Intracorneal ring segments a safe and stable option for keratoconus treatment

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in Paris

INTACS implants (Addition Technologies) offer a safe and effective means of improving the visual acuity of selected keratoconus patients and demonstrate excellent stability up to two years after implantation, according to Joseph Colin MD, Hôpital Pellegrin-Tripode Bordeaux France.

Speaking at the XXII Congress of the ESCRS, Dr Colin said that the study outcome thus far was extremely encouraging news for the treatment of keratoconus.

“We can conclude from this data that INTACS implants are safe and efficacious for treating keratoconus. More than 60% of eyes demonstrated improved objective visual outcomes and the results were stable during the one to two year follow-up period,” he said.

In the prospective study carried out the University Hospital, Bordeaux, France, 100 eyes of 82 patients with clear central corneas and diagnosed with keratoconus were followed for up to two years.

The primary objectives, said Dr Colin, were to assess safety and stability of the effects of the intracorneal ring segments, as well as visual outcomes, by measuring uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), manifest refraction spherical equivalent (MRSE), keratometry, pachymetry and patient satisfaction.

At one-year’s follow-up, INTACS extruded in two eyes and removal of the implants was necessary. By the second postoperative year penetrating keratoplasty was performed in two eyes due to patient dissatisfaction. There were no adverse effects or complications associated with INTACS removal, noted Dr Colin.

At two years’ follow-up, 63.8 % and 62.7 % of eyes showed improvement in UCVA and BCVA respectively. The proportion of patients with a best corrected visual acuity of 0.5 (20/40) or better improved from 15.6 % of patients pre-operatively to 32.2 %, and 33.3 % at the one year and two year exam, respectively. MRSE improved from an average of -7.05 +/- 3.87D preoperatively to -3.98 +/- 4.9D and -4.03 +/- 3.71D at one and two years. Mean keratometry decreased from 50.5 D preoperatively to 46.0D and 46.5D at one and two years. These changes appeared to be stable over time.

In outlining the rationale behind using Intacs implants, Dr Colin said that keratoconus is a progressive, non-inflammatory, bilateral corneal dystrophy characterised by paracentral ‘cone-like’ steepening of the cornea and corneal ectasia.

“The progressive thinning and subsequent anterior bulging of the cornea leads to severe astigmatism and central scarring of the cornea producing visual distortion, increased sensitivity to light and an associated reduction in BCVA,” he said.

Dr Colin explained that INTACS were first used for the correction of low myopia, acting as passive spacing elements that shorten the arc length of the anterior corneal surface and flattening the central cornea. The biomechanical effect of rings should be greater in keratoconic eyes, which have thinner corneas.

“The major objective is to re-shape keratoconic corneas with two ring segments of differing thickness. The INTACS inserts are applied to lift the inferior ectasia and flatten the soft keratoconic corneal tissue in an attempt to decrease the asymmetric astigmatism induced by keratoconus, without removing any corneal tissue or touching the central cornea. The rings may be explanted at a later stage if needed,” he said.

Dr Colin noted that there are many reasons why an alternative to penetrating keratoplasty could be of great value to keratoconus patients.

“These patients are often fitted with rigid gas permeable contact lenses in an attempt to improve the quality of their vision. Although spectacles and contact lenses can be successful in treating the early stages of the disease, a corneal transplant procedure is the only method of treatment currently available when these modalities are no longer successful,” he said.

Moreover, the relatively young age of many of the patients is a key factor in seeking alternatives to penetrating keratoplasty.

“In selected cases, the cornea is still transparent. These relatively young patients may be reluctant to pursue PKP and seek a less invasive intervention to improve BCVA and/or UCVA. Many of the keratorefractive options for the treatment of keratoconus such as radial keratotomy, astigmatic keratotomy, PRK and LASIK have been reported to weaken the structural integrity of the cornea. These procedures have not gained popularity in treating keratoconus because of reported complications, corneal instability and poor predictability,” he said.

In terms of surgical technique, Dr Colin said that implanting Intacs was a relatively straightforward procedure.

“Two ring segments of 0.45 mm or 0.40 mm are inserted in the cornea of each eye. The geometric centre of the cornea is identified using the 11.0 mm Zone Marker, and the centre marked using a Sinskey Hook. A temporal radial 1.0 mm incision is then created to approximately 70% of the corneal thickness at the incision site. The corneal incision is performed temporally in all cases with no suture,” he said.

Intacs inserts are currently approved in the U.S. by the Food and Drug Administration and in Europe by CE mark for use in the reduction or elimination of myopia.

Dr Colin stressed that the purpose of the implants was to reduce the impact of keratoconus, since Intacs do not affect the underlying pathology.

“Treatment with INTACS inserts will not eliminate the progression of keratoconus, however it may delay a corneal transplant procedure and may slow the progression of the corneal thinning associated with the disease. Results from preliminary studies indicate that INTACS seem to allow for better quality of vision in patients with advanced keratoconus, may permit re-fitting these patients with contact lenses and may delay or eliminate the need for a corneal transplant procedure,” he concluded.

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