Patients who undergo presbyopia correction have come to expect unaided distance, intermediate, and near vision without compromising quality of vision. Advances in the designs and materials of corneal inlays over the past few decades have led to successful outcomes with their use in this population. Current corneal inlays are typically 2 to 4 mm in diameter and 5 to 40 µm thick. They are implanted in the stroma of the nondominant eye, under a corneal flap or within a corneal pocket. The Raindrop Near Vision Inlay (ReVision Optics; Figure 1) creates a profocal cornea, leaving patients with smooth transitions from near to distance vision. This transparent hydrogel inlay allows 99.7% of light to transmit through the cornea to the retina and oxygen and nutrients to permeate the cornea. It is implanted under a femtosecond-laser–created corneal flap (one-third corneal thickness; minimum, 150 µm) and centered over a light-constricted pupil.

We recently started implanting the Raindrop bilaterally in presbyopic patients with low hyperopia (1.00–1.75 D) in order to provide them with enhanced near vision in both eyes. In this population, the inlay is first implanted in the nondominant eye without an excimer ablation. After 3 months, if the patient has good distance visual acuity and wants to further improve his or her near vision, we offer him or her a second inlay in the dominant eye. We have noticed that results are even better than they are with unilateral implantation, with few visual side effects.

BILATERAL STUDY

We are conducting a bilateral study with the Raindrop in this presbyopic, low-hyperopic population. Our interim 9-month results have been presented previously, and baseline data for the 23 enrolled patients are presented in Table 1. No patient had an ocular pathology (ie, dry eye) or history of previous refractive surgery.

We used a two-step surgical approach. After implanting the Raindrop inlay in the nondominant eye, we prescribed a contact lens in the dominant eye to correct for distance. Three months later, patients were evaluated for and received a second inlay if they met the following criteria: good visual acuity with the first implant in the near (20/32 or better) and distance (20/25 or better) fields, no complications with the first implant, and motivation and desire to receive a second inlay. Patients who did not qualify for bilateral implantation underwent hyperopic LASIK with a target of plano in the dominant eye. Follow-up was scheduled at 1, 3, 6, 9, and 12 months postoperatively.

OUTCOMES

The main outcome measures were monocular (nondominant) and binocular visual acuities measured with the Early Treatment Diabetic Retinopathy Study chart. Near, intermediate, and distance vision were measured at 40 cm, 80 cm, and 4 m, respectively. Visual tasks were administered under dim and good light conditions; we evaluated visual symptoms including halos and glare, patient satisfaction, and safety.

Figure 1. The Raindrop Near Vision Inlay.
Near, distance, and binocular UCVs. Bilateral implantation of the Raindrop inlay provided approximately 1 additional line of improved near UCVA over the results with unilateral inlay implantation (Figure 2). These benefits were sustained over 9 months. Bilateral implantation also improved distance vision, with an average distance UCVA of better than 20/20 at all follow-ups (Figure 3). All patients also had a significant improvement in their full range of vision over preoperative measurements when evaluated binocularly, and more than 80% achieved 20/20 or better binocular UCVA at all distances and follow-ups (Figure 4).

Visual symptoms and patient satisfaction. Reports of marked or severe visual symptoms were infrequent (no more than 10% at 3 months). After 6 months, no patient noted marked or severe halos and glare.

At 9 months, 100% overall satisfaction with vision was reported. Patients were either satisfied (56%) or very satisfied (44%) with their spectacle-free visual outcomes.

Safety. All patients evaluated at 9-month follow-up were within 1 line of preoperative BCVA for distance and near. There were no cases of corneal haze in either eye, no explants, and no exchanges.

CONCLUSION

Our data indicate that bilateral implantation of the Raindrop Near Vision Inlay is an option for presbyopia correction in low hyperopes. The Raindrop creates a gradual steepening of the central cornea, effectively increasing depth of focus and allowing the patient to see at all distances without interruption. Further studies are still needed to confirm our results and provide greater understanding of the potential of implanting bilateral inlays in conjunction with excimer laser ablation in other populations including myopes and higher hyperopes.

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2. Bilateral implantation of hydrogel corneal inlays in hyperopic presbyopes. Paper presented at: the XXXI Congress of the ESCRIS; October 5-9, 2013; Amsterdam, Netherlands.