Corneal inlays for spectacle independence: Friend or foe?

Whether you think you can, or think you can’t…you are right!  
—Henry Ford

Presbyopia is primarily an inevitable, age-related condition that causes irreversible loss of the accommodative amplitude of the eye. Despite its ubiquity, the exact mechanism behind presbyopia remains unclear. Worldwide in 2005, more than 1.04 billion people were estimated to have presbyopia. By the year 2020, the worldwide prevalence is expected to rise to 1.37 billion. The underlying cause for this age-related loss of accommodation has yet to be fully elucidated and continues to remain a topic of controversy. Models for presbyopia are broadly divided into 2 areas and are referred to as lenticular mechanisms and extralenticular mechanisms. Although the lenticular theories propose age-related changes to the lens, capsule, and zonular fibers, the extralenticular mechanism includes ciliary muscle dysfunction, loss of elasticity in the posterior zonular fibers, and even decreased resistance on the vitreous against the lens capsule.

Presbyopia affects the quality of life. McDonnell et al. showed that presbyopia was associated with substantial negative effects on health-related quality of life in a population study based in the United States. The safest and least invasive method to treat presbyopia consists of corrective glasses as a separate pair of reading glasses, bifocals, or progressive lenses. Several options to treat presbyopia have been pursued; these include monovision with contact lenses or with laser vision correction, multifocal ablation patterns on the cornea (termed presbyLASIK), and lenticular approaches with refractive lens exchange with multifocal or extended depth of focus intraocular lenses.

One of the earliest approaches for presbyopia correction was additive refractive keratoplasty, in which a foreign material, either biological or synthetic, is added to the corneal tissue to alter the refractive status. Synthetic corneal inlays have been investigated for well over half a century. Barraquer was the first to use them in 1949 for the treatment of aphakia and myopia. The materials used for the synthetic inlays have improved from the early use of flint glass or poly(methyl methacrylate) to hydrogel polymers. The older generation of inlays led to several complications, which included corneal opacification, epithelial and stromal thinning, intracorneal deposits, and decentration.

With the developments of newer synthetic materials with improved biocompatibility, better understanding of the wound healing in the cornea, and technological developments with femtosecond laser and stromal pocket creation software, there has been a rekindling of interest in corneal inlays.

The current generation of corneal inlays based on the mechanism of action can be divided into 3 categories: small aperture (Kamra, Acufocus, Inc.); shape altering, which do not have intrinsic refractive power but do create a central hyperprolate cornea (Raindrop Near Vision Inlay, Revision Optics, Inc.), and zonal refractive, which provide corneal multifocality (Flexivue MicroLens, Presbia Coöperatief U.A.). Table 1 shows the physical, biomechanical, and functional characteristics of these inlays. All these inlays are implanted in only 1 eye—the nondominant eye—with the dominant eye corrected to provide uncorrected distance vision. The benefits of these inlays are that they are potentially reversible, easy to implant, additive, and tissue sparing and one can combine them with other corneal refractive procedures to correct ametropia.

The first publication on these new generations of corneal inlays was by Yilmaz et al. in 2008, who reported 1-year data for a small-aperture corneal inlay (ACI-7000, Acufocus, Inc.) in 39 eyes with an uncorrected near visual acuity (UNVA) of Jaeger (J) 3 or better and uncorrected distance visual acuity (UDVA) of 20/40 or better in the eye with the inlay. The long-term follow-up data with the small-aperture corneal inlay showed the UNVA to be J3 or better in 96.9% of eyes at 2 years and in 74.2% of eyes at 5 years. The uncorrected intermediate visual acuity was 20/40 or better in 95% of eyes with the inlay at 2 years and 20/32 or better at 5 years in 87.1% of eyes with the inlay. The UDVA was 20/32 or better in all eyes with the inlay at 2 years and 20/20 or better in 93.5% at 5 years. Between 2006 and 2010, the small-aperture Kamra inlay has undergone design iteration, with the current model (ACI-7000 PDT, Acufocus, Inc.) measuring 6 μm thick with 8400 laser-etched microperforations ranging in size from 6 to 12 μm to allow water, carbon dioxide-oxygen diffusion, and nutrient flow.
In this issue (pages 965–971), Whitman et al. report 1-year data on the visual performance and contrast sensitivity after implantation of the Raindrop Near Vision Inlay in 30 emmetropic presbyopes. At 1 year, 77% of patients achieved a UDVA of 0.1 logMAR at distance, intermediate (80 cm), and near (40 cm) test targets. Earlier this year, the same group of authors published the 1-year clinical outcome data on a larger cohort as part of the phase III clinical study for U.S. Food and Drug Administration approval. Although it is difficult to have a direct head-to-head comparison between these 3 new generations of corneal inlays because of their different mechanism of action, the surge in the peer-reviewed literature on the short-term and medium-term results seems to suggest that these inlays are more biocompatible than the earlier generations and they seem to provide good unaided near and intermediate vision with minimal compromise to the unaided distance vision in the eye with the inlay. I believe that the current generation of corneal inlays adds to our armamentarium of surgical tools that we have in treating presbyopia. Let us watch “this space.”

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REFERENCES