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HYDROGEL INLAY IMPROVES UNCORRECTED NEAR VISUAL ACUITY IN PRESBYOPIC EMMETROPIC EYES

The inlay creates multifocality at the corneal plane, with near vision on the visual axis and a transition to intermediate, distance vision out to the periphery.

A hydrogel corneal inlay improved uncorrected near visual acuity in patients with emmetropic presbyopia, according to a study.

The study authors reported results from the Raindrop corneal inlay (Re-Vision Optics), a clear, permeable hydrogel inlay with roughly the same refractive index as the cornea.

“The most important findings in this study were consistent visual acuities and high patient satisfaction. Overall, the patient satisfaction was 95% for this study. We attribute the high patient satisfaction to excellent visual acuities … and low visual symptoms,” **Enrique Barragan Garza, MD,** the corresponding author, said.

The Raindrop inlay has a diameter of 2 mm and thickness of 32 µm. It is implanted under a 150-µm corneal flap cut with a femtosecond laser.

“The cornea reshapes to a natural prolate curvature, creating near vision on the visual axis with a gradual transitioning to intermediate and distance out to the periphery of the cornea,” Garza said in an email interview. “Unlike other technologies that ablate the corneal tissues to try to reshape it, Raindrop acts as a spacer to naturally change the shape of the cornea, giving patients improved near and intermediate vision. With the addition of the Raindrop in the cornea, I have found it has lasting presbyopic-correcting effects for all of my presbyopic patients.”

Enrique Barragan Garza

The study was published in the Journal of Refractive Surgery.

Procedure and parameters

The feasibility study included 20 nondominant eyes of 20 patients who underwent implantation of the Raindrop corneal inlay. Average patient age was 50 years.

The inlay was implanted on the corneal stromal bed, over the pupil center, under a keratotomy flap created with an IntraLase femtosecond laser (Abbott Medical Optics).

“It is important for the surgeon to place the inlay over the constricted pupil during the procedure. There is no additional equipment required for centration of the Raindrop inlay. Even at 0.75 mm off the constricted pupil, the patient will not experience any negative visual acuity effects with the Raindrop,” Garza said.

Patients were examined preoperatively, on the day of surgery and 1 day, 1 week, and 1, 3, 6, 9 and 12 months postoperatively. One patient underwent explantation of the inlay and left the study after 6 months.

The benchmark for efficacy was at least 75% of eyes with Snellen uncorrected near visual acuity of 20/40 or better at 6 months. Safety outcomes were retention of best corrected distance visual acuity; adverse events; contrast sensitivity; near, intermediate and distance visual acuity; patient satisfaction; spectacle use; and complications.

Outcomes and observations

Uncorrected near visual acuity was 20/40 or better in all implanted eyes at 1 week. Mean visual acuity was 20/22 to 20/23 at 1 week and all subsequent follow-up points; mean improvement in uncorrected near visual acuity was statistically significant at all subsequent points.

Mean binocular uncorrected near visual acuity was 20/21 at 1 month and remained less than 20/25 at all subsequent points.

Corrected distance visual acuity was 20/22 or better in all eyes at 12 months.

Mean uncorrected distance visual acuity was 20/28 at 1 week and remained less than 20/32 at all follow-up points.

Mean uncorrected intermediate visual acuity was 20/25 at 1 month and remained less than 20/32 at all subsequent points.

“In addition to excellent visual acuities in the emmetropic population, it is important to note two other key findings. One, the low visual symptoms patients experience with the Raindrop, even though it creates a multifocal cornea, and second, the same excellent contrast sensitivity measurements in both mesopic and photopic conditions,” Garza said.

No visual symptoms were reported, and 16 patients were partly or completely spectacle independent at 12 months. – by Matt Hasson

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Reference:

Garza EB, et al. *J Refract Surg.* 2013;doi:10.3928/1081597X-20130129-01.

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Disclosure: Garza and fellow authors are consultants and investigators for ReVision Optics.