Intacs Treatment for Ectatic Corneal Diseases

Indications for the additive corneal procedure are expanding.

BY AYLIN KILIÇ (ERTAN), MD

Intacs Prescription Inserts for Keratoconus (Addition Technology, Sunnyvale, California) are available to physicians in the United States through a humanitarian device exemption (HDE) from the US Food and Drug Administration (FDA). According to the HDE, they are intended for the reduction or elimination of myopia and astigmatism in patients who are no longer able to achieve adequate vision with contact lenses and spectacles, so that their functional vision can be restored and the need for corneal transplant may be deferred. The specific subset of keratoconic patients proposed to be treated with Intacs, according to the HDE, are those who (1) have experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision on a daily basis with their contact lenses or spectacles; (2) are 21 years of age or older; (3) have clear central corneas; (4) have a corneal thickness of 450 µm or greater at the proposed incision site; and (5) have corneal transplantation as the only remaining option to improve their functional vision.

The literature shows that management of keratoconus varies with disease severity. In early stages of disease, rigid gas permeable (RGP) contact lenses are one of the primary treatment alternatives.

In the Collaborative Longitudinal Evaluation of Keratoconus (CLEK), 65% of patients enrolled wore RGP contact lenses at the baseline visit, and 73% reported that their lenses were comfortable.

Long-term wear of RGPs, however, may be a risk factor for the development of keratoconus. An apical touch fitting relationship may promote corneal scarring and ultimately contribute to the progression of the disease.

Fitting with apical touch results in statistically significant but clinically insignificant improved visual acuity. In another study, the CLEK authors concluded that there may be a causal relationship between contact lens wear and the development of corneal scarring in keratoconus.

INTACS FOR KERATOCONUS

Intacs treatment can be performed in early stages of contact-lens intolerance. We performed a study to evaluate the efficacy of Intacs implantation using a femtosecond laser to create the implant channels and to analyze outcomes in different stages of keratoconus. Reviewing the results in 306 eyes of 255 patients with keratoconus who underwent Intacs segment implantation, we observed that the mean BCVA and UCVA improved significantly from preoperative to postoperative (both P<.05) in stage 2 (early) keratoconus. There were no significant differences among three groups (stage 2, 3, and 4) in the amount of change in BCVA, and there was more change in UCVA in stage 2 (P<.05, analysis of variance).

Severely keratoconic eyes can now be treated with Intacs SK, a recently introduced Intacs segment design with an inner diameter of 6 mm and an oval cross-section shape. Two thicknesses of Intacs SK are available: 400 µm for steep keratometry (K) readings of 57.00 to 62.00 D and cylinder of less than 5.00 D; and 450 µm for steep K readings of less than 62.00 D and cylinder greater than 5.00 D. There are no published reports regarding results with these new segments.

Placement of a ring segment in the peripheral cornea results in central flattening, and the ring segment diameter determines by how much the cornea will be flattened. In our study, we evaluated outcomes in severely keratoconic eyes with mean K of 58.90 ±3.92 D. No patient had central corneal scarring, and there was significant improvement in manifest refraction spherical equivalent (MRSE), BCVA, and mean K values. Changes in UCVA and cylindrical refraction were not significant in eyes with severe keratoconus. The smaller change in UCVA in these eyes may be related to the smaller change in cylindrical refraction.

Boxer Wachler and colleagues reported improvement in...
visual acuity and astigmatism in corneas with and without scarring. According to the FDA HDE, Intacs treatment should be performed in eyes with K readings less than 52.00 D, but our experience and clinical studies show that Intacs can be effective in severely keratoconic eyes.10,11

INTACS IN YOUNGER EYES

Recently, the biomechanical properties of the cornea in different age groups have been the focus of intense interest.12 Experimental ex vivo studies have shown an age-related change in corneal collagen fibril properties that may contribute to an increased stiffness of the cornea with age.13,14 It has been proposed that progression of keratoconus slows with age. During adolescence and peak life activity, patients may be intolerant of hard contact lenses. Even with slower progression, one might expect older patients to have more severe disease such as higher mean steepest K value.

However, in a study we performed,15 there was no significant correlation between patient age and the mean MRSE, mean K, and central corneal thickness (CCT) in keratoconic eyes. We further investigated whether age-related increase in corneal stiffness may influence outcomes of Intacs treatment,16 and we found that Intacs improves UCVA, BCVA, refraction, and topographic findings in keratoconic patients of all ages similarly.

We concluded from this study that, in adolescent patients with keratoconus, Intacs is as safe and effective as in other age groups. There was no specific complication related to younger age.

The long-term results of Intacs inserts for keratoconus are still under investigation, and data regarding patient selection and predictability of the procedure are lacking.

Intacs implantation is an alternative minimally invasive and reversible method for the treatment of keratoconus; however, it does not replace penetrating keratoplasty. The limited success of penetrating keratoplasty in younger patients can be attributed to pre-, intra-, and postoperative problems.17 When we analyzed the response to Intacs implantation in different age groups,16 our experience showed no significant progression or complication in the younger group.

ENHANCING INTACS

After Intacs implantation, contact lenses can be prescribed or toric phakic IOLs can be implanted for enhancement. Corneal collagen crosslinking (CXL) is

Figure 1. Riboflavin injection into the Intacs channel after femtosecond laser application. The intrastromal channel is more visible with the yellow reflex of the riboflavin.

Figure 2. Riboflavin distribution into the corneal stroma around the channel just before CXL.

Figure 3. Stromal tissue around the Intacs is more visible. This may be related to thickening of the collagen bundles that create stronger stromal tissue.
another surgical option that can be combined with or performed after Intacs segment implantation. CXL, unlike intrastromal corneal ring segments, has been shown experimentally to increase the biomechanical rigidity of the cornea by a factor of 4.5.18

We evaluated the efficacy of transepithelial CXL after Intacs implantation in keratoconic eyes.19 Mean time between implantation of Intacs and CXL was 3.98 months. CXL after Intacs resulted in additional improvements in UCVA, BCVA, spherical and cylindrical refraction, and keratometry. CXL performed after Intacs treatment yielded an additional improvement of 1.2 Snellen lines of UCVA and 0.36 Snellen lines of BCVA. We concluded that CXL has an additive effect on Intacs implantation in these eyes and may be considered as an enhancement and stabilizing procedure.

Recently, we have injected riboflavin into the corneal channel before Intacs implantation and then immediately inserted the ring segment. This maneuver has several advantages: Because we do not remove the epithelium due to direct penetration of riboflavin into the corneal stroma, we can treat corneas that are less than 400 µm in thickness due to stromal edema, so we can create a thicker cornea; the yellow reflex of the riboflavin makes the corneal channel more visible; and the force of injection can break bridges between air bubbles after femtosecond laser channel creation, so the surgical maneuvers for Intacs insertion are easier to perform.

In a study recently presented at the European Society of Cataract and Refractive Surgeons (ESCRS) meeting in Barcelona, 15 eyes had Intacs implantation with corneal riboflavin injection and same day CXL (group 1), and 13 eyes had CXL at least 6 months after Intacs (group 2). Mean follow-up was 5.7 months; UCVA, BCVA, refraction, and K readings were evaluated.

Mean UCVA and BCVA improved more in group 1 than group 2 (P=.018). In groups 1 and 2 respectively, changes in spherical refraction were 2.73 ±2.88 D and 2.00 ±0.55 D (P=.81), and changes in K-readings were 4.82 ±2.46 D and 2.19 ±2.41 D (P=.00). We observed that riboflavin distribution into the stromal tissue around the Intacs segments caused immediate injection and collagen thickening around Intacs during follow-up (Figures 1 through 3).

CONCLUSION

In recent years, Intacs inserts have been used with broad variations in indications and with different segment sizes around the world. Experience indicates that Intacs can be effective in younger patients16 and in moderately keratoconic eyes with or without corneal scarring.10,11 These indications may not comport with the rules dictated in the FDA HDE for Intacs. We have not seen high rates of complications, with only three cases in our series of 306 keratoconic eyes.10

Our experience suggests that Intacs can be a simple, safe, rapid, reversible, adjustable, and effective treatment for ectatic corneal diseases. It can be combined with CXL treatment, but CXL cannot be replaced with Intacs treatment. ■

Aylin Kilç (Ertan), MD, is Director of the Department of Cataract and Refractive Surgery and Chief of the Eye Hospital at Kudret Eye Hospital, Ankara, Turkey. Dr. Kilç did not provide financial disclosure information. She may be reached at e-mail: aylincily@gmail.com.