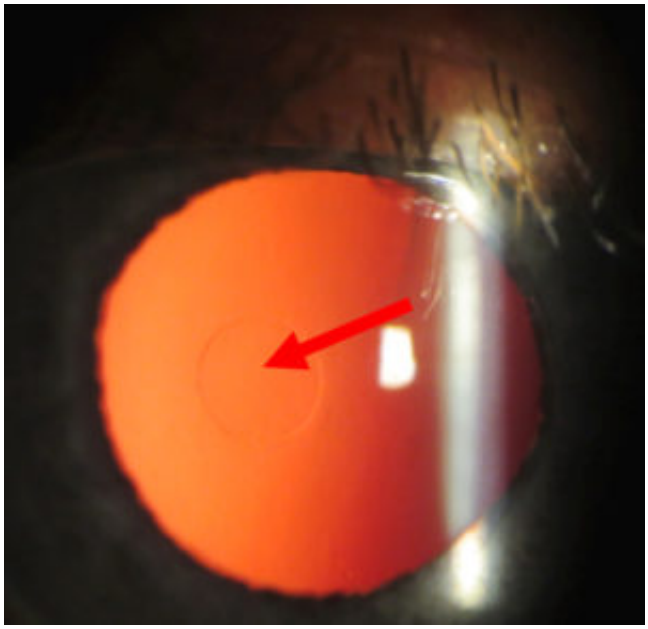
Treatment for age related loss of near vision: Raindrop near vision inlay one-year clinical results

Presbyopia is an ocular condition associated with age related loss of near vision. The eye loses the ability to focus well on near objects due to the hardening of the natural lens. It affects billions of people worldwide with the onset occurring around age 45. The most common treatment for presbyopia is the use of reading glasses. Recently, surgical correction of presbyopia has been tested as part of a clinical study by implanting a small device into the cornea, the clear front part of the eye. The Raindrop Near Vision Inlay is an investigational device that is being evaluated to treat this condition so that dependence upon reading glasses may be reduced in order to see objects up close.



Photograph of the Raindrop Near Vision Inlay (arrow) centered on the cornea.

The Raindrop Inlay is a 2 mm inlay which is transparent and is made of hydrogel, similar material to a soft contact lens. The hydrogel material (~80% water) is designed to be biocompatible with the cornea. The inlay is implanted in the center of the cornea underneath a flap which has been created with an ophthalmic laser, similar to what they use in LASIK procedures. Both eyes work together to create a single image, so to maintain distance vision the inlay is placed in only one eye, the non-dominant eye. The inlay reshapes the cornea so that the central region becomes steeper, which improves the eye's ability to focus on objects up close while maintaining the ability to focus properly on intermediate and distant objects.

As part of a US FDA Clinical Trial, the Raindrop Inlay was placed in 373 non-dominant eyes of presbyopic patients that can see distant objects without the use of glasses or contacts. 340 patients were analyzed at one year and their visual outcomes were reported. The visual stability, visual function, symptoms, and satisfaction of the patients were also reported at one year.

On average, in the implanted eye, patients improved 5 lines of near acuity (reading 16 inches) on the vision chart improved 2.5 lines of intermediate acuity (reading at 30 inches), at and experienced a a loss of only 1 line of distance acuity (reading at 20 feet) Using both eyes together, the distance vision remained unchanged and patients could see 20/20 or better. The vision of the patients also remained stable by 6 months after implantation.

Patient satisfaction was greatly improved after implantation of the Raindrop Inlay. Before the surgery, 66% of patients were satisfied when their vision was corrected with glasses. After implantation with the inlay, 92% of patients were satisfied without any additional use of glasses for correction. Some patients reported visual symptoms such as halos and glare, 4.1% and 2.1%, respectively.

Similar to any surgery, there are potential risks for dryness and other ocular symptoms. At one year, 4.7% of patients had moderate or worse ocular dryness and incidence of ocular symptoms such as pain, light sensitivity, and discomfort were even lower. Additionally, corneal haze (cloudiness or opacity in the cornea as a reaction to the inlay) can occur as part of the healing process. 14% of subjects experienced corneal haze through the 1-year visit. The corneal haze resolved in all but one patient with the treatment of steroids. The inlay can easily be removed if there are any complications or if the patient is dissatisfied with their vision. In this study, 11 eyes were explanted due to patient dissatisfaction, surgical complications, or corneal haze. In these cases, all patients' vision returned to pre surgical levels by 6 months.

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Publication

Treatment of Presbyopia in Emmetropes Using a Shape-Changing Corneal Inlay: One-Year Clinical Outcomes.
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