

# Combined hydrogel inlay and laser in situ keratomileusis to compensate for presbyopia in hyperopic patients: One-year safety and efficacy

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**PURPOSE:** To perform a feasibility study of the safety and efficacy of a corneal-contouring inlay with concurrent laser in situ keratomileusis (LASIK) to treat hyperopic presbyopia.

**SETTING:** Private clinic, Tijuana, Mexico.

**DESIGN:** Prospective interventional case series.

**METHODS:** Hyperopic patients received LASIK in both eyes and a corneal inlay under the femto-second laser flap in the nondominant eye. The inlay is designed to reshape the anterior corneal curvature, creating a near-center multifocal refractive effect. Main safety outcomes were retention of preoperative corrected distance and near visual acuities and reports of adverse events. Efficacy was determined through measurements of near, intermediate, and distance visual acuities and patient questionnaires on visual task ability and satisfaction.

**RESULTS:** The study enrolled 16 patients. All eyes with an inlay achieved an uncorrected near visual acuity (UNVA) of 20/32 or better by the 1-week postoperative examination and at every visit thereafter. The mean monocular and binocular UNVA was 20/27 or better at all visits. The mean binocular uncorrected distance visual acuity improved significantly from 20/53 preoperatively to 20/19 postoperatively ( $P < 10^{-5}$ ). One inlay was explanted during the study. At 1 year, all 14 patients analyzed were satisfied or very satisfied with their near, distance, and overall vision.

**CONCLUSIONS:** The hydrogel corneal inlay with concurrent LASIK improved uncorrected near, intermediate, and distance visual acuity in hyperopic presbyopic patients with high patient satisfaction and visual task ability. This represents a new indication for this recently developed technology.

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Laser in situ keratomileusis (LASIK) has been shown to be a safe and effective method for treating distance refractive error in the presbyopic age group (40 to 69 years of age).<sup>1</sup> However, because these patients have age-related loss of accommodation, they often need the assistance of reading glasses after LASIK to perform near tasks. Laser in situ keratomileusis monovision correction is a popular treatment that compensates for presbyopia by correcting 1 eye for distance vision and the fellow eye for near vision. However, monovision patients have a higher enhancement rate than patients who have standard LASIK correction.<sup>2</sup>

In a study of monovision, Durrie<sup>3</sup> used contact lenses to replicate imbalanced LASIK refractions and observed more visual symptoms, a decrease in distance stereopsis, and a decreasing acceptance of monovision as the contact lens power increased in the nondominant eye. Laser in situ keratomileusis can also be used to create a multifocal cornea.<sup>4,5</sup>

This paper describes the use of a corneal inlay that acts in a manner similar to multifocal LASIK treatments except that instead of removing tissue to create the shape, a small amount of hydrogel with the same refractive index as the cornea is implanted.<sup>6</sup> Other corneal inlays have alternative methods of action;

they implant a higher refractive index material deep in the cornea<sup>7</sup> or limit the pupil entrance diameter using a pinhole design.<sup>8</sup> Such inlays have been used as a treatment for presbyopia in emmetropic patients<sup>6-8</sup> as well as in myopic and hyperopic patients when combined with LASIK.<sup>8</sup> The inlays are positioned on the corneal stroma under a corneal flap after LASIK has been performed or within a corneal pocket under the flap.

This study evaluated the first cases performed with a small-diameter hydrogel inlay, the Raindrop near vision inlay (Revision Optics, Inc.), to compensate for presbyopia when combined with concurrent LASIK. This paper describes a feasibility study for presbyopic hyperopic patients.

## PATIENTS AND METHODS

All patients provided informed consent before any study-specific procedures were performed. The study was approved by the Centro Oftalmologico de Tijuana S.A. de C.V. Comision de Investigacion y Etica (institutional review board) and adhered to the tenets of the Declaration of Helsinki.

Inclusion criteria included a near addition (add) requirement between +1.50 diopters (D) and +2.50 D, a stable manifest refraction spherical equivalent (SE) between +1.00 D and +3.00 D with no more than 1.50 D of refractive cylinder, and corrected distance (CDVA) and near (CNVA) visual acuities of 20/25 or better. Patients enrolled in this study had a distance-corrected near visual acuity of 20/50 or worse. A minimum 5-day monovision trial was performed with a multifocal contact lens (Purevision, Bausch & Lomb) to correct the near and distance vision in the nondominant eye and a monofocal contact lens to correct the distance vision in the dominant eye. Patients had inlay implantation only after expressing satisfaction with their vision and confidence that they could conduct their lives normally. In the eye with the inlay, the central corneal thickness (CCT) was required to be 500  $\mu\text{m}$  or more with a residual bed thickness (CCT - [intended ablation depth + intended flap thickness]) of 300  $\mu\text{m}$  or more. Exclusion criteria included previous ocular surgery, ocular or eyelid pathology, infection or inflammation, clinically significant dry eye, corneal topographic irregularities, systemic disease or therapies that may affect wound healing or visual outcomes (eg,

diabetes, lupus, cancer), and any condition associated with hormone fluctuations that could lead to refractive changes.

## Testing

Eye dominance was determined in all patients before surgery. Patients fixated on a distant object through a 1-inch hole in the center of a card held at arm's length. The eye framed by the hole when the card was moved close to the face was considered to be the dominant eye.

Examination visits were pretreatment, on the day of surgery, and 1 day, 1 week, and 1, 3, 6, 9, and 12 months after surgery. Assessments included manifest and cycloplegic refractions, intraocular pressure, slitlamp examination, corneal pachymetry (Pentacam, Oculus, Inc.), visual acuities, a patient questionnaire, and self-reported visual symptoms. The CNVA and uncorrected near (UNVA) (40 cm/16 in) and distance (6 m/20 ft) visual acuities and uncorrected intermediate (80 cm / 32 in) visual acuity were assessed using the Early Treatment Diabetic Retinopathy Study charts with the Optec 6500 Vision Tester (Stereo Optical Co.) set to photopic luminance. Monocular uncorrected visual acuities were measured at near (UNVA), intermediate (UIVA), and distance (UDVA) in the inlay eye at baseline and postoperatively; however, the UIVA was not measured until 1 month postoperatively. Binocular visual acuity was measured at the same visits as monocular UIVA, although binocular UIVA was not measured 3 months and 9 months postoperatively. The patients were examined with the slitlamp at baseline and all postoperative visits.

Ocular discomfort (light sensitivity, pain, dryness, discomfort) and visual symptoms (glare, halos, double vision, fluctuations in vision) were self-reported. Patients rated their visual symptoms on a scale of 0 (absent) to 4 (severe).

Patients were also asked about their ability to perform tasks, 5 each for near, intermediate, and distance vision. Responses were scored as follows: 0 = not at all; 1 = with difficulty; 2 = with ease. The points were added to obtain a cumulative task score for each range, with a maximum score of 10. Figure 1 shows the specific tasks.

Patient satisfaction was assessed at distance, intermediate, near, and overall. Patients were asked at the preoperative examination and all postoperative visits, "How do you rate your satisfaction with your current vision without corrective lenses for distance, intermediate, near?" The answer options were very satisfied, satisfied, neutral, dissatisfied, or very dissatisfied.

## Corneal Inlay

The Raindrop near vision inlay has a 2.0 mm diameter and a central thickness of 32 to 36  $\mu\text{m}$ . It is of a clear permeable hydrogel material with a positive meniscus shape but has no intrinsic power because the material index of refraction is the same as the surrounding corneal tissue. The inlay alters the eye's refractive power by reshaping the cornea's anterior radius of curvature at the center of the pupil. The inlay's shape is thicker at the center and thinner at the edges, limiting the near-power effect to the center of the pupil and transitioning to the unaltered cornea in the peripheral pupil. The final anterior corneal shape is influenced by the biomechanical remodeling of the overlying anterior flap and remodeling of the epithelium. Because the inlay effect (less than 4.0 mm diameter) is much smaller than the LASIK ablation zone, when combined with LASIK, the final

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Near Tasks	Intermediate Tasks	Distance Tasks
Read medicine instructions Read newspaper article Examine fingernails Dial cell phone Read magazine	Find items on kitchen shelf Read a computer screen Use a bathroom mirror Use a wall calendar Recognize framed photo portraits	Read street signs Identify people across a room Judge car distances Read house numbers Tell the time from a wall clock

**Figure 1.** Patient subjective task assessment.

inlay-influenced surface change is very similar to that of emmetropic patients. Wavefront maps and images of the inlay within the cornea have been published.<sup>5</sup>

## Surgical Technique

Both eyes were prepared for LASIK according to the clinic's standard clinical procedures. Flaps with a diameter larger than 8.0 mm and a depth of 130 to 150  $\mu$ m were created using a femtosecond laser (Intralase, Abbott Medical Optics, Inc.). The flaps were lifted, and a hyperopic LASIK ablation was performed using a Wavelight Allegretto system (Alcon Laboratories, Inc.). The LASIK treatment in the nondominant eye was targeted for 0.00 to +0.50 D with zero cylinder, while the dominant eye was treated for a 0.00 D outcome with zero cylinder. The inlay was delivered from a preloaded inserter to the stromal bed in the nondominant eye immediately after the ablation. The inlay was positioned over the center of the light-constricted pupil and allowed to dry for approximately 1 minute before the flap was replaced.

For the first week, the following medications were prescribed: moxifloxacin hydrochloride ophthalmic solution 0.5% (Vigamox) 4 times a day, difluprednate ophthalmic suspension 0.05% (Durezol) or dexamethasone 0.1% (Etacortilen) 4 times a day, and carboxymethylcellulose sodium 0.5% (Refresh Plus Artificial Tears) as needed. After the first week, the patient discontinued use of the moxifloxacin hydrochloride and tapered off steroids over 4 weeks. Artificial tears, cyclosporine ophthalmic emulsion 0.05% (Restasis), and omega-3 supplements were used over varying periods to ensure a good tear film.

## Statistical Analysis

Descriptive statistics were used to calculate the frequency of events, defined by the safety and efficacy results in this study, using R open-source software environment for statistical computing and graphics. A paired *t* test was used on the mean of the differences (in the outcomes) from preoperatively to postoperatively. An  $\alpha$  level of 0.05 was selected to determine statistical significance and potential clinical significance.

Analyses were performed to determine the statistical significance of changes in visual parameters, such as near, intermediate, and distance visual acuities. The mean and standard deviation (SD) of the visual acuities were calculated using the total chart letters read on an Optec Vision Tester (Stereo Optical Co., Inc.) and converted directly into logMAR notation. Snellen means were calculated by direct conversion from logMAR notation. This process is equivalent to geometrically averaging Snellen acuities.

## RESULTS

The study comprised 16 patients. Table 1 shows the patients' demographics. Preoperatively, the mean

**Table 1.** Patient demographics.

Parameter	Value
Age (y)	
Mean $\pm$ SD	51.6 $\pm$ 3.5
Range	47, 60
Sex (%)	
Male	6
Female	94
Eye with inlay (%)	
Right	56
Left	44
Pupil size (mm)	
Mesopic	
Mean $\pm$ SD	5.1 $\pm$ 0.8
Range	3.9, 6.5
Photopic	
Mean $\pm$ SD	3.2 $\pm$ 0.3
Range	3.0, 4.1
MRSE (D)	
Mean $\pm$ SD	1.77 $\pm$ 0.53
Range	0.75, 2.75

MRSE = manifest refraction spherical equivalent

add power was +1.92 D  $\pm$  0.2 (SD). One patient was discontinued after the 9-month visit after inlay removal, 1 patient missed the 9-month visit, and another patient was lost to follow-up after the 9-month visit.

## Visual Acuity

**Monocular** Table 2 and Figure 2 show the mean monocular uncorrected visual acuities at near, intermediate, and distance. By 1 day postoperatively, the eyes with the inlay had statistically significantly improved UNVA over the preoperative value ( $P < 10^{-11}$ ). The mean near acuity ranged between 20/21 and 20/25 at all visits from 1 week onward, with a statistically significant improvement over preoperative values at all visits ( $P < 10^{-10}$ ). The UNVA stabilized at 1 week, with a mean improvement of more than 7 lines; the change in UNVA was not statistically significant from 1 week to 1 month ( $P > .2$ ). The mean differences in UNVA between adjacent postoperative examinations were within half a line. The improvement in the mean UDVA from preoperatively to the 1-week follow-up onwards was statistically significant ( $P < .0001$ ). At the 1-month follow-up (first measurement), the mean UIVA was significantly improved from the preoperative visit ( $P < 10^{-9}$ ). The mean UIVA remained 20/30 or better at all subsequent postoperative visits.

Figure 3 shows the monocular UDVA plotted against monocular UNVA over time in eyes with

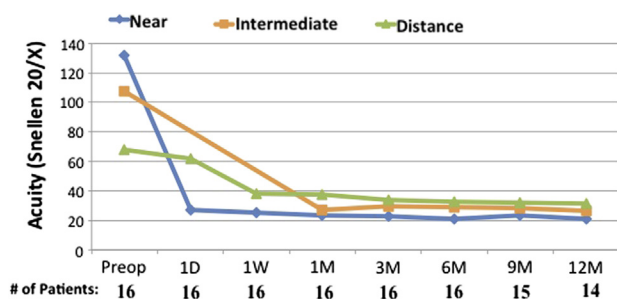
**Table 2.** Uncorrected monocular and binocular visual acuities over time.

Parameter	Mean (Snellen 20/x) ± SD (LogMAR)							
	Postop							
	Preop (n = 16)	1 D (n = 16)	1 Wk (n = 16)	1 Mo (n = 16)	3 Mo (n = 16)	6 Mo (n = 16)	9 Mo (n = 15)	12 Mo (n = 14)
<b>Monocular</b>								
UNVA	132 ± 0.15	27 ± 0.05	25 ± 0.07	23 ± 0.08	23 ± 0.08	21 ± 0.05	24 ± 0.06	21 ± 0.04
UIVA	107 ± 0.16	—	—	27 ± 0.07	29 ± 0.07	29 ± 0.07	28 ± 0.08	26 ± 0.07
UDVA	68 ± 0.17	62 ± 0.14	38 ± 0.08	38 ± 0.07	34 ± 0.11	33 ± 0.12	32 ± 0.13	31 ± 0.14
<b>Binocular</b>								
UNVA	112 ± 0.18	—	—	23 ± 0.09	23 ± 0.08	23 ± 0.05	23 ± 0.06	21 ± 0.03
UIVA	91 ± 0.18	—	—	25 ± 0.08	—	25 ± 0.10	—	26 ± 0.08
UDVA	53 ± 0.22	—	—	19 ± 0.06	19 ± 0.05	19 ± 0.04	19 ± 0.03	19 ± 0.11

UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UDVA = uncorrected near visual acuity

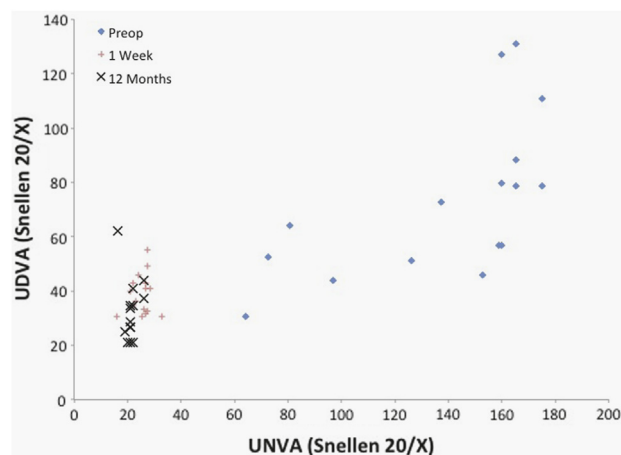
an inlay. Very small offsets, directed equally in the *x*-direction and *y*-direction, were added to some data points to prevent overlapping data points from being obscured. One week postoperatively, all eyes with the inlay had a UNVA of 20/32 or better and all patients had a UDVA of 20/50 or better. By 12 months postoperatively, all 14 patients analyzed had a UNVA of 20/25 or better in the eye with the inlay. At 12 months, 1 patient had a UDVA of 20/63, which improved to 20/40 when the patient returned for an informal 2-year visit. All other patients had a UDVA of 20/40 or better.

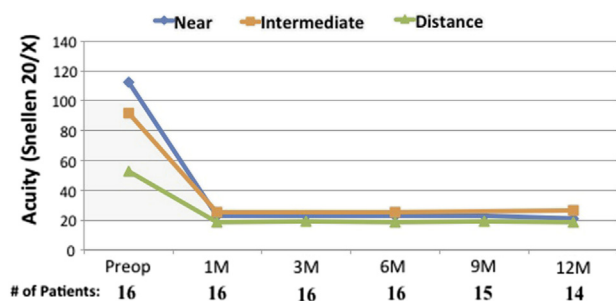
**Binocular** Table 2 and Figure 4 show the mean binocular near, intermediate, and distance visual acuities. By 1 month postoperatively (first measurement), the mean binocular UNVA improved significantly from baseline ( $P < 10^{-10}$ ) and remained 20/23 or better at all subsequent postoperative visits. The mean binocular UIVA improved significantly from baseline to 1 month after surgery ( $P < 10^{-8}$ ). The mean binocular UIVA was stable from 1 month to 12 months

**Figure 2.** Monocular UNVA, UIVA, and UDVA in eyes with the inlay over time.

postoperatively. The mean binocular UDVA was 20/19 or better at all visits from 1 month forward.

Figure 5 shows the binocular UDVA plotted against binocular UNVA in the eyes with the inlay over time. Very small offsets, directed equally in the *x*-direction and *y*-direction, were added to some data points to prevent overlapping data points from being obscured. One month postoperatively, 15 (93%) of 16 patients had a UNVA of 20/28 or better and all patients had a UDVA 20/22 or better. The patients' vision was similar 12 months postoperatively, at which time all 14 analyzed patients had a UNVA of 20/25 or better and 13 (93%) had a UDVA of 20/21 or better. One patient developed an unrelated retinal problem (hole in the peripheral retina) in the dominant eye at 12 months, which reduced the binocular UDVA to 20/40 from 20/25 at the 9-month visit.

**Figure 3.** Monocular UDVA versus monocular UNVA in the eye with the inlay at baseline (blue diamonds), 1 week (small red crosses), and 12 months (black crosses).

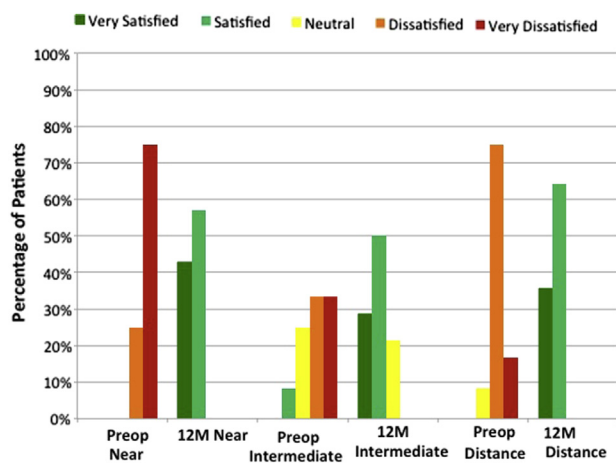


**Figure 4.** Binocular uncorrected near, intermediate, and distance visual acuity relative to pretreatment acuity. Binocular acuities were not recorded before 1 month postoperatively.

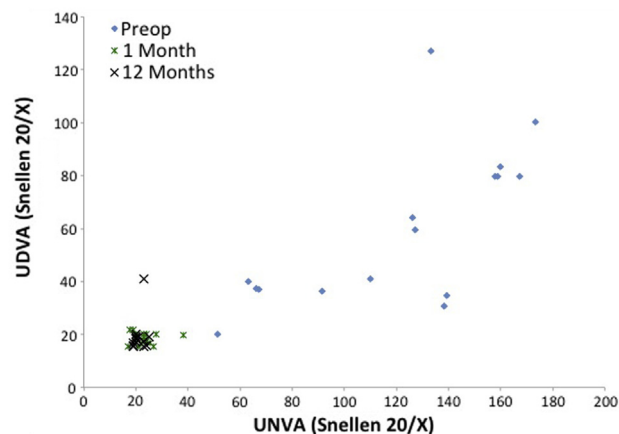
**Corrected Monocular Acuity** The CDVA was 20/20 or better in the 14 patients at the 12-month visit, and all patients achieved a CNVA of 20/25 or better. Nine patients (64%) lost at least 0.02 logMAR units of CDVA. The mean loss was  $0.03 \pm 0.06$  logMAR units. Three (21%) of 14 patients lost at least 0.02 logMAR units of CNVA; however, the mean gain in CDVA was  $0.01 \pm 0.05$  logMAR. One patient had lost 2 lines of CDVA in the eye with the inlay by the 6-month and 9-month postoperative examinations; however, the CDVA recovered to a loss of 2 letters by 12 months. No patient lost 2 lines of CNVA or more in the eye with the inlay at any timepoint.

### Patient Satisfaction

At 12 months, all 14 patients reported being satisfied or very satisfied with their near, distance, and overall vision. Eleven patients (79%) reported they



**Figure 6.** Patient satisfaction over time.



**Figure 5.** Binocular UDVA versus binocular UNVA over time (UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity).

were satisfied or very satisfied with their intermediate vision. Similar satisfaction scores were recorded at all postoperative visits at which the questionnaire was used (1 month onward). No patient reported being very dissatisfied with any range at any visit, and no patient reported being dissatisfied at near, intermediate, distance, or overall from the 6-month visit onward. Figure 6 shows the preoperative and 12-month near, intermediate, and distance satisfaction results.

### Task Assessment

Distance ( $P < .02$ ), intermediate ( $P < .001$ ), and near ( $P < 10^{-7}$ ) task performance improved significantly from the preoperative visit (Table 3 and Figure 7). Ten patients (71%) reported being able to perform all 15 tasks with ease at 12 months, and 2 additional patients (14%) reported being able to perform all answered tasks with ease. ("Not applicable" was entered for "Read a computer screen.") The remaining 2 patients also reported being able to perform all tasks, although they could perform 1 task and 2 tasks, respectively, with difficulty.

### Visual Symptoms

Figure 8 shows the mean score for each visual symptom at baseline and all postoperative visits when symptoms were recorded. The data are shown with SDs in Table 4. The only statistically significant change in any visual symptom between preoperatively and postoperatively was in halos at the 1-month visit ( $P < .02$ ). At 12 months, no patient reported moderate, marked, or severe visual symptoms in any category. Nine patients (64%) reported no visual symptoms in any category.

**Table 3.** Visual task performance over time.

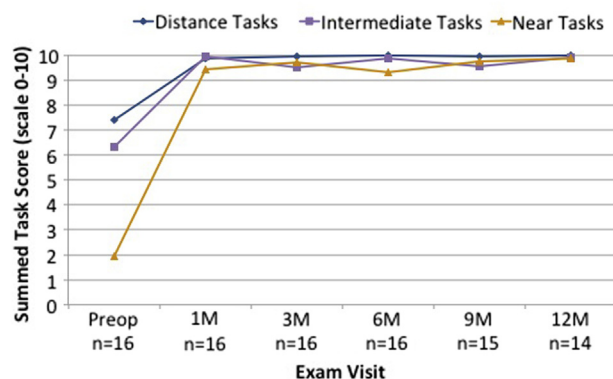
Parameter	Mean $\pm$ SD					
	Preoperative (n = 16)	Postoperative				
		1 Mo (n = 16)	3 Mo (n = 16)	6 Mo (n = 16)	9 Mo (n = 15)	12 Mo (n = 14)
Near tasks	1.9 $\pm$ 2.3	9.4 $\pm$ 1.0	9.7 $\pm$ 0.9	9.3 $\pm$ 1.5	9.7 $\pm$ 0.8	9.9 $\pm$ 0.5
Intermediate tasks	6.3 $\pm$ 2.7	9.9 $\pm$ 0.3	9.5 $\pm$ 0.8	9.9 $\pm$ 0.5	9.5 $\pm$ 0.6	9.9 $\pm$ 0.3
Distance tasks	7.4 $\pm$ 3.6	9.9 $\pm$ 0.5	9.9 $\pm$ 0.3	10.0 $\pm$ 0.0	9.9 $\pm$ 0.3	10.0 $\pm$ 0.0

Figure 9 and Table 4 show mean scores for ocular discomfort. The only statistically significant changes in ocular discomfort symptoms between preoperatively and postoperatively was in pain at the 3-month visit ( $P < .01$ ), although no level worse than mild was recorded, and in dryness at the 6-month and 12-month visits ( $P < .02$ ), although no level worse than moderate was recorded.

At 12 months, no patient reported severe ocular discomfort in any category. One patient reported marked light sensitivity, 1 patient reported moderate light sensitivity, and 2 patients reported moderate dry eye. Four patients (29%) reported no ocular discomfort in any category.

### Slitlamp Examination

At the 6-month visit, 1 patient (6%) developed a trace level of haze across the inlay visible by broad tangential illumination of the cornea in the slit-lamp. The haze did not resolve by the 9-month visit, and the inlay was explanted. The other 15 corneas with inlays (94%) remained clear throughout the study.

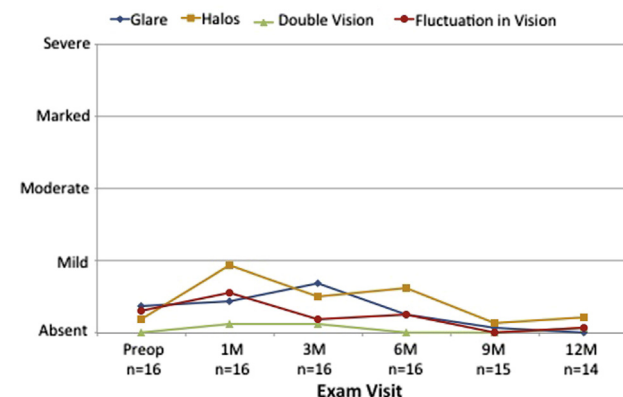
**Figure 7.** Patient assessment of ease of performing visual tasks at distance, intermediate, and near.

### Complications and Adverse Events

There were no complications and 2 adverse events. As discussed, 1 patient had recurrent haze with corneal inlay removal after the 9-month visit. One week after explantation, the UDVA in the treated eye improved from 20/50 to 20/20. In the case in which there was a loss in CDVA at 6 months and 9 months, the CDVA returned to baseline (20/20) at the 12-month postoperative visit.

### DISCUSSION

In this study, the Raindrop near vision inlay safely compensated for presbyopia in patients having concurrent hyperopic LASIK distance correction. At the 12-month visit, all patients available for analysis achieved a UNVA of 20/25 in the eye with the inlay and binocularly. The eye with the inlay gained 8 lines of near acuity over the measured preoperative value. As expected, the UDVA was slightly compromised in the eye with the inlay relative to the LASIK-only eye; however, by the 12-month visit, the eye with the inlay gained more than 3 lines on average over preoperatively. More important, these eyes

**Figure 8.** Mean visual symptom scores for glare, halos, double vision, and fluctuation in vision. The y-axis provides a description of the symptom levels by converting the numeric score (0 = absent; 1 = mild; 2 = moderate; 3 = marked; 4 = severe) back to the original scale of the self-questionnaire.

**Table 4.** Ocular and visual symptoms scores over time.

Symptom	Mean $\pm$ SD					
	Preoperative (n = 16)	Postoperative				
		1 Mo (n = 16)	3 Mo (n = 16)	6 Mo (n = 16)	9 Mo (n = 15)	12 Mo (n = 14)
Light sensitivity	0.7 $\pm$ 0.9	1.0 $\pm$ 1.2	0.9 $\pm$ 1.3	0.7 $\pm$ 1.1	0.3 $\pm$ 0.7	0.6 $\pm$ 0.9
Pain	0.0 $\pm$ 0.0	0.3 $\pm$ 0.6	0.4 $\pm$ 0.5	0.1 $\pm$ 0.3	0.0 $\pm$ 0.0	0.0 $\pm$ 0.0
Dryness	0.1 $\pm$ 0.3	0.4 $\pm$ 0.6	0.3 $\pm$ 0.6	0.5 $\pm$ 0.6	0.4 $\pm$ 0.6	0.7 $\pm$ 0.7
Discomfort	0.2 $\pm$ 0.5	0.3 $\pm$ 0.5	0.1 $\pm$ 0.3	0.2 $\pm$ 0.4	0.1 $\pm$ 0.3	0.1 $\pm$ 0.4
Glare	0.4 $\pm$ 0.8	0.4 $\pm$ 0.8	0.7 $\pm$ 0.7	0.3 $\pm$ 0.6	0.1 $\pm$ 0.3	0.0 $\pm$ 0.0
Halos	0.2 $\pm$ 0.4	0.9 $\pm$ 1.2	0.5 $\pm$ 0.8	0.6 $\pm$ 0.9	0.1 $\pm$ 0.4	0.2 $\pm$ 0.4
Double vision	0.0 $\pm$ 0.0	0.1 $\pm$ 0.3	0.1 $\pm$ 0.3	0.0 $\pm$ 0.0	0.0 $\pm$ 0.0	0.1 $\pm$ 0.3
Fluctuation in vision	0.3 $\pm$ 0.6	0.6 $\pm$ 0.7	0.2 $\pm$ 0.4	0.3 $\pm$ 0.6	0.0 $\pm$ 0.0	0.1 $\pm$ 0.3

did not lose CDVA at 12 months. Binocular vision tested at all distances improved significantly from preoperatively to the early postoperative period and remained stable over time. The visual acuity results were in keeping with task performance at all distance ranges.

The endothelial cell count was not measured in this study but has been measured elsewhere in a United States Investigational Device Exemption study on the Raindrop inlay in emmetropic patients.<sup>A</sup> In that study, there was a loss in endothelial cell density of 1.6% at 1 year. The SD in the density variation was 3.2% however; thus, the change was not statistically significant.

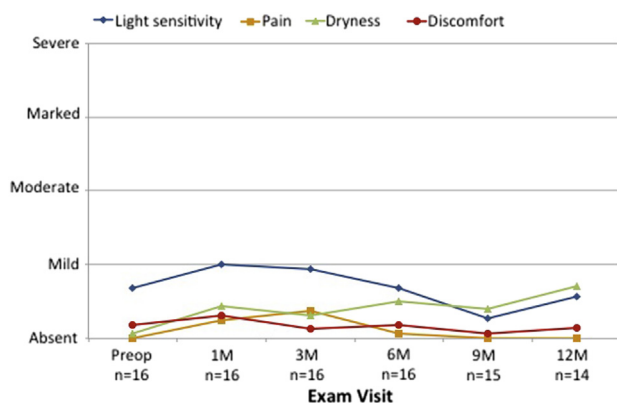
Performing LASIK in a hyperopic eye will improve vision at all 3 measured ranges without the use of an inlay. The dominant eye was targeted for emmetropia. At 12 months, near vision was considerably better in the eye with the inlay, in which the UNVA was 20/25 or better in all cases. In the LASIK-only eye,

the UNVA was 20/50 or 20/63 except in 1 case, in which it was 20/40. Similarly, the eyes with the inlay achieved a UNVA between 20/20 and 20/32. Eyes with LASIK achieved only 20/40 to 20/63 except in 1 case, in which it was 20/32. As expected, all dominant eyes achieved a UDVA of 20/20 or better except for 1 eye, in which the UDVA was 20/25. Only 50% of eyes with an inlay achieved a UDVA of 20/25. Thus, the effect of an inlay on formerly hyperopic eyes after LASIK is similar to its effect in an emmetropic eye.<sup>6</sup>

Nine of the fourteen patients (64%) returned for an informal 2-year follow-up visit. All patients maintained a UNVA of 20/25 or better in the inlay eye and 8 (89%) of 9 patients achieved a UNVA of 20/20. Monocularly, all patients achieved a UDVA of 20/40 or better in the eye with the inlay; binocularly, all patients achieved 20/20 or better.

There were few reports of dry eye during the postoperative period. One patient reported moderate dry eye in both eyes at 4 successive visits; the patient reported no dry eye at the 12-month postoperative visit. Most patients (15 of 16 at 1 month and 12 of 14 at 12 months) reported absent or mild dry eye; patients reporting mild dry eye did so sporadically across visits. During the first 6 months after surgery, dry eye is a common side effect of LASIK and can be severe.<sup>9,10</sup> It has been suggested that cutting the corneal nerves during flap creation is responsible for the dry eye.<sup>11</sup> However, in this study, increased dry eye after surgery was minimal, with some eyes showing an improvement in dry-eye symptoms postoperatively.

Halos and glare can also be problematic for post-LASIK patients, particularly during night driving.<sup>8</sup> Reports of halos and glare were minimal in this study, decreasing over time until they approached preoperative levels by the 12-month visit. Overall, halos and glare were not problematic in this study group.



**Figure 9.** Mean ocular discomfort symptom scores for light sensitivity, pain, dryness, and discomfort. The y-axis provides a description of the symptom levels by converting the numeric score (0 = absent; 1 = mild; 2 = moderate; 3 = marked; 4 = severe) back to the original scale of the self-questionnaire.

Monovision is probably the most popular form of presbyopia treatment for phakic patients in the U.S. Typically, the dominant eye is corrected, if necessary, for distance vision and the nondominant eye is corrected for near vision. Durrie<sup>3</sup> found that UNVA in the near-corrected eye improved with increased contact lens power, while the UDVA decreased, becoming worse than 20/80 with +2.50 D lens power. In that study, patients also had significant losses in photopic and mesopic contrast sensitivity in the near-corrected eye. Unlike monovision, the corneal inlay used in this study creates a smooth corneal gradient in the center of the cornea to provide in-focus rays from all object distances. Distance vision in the eye with the inlay does not decrease to the levels in near-corrected eyes treated as a part of a monovision method. In this study, more than 90% of the eyes with an inlay achieved a UDVA of 20/50 or better by the 1-week visit. Contrast sensitivity was not measured in this study but can be expected to be similar to the results obtained in emmetropic cases, in which minor decreases were reported.<sup>5</sup>

Other corneal inlays have been reported in the literature.<sup>7,8</sup> The Invue lens (Biovision AG) is embedded deeper in the cornea to prevent changes in corneal shape. Its material has a refractive index higher than that of the cornea, and it has a doughnut shape to provide a midperipheral near zone. Results in emmetropes presented to date suggest poorer UNVA in the treated eye than in the present study, in particular in the early postoperative stages, with the UDVA at a similar level.<sup>7</sup> It is unclear whether the Invue inlay will be able to treat ametropia. The Kamra inlay (Acufocus, Inc.) is a black pinhole designed to increase depth of field by blocking midperipheral rays.<sup>8</sup> Results for hyperopia are considerably poorer than those presented here for UNVA in the treated eye, although the UDVA is better in the treated eye. Binocularly, the Raindrop inlay was equivalent to these other devices but with better UNVA.

One patient had recurrent haze during the study. The inlay was explanted. The patient's UDVA improved to 20/20 within 1 month of explantation. Twelve months after explantation, this patient had no adverse sequelae. Although the precise mechanism for haze formation is not known, its response to steroid treatment indicates that it has an inflammatory basis that may initiate a response from keratocytes to deposit disordered collagen. Some scatter can result from inflammatory cells and activated keratocytes; however, the presence of disordered collagen may lead to a breakdown in the ordered

structure of the cornea and a resultant reduction in transparency. Since the completion of this study, a new regimen has been instituted that uses a taper with a weaker steroid after the initial 4 weeks. The results in this study strengthen the evidence for the haze mechanism and will be presented in a subsequent report.

The clinical outcomes in this small introductory study show good safety and efficacy of the Raindrop near vision inlay with concurrent hyperopic LASIK for improvement in distance, intermediate, and near vision in hyperopic presbyopic patients. No serious safety issues were noted.

#### WHAT WAS KNOWN

- The small-diameter hydrogel inlay improves near and intermediate vision in presbyopic emmetropic patients. Small-diameter presbyopia-compensating hydrogel inlays concurrently combined with LASIK distance vision correction had not been studied.

#### WHAT THIS PAPER ADDS

- A small-diameter presbyopia-compensating hydrogel inlay was safely and effectively combined with LASIK in hyperopic patients to improve near, intermediate, and distance vision simultaneously without induction of significant visual symptoms.
- Vision improved most rapidly (over a few days) in the near range, while distance vision took several weeks to reach stability.

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