmology.* 2003;110:1031-1040.
5. Kymionis GD, Aslanides IM, Siganos CS, Pallikaris IG. Intacs for early pellucid marginal degeneration. *J Cataract Refract Surg.* 2004;30:230-233.
6. Rodriguez-Prats J, Galal A, Garcia-Lledo M, et al. Intracorneal rings for the correction of pellucid marginal degeneration. *J Cataract Refract Surg.* 2003;29:1421-1424.

INDICATION AND TECHNIQUE

Patient Selection

In most studies, the implantation of Intacs was performed in patients with keratoconus who had clear central corneas and suffered from contact-lens intolerance.¹⁻³ Boxer Wachler et al⁴ reported that the severity of corneal damage ranged from forme fruste to advanced cones with scarring.

The FDA approved the Intacs procedure for patients more than 20 years old who have experienced progressive deterioration in their vision, who have clear central corneas with a minimal thickness of 450 μ m at the proposed incision site, and for whom corneal transplantation is the only remaining option to improve visual function.

Placement of Segments

Only 0.25-, 0.30-, and 0.35-mm segments are available in the US. The size and positioning of the segments used varied across the studies. Boxer Wachler et al⁴ used a thick ring segment inferiorly and a thin segment superiorly. Ring segment size depends upon the amount of myopia present (eg, the larger the refractive error, the larger the segment size required) and the thickness of the cornea.

Colin et al² reported using 0.45mm superiorly and 0.25mm inferiorly, although Siganos et al¹ reported using two 0.45-mm segments in all patients. Kymionis et al⁵ used two 0.45-mm segments and noted that a smaller segment size for the inferior cornea may decrease the likelihood of perforation in thin corneas, a common occurrence in patients with keratoconus and pellucid marginal degeneration. The depth of insertion reportedly ranged from 66% to 77% of the thinnest corneal measurement.

COMPLICATIONS

Theoretical complications associated with Intacs implantation include infection, inflammation, segment migration, expulsion, and perforation. Boxer Wachler et al⁴ described one eye that suffered a superficial channel dissection with anterior Bowman's perforation. A segment was successfully implanted that day using a deeper channel. Mild inflammatory reactions were noted in two eyes. Segment migration and externalization were found 1 day after surgery in one eye with severe keratoconus. This segment was explanted, followed by the second segment in the same eye and the pair in the fellow eye (the fellow eye also had severe keratoconus). Foreign body sensation was noted in a total of three eyes, and all required explantation of the Intacs.⁴

In some studies, mild-to-moderate intralamellar channel deposits were noted.^{1,3} Additionally, one eye showed neovascularization at the wound site at 2 months postoperatively, but the condition did not progress.¹ Segment migration may occur when segments are positioned too close to the wound site.⁶

EFFECT ON REFRACTIVE ERROR AND KERATOMETRY

Intacs placement should decrease myopia and flatten keratometric values, but its effect on astigmatism remains less clear. However, some patients achieved a decrease of 2.43D in refractive myopia with a significant improvement in refractive astigmatism following the implantation of Intacs.⁴

Siganos et al¹ found a mean reduction of 1.82D in spherical equivalent, with no significant change in refractive astigmatism. Colin et al³ reported a mean increase of two lines of BSCVA over baseline and the largest reduction in manifest refractive cylinder (2.70D).

With keratometry, all authors reported a flattening of central corneal curvature. Colin et al³ found an average flattening of 4.00D using keratometry, as well as a qualitative reduction of corneal ectasia as seen with topographic mapping. Siganos et al¹ reported a mean reduction in mean keratometry value of 1.94D.

CHANGE IN BSCVA

Although the treatment goal for this procedure is to stabilize the progression of the disease, an improvement in best-corrected vision would certainly be beneficial, and any loss of BSCVA must be avoided. In one study,⁴ three of 74 eyes lost two or more lines of BSCVA, although 33 of 74 gained two or more lines of BSCVA. The same study noted the greatest improvement in BSCVA in eyes with corneal scarring when compared with those with no corneal scarring.

“The use of Intacs in patients with keratoconus appears to be a cost-effective alternative to penetrating keratoplasty.”

Siganos et al¹ reported that, of 33 eyes, four lost one to two lines of BSCVA, and the remaining eyes experienced a one- to six-line improvement. A separate study's patients achieved a mean improvement of two lines at 12 months.¹ Colin et al³ reported a mean increase of two lines of BSCVA over baseline.

THE BOTTOM LINE

The use of Intacs in patients with keratoconus appears to be a cost-effective alternative to penetrating keratoplasty. The appropriate size and placement of Intacs in keratoconus patients require further evaluation. Combinations varied across these studies. It must be established whether Intacs segments actually inhibit the progression of keratoconus as well as delay the need for a penetrating keratoplasty procedure or eliminates the need for the procedure completely. ■

Co-Editor and Reviewer

Tracy Swartz, OD, MS, states that she holds no financial interest in any product or company mentioned herein. Dr. Swartz may be reached at (615) 321-8881; drswartz@wangvisioninstitute.com.

Panel Members

Helen J. Abdelmalak, OD, is a resident in optometry at the Wang Vision Institute in Nashville, Tennessee. She states that she holds no financial interest in any product or company

mentioned herein. Dr. Abdelmalak may be reached at (615) 321-8881; dra@wangvisioninstitute.com.

Jay S. Pepose, MD, PhD, is Professor of Clinical Ophthalmology at Washington University, St. Louis, Missouri. He states that he holds no financial interest in any product or company mentioned herein. Dr. Pepose may be reached at (636) 728-0111; jpepose@peposevision.com.

Arun Gulani, MD, is Assistant Professor, Department of Ophthalmology; Director of Refractive Surgery; and Chief, Cornea and External Disease for the University of Florida at Jacksonville. He states that he holds no financial interest in any product or company mentioned herein.

Dr. Gulani may be reached at (904) 504-0090; arun.gulani@jax.ufl.edu.

Walid Haddad, MD, is a cornea fellow at the Wang Vision Institute in Nashville, Tennessee. He states that he holds no financial interest in any product or company mentioned herein. Dr. Haddad may be reached at (303) 470-8388; md@walidhaddad.com.

Paul Karpecki, OD, FAAO, is Clinical Director of Cornea, Cataract, and Refractive Surgery at the Moyes Eye Institute in Kansas City, Kansas. He states that he holds no financial interest in any product or company mentioned herein. Dr. Karpecki may be reached at (816) 746-9800; pkarpecki@moyeseye.com.

Ming Wang, MD, PhD, states that he holds no financial interest in any product or company mentioned herein. Dr. Wang may be reached at (615) 321-8881; drwang@wangvisioninstitute.com.

Keming Yu, MD, PhD, is a cornea fellow at the Wang Vision Institute in Nashville, Tennessee. He states that he holds no financial interest in any product or company mentioned herein. Dr. Yu may be reached at (615) 321-8881; yukeming66@hotmail.com.

Reduce Astigmatism

Cut the Donor Cornea from the Epithelial Side



K20-2125

The Barron Disposable Anterior Chamber



donor cornea in AAC



for the best recipient match

Introducing the world's first, totally disposable Artificial Anterior Chamber with the Barron name that you have come to know and trust! Its unique design allows the surgeon to safely position, secure and inflate the donor cornea so that the button can be cut from the epithelial side. By cutting the recipient and donor corneas from the same direction, a near perfect match is achieved resulting in a dramatic reduction in surgically induced astigmatism.



Kolena Products, Inc.

4 Stewart Court, Dennis, NJ 0 7034 • USA

☎ 973-989-1600 • 800-225-1195 • Fax 973-989-8175
www.kolena.com • email globe@kolena.com