Small aperture corneal inlay for the correction of presbyopia: visual results and complications

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ABSTRACT: Small aperture corneal inlay is one of the surgical procedures currently used in the correction of presbyopia. The latest advances have permitted the device to be implanted in both emmetropic presbyopic patients and post-LASIK patients. Postoperative visual results are significantly affected by the design and centering of the device. Good results can be obtained in near vision and in distant vision, due to an increase in the depth-of-focus. The implantation of this device is safe, effective and reversible. Although the complications associated with this technique are few, there may be a loss of visual acuity, so a postoperative evaluation must be made to check device status and centering.

KEYWORDS: Corneal inlay; presbyopia.

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Presbyopia occurs due to a loss in lens accommodation, causing a deterioration in near vision that gradually increases with the patient’s age. Treatment is necessary to improve the patient’s near visual acuity. Nowadays there are several alternatives, both surgical and non-surgical, for the correction of presbyopia, such as intraocular lens implantation (accommodating and multifocal), conductive keratoplasty (CK), corneal surface multifocal ablation techniques (PresbiLasik), monovision contact lenses or small aperture corneal inlay. These small aperture corneal inlays are inserted into the patient’s corneal stroma after creating a corneal flap with femtosecond laser. Previously, the corneal flap was created with a mechanical microkeratome, but the advantages of the femtosecond laser in performing the corneal flap have led it to replace the mechanical microkeratome. The corneal flap prepared by femtosecond laser is somewhat thicker than the flap made in corneal refractive surgery for the correction of the myopic and hypermetropic refractive errors.

Device design

Intrastromal inlays are implanted into the emmetropic presbyopic patient’s non-dominant eye with the aim of producing monovision. The eye with the corneal inlay is used for near vision, whereas the contralateral eye performs the functions of distant vision. The best-known intrastromal inlay to date is Kamra® (also called ACI 7000; AcuFocus Inc, Irvine, USA). It is 10 µm thick with an outer diameter of 3.8 mm and an inner diameter of 1.6 mm (Figure 1). There is controversy in the scientific studies published in the current literature regarding the best location for the centering of the corneal inlay. Some studies suggest that it should be centered over the patient’s pupil, others recommend it is placed over the visual axis, and some others propose over the first Purkinje image. The working principle of the corneal inlay consists of achieving an increase in depth-of-focus through its 1.6 mm fixed central opening, thus improving the presbyopic patient’s near vision. The increased depth-of-focus from the corneal inlay allows clear images to be obtained in distant vision, intermediate vision and near. The best increase in depth-of-focus is achieved by the correct centering of the
Corneal inlay, and when patients have a residual myopic defect (range from −0.75 D to −1.00 D). Despite the design of the small aperture corneal inlay for correction of presbyopia, there is no obstacle to the visualization or imaging of the retina (central and peripheral) under pharmacological mydrias. Moreover, high-quality images can be obtained with Optical Coherence Tomography (OCT). Thanks to advances made in recent years, the small aperture corneal inlay for the presbyopic correction is now considered a simple and safe technique associated with few complications.

**Device material**

As the corneal inlay is inserted into the corneal surface, it must be made of a material that is biocompatible with the cornea to avoid any chance of rejection and that allows the correct transmission of gases and nutrients. If the material meets these conditions, the corneal inlay remains stable for a long period. The surface of the ACI 7000 corneal inlay is made of polyvinylidene fluoride (PVDF) and carbon. It contains approximately 7,000 carbon nanoparticles so that the corneal implant is opaque. The ACI 7000 surface has approximately 1,600 randomly placed pores, allowing the easy exchange of nutritional fluids through the corneal tissues and avoiding the deposit of substances on the surface. In recent years, a new device, the ACI 7000PDT (Kamra corneal inlay, AcuFocus Inc, Irvine, USA), has been developed. Certain parameters have changed with the introduction of the new device. The pores are of variable sizes, ranging between 5 and 11 microns, and there are 8,400 pores instead of the 1,600 in the ACI 7000. The surgical technique and the thickness of the corneal inlay have also been modified, going from 10 microns in the ACI 7000 to 5 microns in ACI 7000PDT.

**Working principle**

It has been known for some time that the depth-of-focus increases when the patient’s pupil diameter decreases. Corneal inlays for the correction of presbyopia follow this same principle. The small aperture corneal inlay is designed with a little aperture to increase the depth-of-focus. The inlay size allows the depth-of-focus to be increased, improving near vision and intermediate vision, without any detriment to the distant vision. The inner diameter is correlated with the improvement in the depth-of-focus, light loss and the visual quality. If the aperture of the inlay were decreased more, the diffraction effects would lead to a loss of retinal image quality and acuity. The outer diameter is designed with the aim of minimizing the obstructions to the passage of nutrients through the corneal surface and increasing illumination, mainly in scotopic or mesopic conditions, when the pupil diameter increases. Scientific studies show that the small aperture corneal inlay performs well in mesopic conditions. An improvement has been documented in the reading performance of some presbyopic patients due to the increase in depth-of-focus generated by the corneal inlay. Dexl et al. achieved improvement in all reading performance parameters in 24 patients using the Salzburg Reading Desk. The average reading speed in the preoperative examination was 141 ± 20 words per minute (wpm), increasing to 146 ± 20 wpm (P = 0.261). The maximum reading speed increased from 171 ± 28 wpm to 180 ± 22 wpm respectively (P = 0.110).

**Preoperative considerations**

Surgery for presbyopia correction by small aperture corneal inlay is carried out in emmetropic presbyopic patients aged between 45 and 60 years. However, the latest advances allow presbyopic patients who have previously undergone refractive surgery (Post-LASIK) to be operated, depending on the corneal thickness. A previous case history must be obtained to determine the main visual needs of the patient’s near vision and distant vision, because ACI implantation in patients with high visual demands is inappropriate. Visual acuity in near vision (40 cm) and in distant vision (80 cm) has to be measured principally with an Early Treatment Diabetic Retinopathy Study (ETDRS) test. Generally patients with Uncorrected Distance Visual Acuity (UDVA) values of 20/20 in both eyes and with no corneal disease are selected. Because the small aperture corneal inlay will be introduced into the corneal stroma, in addition to the evaluation of visual acuity at different distances, a series of pre-surgical diagnostic tests must be performed to evaluate the suitability of the stroma for receiving the implant. These diagnostic tests consist of...
of an endothelial cell count, pupillometry in photopic, mesopic and scotopic conditions, pachymetry to evaluate central corneal thickness, corneal topography, contrast sensitivity and corneal biomicroscopy.  

**Visual results of small aperture corneal inlay**

Decreasing the patient’s pupil diameter causes an increase in depth-of-focus. Following this principle, the small aperture corneal inlay allows an increase in depth-of-focus, providing an improvement in visual acuity in near vision. Clinical research suggests a high level of satisfaction among patients, with improvement of tasks performed in binocular vision, mainly in near and intermediate vision. Alió et al. showed that in 60% of patients, Corrected Near Visual Acuity (CNVA), Corrected Distance Visual Acuity (CDVA), Uncorrected Near Visual Acuity (UNVA) and UDVA after removal of the inlay were similar to the preoperative period. Although under certain circumstances, the levels of satisfaction obtained are considered acceptable, it must be remembered that in some situations, corneal inlays involve a decrease in stereopsis and contrast sensitivity and obviously binocular vision will decrease too.

Because the patient’s pupil size decreases with age, the contrast sensitivity values associated with the smaller amount of light entering the eye also fall. The small aperture corneal inlay, by reducing the aperture of the pupil, may cause a decrease in contrast sensitivity because of a smaller amount of light entering. In a prospective, randomized and multicenter trial performed in 45 to 60-year-old presbyopic patients, Waring measured the preoperative contrast sensitivity using the Optec® and Functional Acuity Contrast Test (FACT) chart system. In the preoperative assessment, the contrast sensitivity level was 85 Cd/m² and 3 Cd/m² in mesopic conditions. After 1 year of monitoring, Kamra® was shown to improve the visual acuity in near vision with a minimal impact on the contrast sensitivity in mesopic conditions.

The best visual acuities are obtained when the small aperture corneal inlay is implanted in emmetropic patients. However, when the spherical equivalents are greater, the results are altered and more improvement is seen in hyperopic patients than in myopic patients. Astigmatism should be corrected before the implantation of the small aperture corneal inlay. Besides implantation in emmetropic patients, corneal inlays can be implanted in post-LASIK presbyopic patients, as has been documented. Tomita et al. conducted a study with 223 presbyopic patients who had previously undergone LASIK (223 eyes) with an average age of 53.6 years (range: 44-65 years) and a spherical equivalent of −0.18 Diopters (D) (Range: −1.00 D a +0.50 D). The UDVA in the operated eye decreased 1 line, from 20/16 in the preoperative assessment to 20/20 six months after the operation (P < 0.001). The UNVA improved four lines, from Jaeger J8 to J2 (P < 0.001). Six months after the operation, the corneal inlay had improved near vision, with a minimal effect on distant vision.

Scientific studies show that the combination of corneal inlays in post-LASIK patients for the treatment of presbyopia in emmetropic, hypermetropic and myopic patients seems to be a safe and efficient procedure, improving near and intermediate vision. Tomita et al. in a study performed with 360 eyes of 180 patients, of which only 64 patients could be evaluated postoperatively after six months, showed that logMar visual acuity in near vision improved seven lines in the hypermetropic eyes which had received the inlay. In emmetropic eyes, logMar visual acuity improved six lines, while in myopic eyes a two-line improvement was found. The UDVA improved by three lines in hypermetropic eyes, one line in emmetropic eyes and two lines in myopic eyes. As regards UDVA, the results obtained with post-LASIK small aperture corneal inlay implantation are poorer than when the inlay is implanted in combination with LASIK. However, with respect to UNVA, similar results are obtained when the small aperture corneal inlay is combined with the LASIK, with better results in hyperopic patients.

The small aperture corneal inlay can also be implanted in pseudophakic eyes, providing good results in near vision. Huseynova et al. presented three cases of presbyopic patients who had a previously implanted anterior chamber phakic intraocular lens. Three months after the operation, there were no significant variations in UDVA. However, UNVA improved by 2-5 lines three months after the surgery.

Because of the good results obtained in near vision after the operation, the use of near vision glasses is ruled out in the vast majority of cases. Dexl et al. in a study performed with ACI 7000PDT in 24 emmetropic presbyopic patients, found that the need for glasses in near vision decreased significantly (P < 0.001). Seyeddain et al. found that 6.3% of the 32 patients who received a Kamra® implant needed reading glasses versus the 87.5% who needed reading glasses before the operation.

During the postoperative period, in addition to visual acuity at all distances and contrast sensitivity tests, it is important to carry out campimetry and endothelial cell counts. A few scientific studies have focused on campimetry for the evaluation of central vision in patients with small aperture corneal inlays. Seyeddain et al. found no defects in the central visual field after the surgery. Seyeddain et al. determined endothelial cell counts for 24 months after the ACI 7000PDT operation and came to the conclusion that there was no variation compared to the preoperative status.
Complications of small aperture corneal inlay

Although the complications associated with the implants are minimal, some patients may suffer dry eye symptoms, halos, glares or night vision disturbances. The vision disorders occur when the pupil diameter increases in night conditions and are associated with an increase in ocular aberrations. Seyeddain performed a study with 32 patients with Kamra® implants, in which 15.6% of the patients had complications in night vision three years after the operation. In other cases, a drastic decrease in visual acuity due to implant decentering has been observed. A lack of stability in the corneal inlay position is the main complication associated with this kind of operation. The correct positioning of the corneal inlay is crucial for achieving acceptable vision, so if the implant is decentered, the surgeons should consider the possibility of a surgical intervention to position it properly.

In two patients with small aperture corneal inlays, Gatinel et al. showed that the corneal inlay was decentered in relation to the corneal vertex in both cases. As a consequence of this decentering, the patients reported visual symptoms and visual acuity deficit. Two weeks after the operation, both inlays were properly centered and, one week later, the visual acuity of the patients improved significantly. Nevertheless, there are situations in which, despite correct centering, the corneal inlay does not suit the patient, so it must be removed. Once the corneal inlay is removed, the corneal topography and the corneal aberrometry may not return to its preoperative state and an increase in ocular aberrations is common. Non-adaptation to the corneal inlay may be produced by difficulty in near vision or visual disturbances such as night glare, halos, photophobia, starburst and blurred vision leading to a loss of visual acuity.

To achieve the best effects in patients with low degree of astigmatism and few aberrations, the small aperture corneal inlay should be inserted close to the corneal reflex position. Ocular aberrations normally increase with an increase in pupil diameter, mainly in scotopic conditions. The outer and inner diameters of the small aperture corneal inlay are designed to reduce the harmful effects of ocular aberrations and diffraction resulting from an increase in pupil size. Nevertheless, in situations in which the small aperture corneal inlay needs to be extracted due to failure to adapt or decentering, an increase in ocular aberration is observed for a period of time. In a study of 10 patients who were implanted with one of the three versions of Kamra® corneal inlay (ACI 7000, 7000T, and 7000PDT), Alió et al. demonstrated that Root Mean Square (RMS) of the High Order Aberrations (HOA) in the preoperative evaluation was $0.50 \pm 0.12$ (range: $0.30$ to $0.70$). Six months after the operation, the RMS of the HOA was $0.69 \pm 0.14$ (range: $0.48$ to $0.95$) ($P < 0.8$).

The changes in the corneal surface due to the small aperture corneal inlay may cause variations in corneal thickness. In a study by Kim et al. in 13 rabbits with small aperture corneal inlay, OCT transversal images showed that corneal thickness increased more than expected after the operation. This is mainly due to an immediate response of the cornea to surgical trauma. One month after the operation, they noticed 25% thinning of the epithelium and 15% flattening of the anterior corneal surface. The epithelial layer was thinner in most of the rabbit eyes. Most of the epithelial layer thickness was located in the anterior corneal surface, causing an increase in the corneal curvature one month after the operation.

Alterations in the composition of the tear film, such as basal cell storage, can lead to the formation of iron deposits in the small aperture corneal inlay surface. In these situations, the iron deposits may present in various configurations; they may appear in a central form, in a crescent-shaped form or in a ring form. The location of the iron deposits is mainly central and peripheral after ACI 7000 implantation. Dexl et al. in a study of 32 patients, found that 18 eyes (56%) developed iron deposits 36 months after the implantation. The time between the implantation and the formation of the iron deposits was $18 \pm 9$ months. They concluded that the iron deposits do not seem to have a significant impact on the visual acuity of the patients. Nevertheless, ACI 7000PDT implants showed a significant reduction in iron deposits compared to the ACI 7000. Likewise, Dexl et al. in a study with ACI 7000PDTs, found no significant variation in cornea topology. The reduced thickness of the ACI 7000PDT, the modified implantation technique, and the increase in the number of nutritional pores are the factors contributing to the reduction of iron deposits on the corneal surface.

CONCLUSIONS

The implantation of the small aperture corneal inlay in emmetropic presbyopic patients provides good results in near and intermediate vision in patients with few visual requirements, eliminating the need for glasses in near vision. It has the advantage of being considered a safe, efficient and reversible procedure, associated with few complications and these inlays may be implanted, depending on the corneal thickness, in presbyopic patients who have previously undergone refractive corneal surgery. The small aperture corneal inlay design provides, in addition to an appropriate transfer of nutrients, the possibility of obtaining good quality images on clinical devices.

Although there are few complications associated with the small aperture corneal inlay, any small decentering can lead to a drastic decrease in visual acuity. After the implantation of the small aperture corneal inlay, ocular
aberrations can be increased, contrast sensitivity is decreased, and some patients reported a reduction of stereopsis, dry eye sensation, halos, glare or night vision disturbances.

REFERENCES