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# The Sensitivity of Clinical Outcomes to Centration on the Light-Constricted Pupil for a Shape-Changing Corneal Inlay

Enrique Barragán-Garza, MD; Douglas D. Koch, MD; Luis G. Vargas, MD; Alan Lang; Adam Roy, MS

### ABSTRACT

**PURPOSE:** To assess the clinically acceptable range of inlay decentration with respect to the light-constricted pupil center and the coaxially sighted corneal light reflex (CSCLR) for an inlay (Raindrop Near Vision Inlay; ReVision Optics, Inc., Lake Forest, CA) that reshapes the anterior corneal surface.

**METHODS:** In this retrospective, observational cohort study of 115 patients with emmetropic or low hyperopic presbyopia who were implanted with a shape-changing corneal inlay, visual acuity, task performance (in good and dim light), reports of halos and glare, and satisfaction data were collected from the preoperative and 3-month postoperative examinations. Inlay centration with respect to the pupil center and CSCLR was determined from the center of the inlay effect derived from iTrace (Tracey Technologies, Houston, TX) wavefront measurements. Multivariate regression models assessed the influence of inlay position on visual outcomes.

**RESULTS:** On average, monocular uncorrected near visual acuity (UNVA) improved  $4.9 \pm 1.7$  lines in the treated eye, with no loss in binocular distance vision. Eighty-three percent of implants were centered radially within 0.5 mm of the pupil center. Multivariate analysis of decentration with respect to both the pupil center and CSCLR revealed no significant interaction with the above clinical outcomes, with the exception of UNVA in the treated eye (all P > .05,  $\alpha = 0.05$ ). For decentration of less than 0.75 mm, the change in UNVA was less than 1 line.

**CONCLUSIONS:** Distance and near visual acuity, task performance, severity of halos and glare, and satisfaction were independent of radial decentration of the Raindrop Near Vision Inlay of less than 0.75 mm from the light-constricted pupil.

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age is coaxial with the patient's fixation point, the CSCLR is a good approximation of the point on the cornea containing the theoretical concept of a "visual axis."1.2 For non-wavefrontguided LASIK and photorefractive keratectomy, centration of the ablation pattern on or close to the CSCLR is currently believed to optimize refractive outcomes and minimize induction of higher order aberrations. This is particularly true when patients exhibit large angle kappa, where the CSCLR or a location between the CSCLR and pupil center is chosen.<sup>1</sup> Similarly, in the physician labeling for the U.S. Food and Drug Administration (FDA)-approved KAMRA corneal inlay (AcuFocus, Inc., Irvine, CA),<sup>3</sup> AcuFocus recommends that the small-aperture corneal inlay be centered on the first Purkinje reflex (CSCLR)<sup>4</sup> if the distance between the CSCLR and pupil center is less than 300 µm. Otherwise, the KAMRA inlay should be centered on the midpoint between the CSCLR and pupil center.

The FDA-approved Raindrop Near Vision Inlay<sup>5</sup> (ReVision Optics, Inc., Lake Forest, CA) remodels the anterior corneal surface,<sup>6</sup> creating a "profocal" add-power profile<sup>7</sup> at the center of the pupil by means of a meniscus-shaped biocompatible hydrogel "spacer" place in the cornea stroma at approximately 30% of the preoperative central corneal thickness. In the stroma, the meniscus-shaped inlay has no optical power because the inlay's index of refraction is the same as the stroma. The

From Laser Ocular Hidalgo, Monterrey, Mexico (EB-G); Cullen Eye Institute, Baylor College of Medicine, Houston, Texas (DDK); and ReVision Optics, Inc., Lake Forest, California (LGV, AL, AR).

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Correspondence: Luis G. Vargas, MD, Revision Optics, Inc., 25651 Atlantic Ocean Dr., Suite A1, Lake Forest, CA 92630. E-mail: Lvargas@revisionoptics.com

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refractive effect is demonstrated in **Figure A** (available in the online version of this article), which plots the postoperative power map for one patient in the study, derived from wavefront measurements (iTrace; Tracey Technologies, Houston, TX). The change to the anterior corneal surface creates a center-near add-power profile confined to slightly larger than the inlay diameter (2 mm), with the corneal surface unchanged in the pupil's periphery.

The purpose of this retrospective analysis was to establish the sensitivity of visual outcomes to the postoperative position of the Raindrop Near Vision Inlay with respect to centration on the light-constricted pupil center and determine whether outcomes could be improved if the device is centered on the CSCLR.

### PATIENTS AND METHODS

Clinical studies were conducted on patients with emmetropic and low hyperopic presbyopia to evaluate the Raindrop Near Vision Inlay for near vision improvement. Data were collected from 115 eyes implanted with the Raindrop Near Vision Inlay between October 2009 and November 2013 in Monterrey, Mexico by a single surgeon (EB-G). The protocols received institutional review board approval from the University of Monterrey and adhered to the tenets of the Declaration of Helsinki.

Informed consent was obtained from each patient. Patients were included if they required a near add between +1.50 and +2.50 diopters (D), had a distance manifest refraction spherical equivalent between -0.50 and +1.50 D, corrected distance and near Snellen visual acuities of 20/25 or better, and a successful monovision tolerance contact lens trial. The central corneal thickness of the non-dominant eye must have been 500  $\mu$ m or thicker as measured by ultrasound pachymetry. Exclusion criteria were previous ocular surgery, ocular/eyelid pathology, corneal topographic irregularities, and any systemic diseases or therapies that could affect wound healing or visual outcomes (eg, diabetes, lupus, or cancer).

### SURGICAL PROCEDURE

A corneal flap with an intended diameter of 8 mm or more and a depth of at least 150 µm was made using a femtosecond laser (Intralase; Abbott Medical Optics, Inc., Santa Ana, CA). The flap was retracted and the inlay was delivered from an inserter onto the stromal bed. The inlay was centered on the center of the light-constricted pupil and allowed to dry for approximately 30 seconds before the flap was repositioned. A variety of postoperative corticosteroid regimens were tested in the protocols, which included the current recommendation<sup>5</sup> of a benzalkonium chloride–free strong topical ophthalmic corticosteroid for 1 month followed by a weaker topical ophthalmic corticosteroid for 2 additional months.

### **INLAY CENTRATION**

Postoperative centration of the device effect with respect to the pupil and CSCLR was determined by iTrace total-eye wavefront measurements obtained at the 3-month postoperative visit. A custom MatLab (The MathWorks, Inc., Natick, MA) program calculated the postoperative minus the preoperative wavefront difference map, from which the location of the inlay effect with respect to the mesopic pupil center could be calculated to within 0.1 mm. Figure B (available in the on-line version of this article) presents one example of the wavefront-difference contour map, showing the center of the inlay effect with respect to the center of the pupil. The iTrace software also provided the location of the CSCLR with respect to the pupil center (Figure A).<sup>1,2</sup>

### **CLINICAL OUTCOMES**

This retrospective analysis focused on visual acuity, task performance, halos and glare, and patient satisfaction. Uncorrected near (UNVA: 40 cm) and distance (UDVA: 6 m) visual acuities were assessed using Early Treatment of Diabetic Retinopathy Study (ETDRS) charts with the Optec 6500 Vision Tester (Stereo Optical Co., Inc., Chicago, IL). Task performance without spectacle correction was assessed via a questionnaire of near and distance tasks, in both good and dim light, on a 3-point scale (0 = none, 1)= barely, or 2 = easily). Near tasks included ease of visualization of cell phones, magazines, medicine instructions, fingernails, and newspapers. Distance tasks included discerning street numbers, reading clocks on a wall, determining distances of cars, recognizing faces, and seeing house or building numbers. The near or distance task score was the sum of the five tasks, ranging from 0 to 10. Patients rated the severity of halos and glare separately on a 5-point scale (0 = absent, 1 = mild, 2 = moderate, 3 = marked, or4 = severe). Patients were also asked how satisfied they were with their separate near and distance visual outcomes after inlay implantation (1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, or 5 = very satisfied). The dependence of the change in the above clinical outcomes between the preoperative and 3-month postoperative examinations was assessed with respect to the inlay decentration.

### STATISTICAL ANALYSIS

Multivariate regression isolated the visual outcomes that were significantly affected by inlay decentration

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Figure 1. Location of the center of the inlay effect with respect to the mesopic pupil center (dots), and the mean location (square). The regularity of the points is due to the 0.1-mm step sampling of the measured wavefront data.



Figure 3. Location of the center of the inlay effect with respect to the coaxially sighted corneal light reflex (CSCLR; dots), and the mean location (square).

with respect to the pupil center and CSCLR at a level of  $\alpha = 0.05$ . Multivariate methods were necessary to isolate any contribution from the temporal/nasal (x-axis) or inferior/superior (y-axis) direction, while also controlling for factors such as patient age, baseline manifest refraction spherical equivalent, and the postoperative



Figure 2. Location of the coaxially sighted corneal light reflex (CSCLR) with respect to the mesopic pupil center (dots), and the centroid (mean) of the points (square).

pupil size recorded during wavefront measurements. This method is based on the Generalized Linear Model, which is firmly rooted in frequentist statistics and the method of maximum likelihood.<sup>8,9</sup> The statistical model was implemented in R version 3.2.2 via the Fitting Generalized Linear Models function within the R Stats Package.<sup>10</sup> The paired t test evaluated the univariate change in outcomes with respect to preoperative values.

# RESULTS

### **POSTOPERATIVE INLAY CENTRATION**

The wavefront measurements were taken in a mesopic lighting condition, in which the mean pupil diameter was 4.7 ± 0.39 mm. A total of 115 eyes with the inlay were measured. Figure 1 plots the center of the inlay wavefront effect with respect to the mesopic pupil center. On average, the inlay effect was radially decentered  $0.31 \pm 0.21$  mm with respect to the mesopic pupil center. Radial centration within 0.5 mm of the pupil center occurred in 96 (83%) eyes and decentration of 0.75 mm or more occurred in 4 (3%) eyes. The inlay was centered horizontally (-0.05 ± 0.21 mm) and slightly decentered inferiorly (-0.19 ± 0.25 mm). Figure 2 plots the position of the CSCLR with respect to the mesopic pupil center. On average, the CSCLR was radially decentered 0.30 ± 0.14 mm, nasally decentered 0.25 ± 0.17 mm, and vertically centered 0.01 ± 0.14 mm. Figure 3 plots the inlay position with respect to the CSCLR. On average, the inlay was radially decentered  $0.45 \pm 0.26$  mm with re-

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Figure 4. For the inlay eye, the change in the uncorrected near (UNVA) and distance (UDVA) visual acuity (lines) as a function of the radial decentration from both the (A) pupil center and (B) coaxially sighted corneal light reflex (CSCLR). The error bars represent the 95% confidence intervals about the mean.

spect to the CSCLR. Relative to the CSCLR, the inlay was positioned slightly temporal (-0.30  $\pm$  0.26 mm) and inferior (-0.20  $\pm$  0.27 mm).

### SENSITIVITY OF CLINICAL OUTCOMES TO THE INLAY POSITION

Compared to the preoperative examination, the UNVA in the treated eye improved by  $4.9 \pm 1.7$  lines at 3 months (P = .000), whereas the UDVA decreased by  $0.7 \pm 2.0$  lines (P = .000). However, binocular UDVA was slightly increased by  $0.3 \pm 1.0$  lines (P = .000). The improvement in UNVA in the treated eye was reflected in the mean change in binocular UNVA  $(4.4 \pm 1.6 \text{ lines},$ P = .000). The mean change between the postoperative 3-month examination and the preoperative examination in lines of monocular UNVA and UDVA is shown in Figure 4A as a function of the radial decentration of the inlay with respect to the pupil center and in Figure 4B with respect to the CSCLR. The error bars represent the 95% confidence interval. There is the suggestion of more than a 1-line decrease in monocular UNVA, with radial decentration greater than 0.75 mm with respect to both the pupil center and CSCLR. Monocular UDVA appeared unaffected by inlay decentration. The multivariate modeling confirmed the graphical sensitivity to radial decentration. With respect to the pupil center, the model predicts a 1.4-line loss in monocular UNVA for every 1 mm of radial decentration (P = .000). With respect to the CSCLR, the model similarly predicts a 1.2-line loss in monocular UNVA for every 1 mm of radial decentration (P = .000). The statistical framework also confirmed the insensitivity of monocular UDVA with respect to the pupil center (P = .098) or CSCLR decentration (P = .548).

The postoperative binocular near task performance without spectacle correction in good and dim light is shown in **Figure 5** as a function of radial decentration from both the pupil center and CSCLR. Near task performance appeared independent of inlay decentration with respect to either the pupil center or CSCLR. The graphic observation was confirmed by the multivariate modeling, showing no statistically significant dependence of near task performance with inlay decentration in good light with respect to the pupil center (P = .063), in good light with respect to the CSCLR (P = .886), in dim light with respect to the pupil center (P = .325), and in dim light with respect to the CSCLR (P = .818). On average, near task performance in good light (five tasks) significantly improved by 7.6  $\pm$  2.4 points on a 10-point scale compared to the preoperative examination (P = .000). In dim light, the postoperative near task performance significantly improved compared to the preoperative examination (6.5  $\pm$  3.0 points; P = .000).

The postoperative binocular distance task performance without spectacle correction in good and dim light is shown in Figure 6 as a function of radial decentration from both the pupil center and CSCLR. Patients could perform nearly all distance tasks in good light (Figure 6A), with only a slight reduction in dim light (Figure 6B). Similar to near, distance task performance appeared independent of inlay decentration with respect to either the pupil center or CSCLR. This was confirmed by the multivariate modeling, showing no statistically significant dependence of near task performance with inlay decentration in good light with respect to the pupil center (P = .209), in good light with respect to the CSCLR (P = .760), in dim light with respect to the pupil center (P = .932), and in dim light with respect to the CSCLR (P = .592). Compared with their preoperative emmetropic abilities, postoperative distance task performance was slightly changed by 0.2  $\pm$  1.0 points (P = .025) in good light and 0.5  $\pm$  1.9 points (P = .013) in dim light.



Figure 5. At the 3-month visit, binocular near task performance in (A) good and (B) dim light as a function of inlay decentration with respect to the pupil center and coaxially sighted corneal light reflex (CSCLR). Error bars represent one standard deviation.



Figure 6. At the 3-month visit, binocular distance task performance in (A) good and (B) dim light as a function of inlay decentration with respect to the pupil center and coaxially sighted corneal light reflex (CSCLR). Error bars represent one standard deviation.

The postoperative binocular satisfaction with near and distance vision in Figure 7 as a function of radial decentration from both the pupil center and CSCLR. On average, patients were "satisfied" with both their near and distance vision. Satisfaction with either near or distance vision appeared independent of inlay decentration with respect to either the pupil center or CSCLR. The graphical observation was again confirmed by the multivariate modeling, showing no statistically significant dependence of satisfaction with inlay decentration at near with respect to the pupil center (P = .236), at near with respect to the CSCLR (P = .641), at distance with respect to the pupil center (P= .410), and at distance with respect to the CSCLR (P= .077). The mean change in near satisfaction from the preoperative examination was  $2.7 \pm 0.9$  (P = .000) and satisfaction with distance vision was slightly changed  $(0.2 \pm 0.9; P = .032).$ 

Reports of significant halos and glare were few. Postoperatively, the mean halo severity score was 0.5  $\pm$  0.7 on a scale of 0 to 4, with 4 indicating "severe halos." The same was true with the severity of glare, with a mean glare score of 0.1  $\pm$  0.3 postoperatively. The multivariate analysis found no statistically significant dependence with inlay decentration: halo reports with respect to the pupil center (*P* = .996), halo reports with respect to the CSCLR (*P* = .140), glare reports with respect to the CSCLR (*P* = .103), and glare reports with respect to the CSCLR (*P* = .232).

### DISCUSSION

Overall, when implanted in only the non-dominant eyes of patients with emmetropia and low hyperopia, the Raindrop Near Vision Inlay significantly improved binocular UNVA ( $4.9 \pm 1.7$  lines) with no loss in binocular UDVA ( $+0.3 \pm 1.0$  lines), consistent with visual acuity

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Figure 7. At the 3-month visit, binocular satisfaction with (A) near and (B) distance vision as a function of inlay decentration with respect to the pupil center and coaxially sighted corneal light reflex (CSCLR). Error bars represent one standard deviation.

outcomes in the FDA trial.<sup>5</sup> This facilitated significant postoperative near task performance, while maintaining distance abilities. Reports of significant halos and glare were minimal. The above outcomes contributed to good satisfaction with near and distance vision.

Total-eye wavefront measurements were used to establish the position of the corneal inlay with respect to the light-constricted pupil and CSCLR. In prior publications, wavefront measurements were used to calculate the change to the anterior corneal surface induced by the corneal inlay's volume,<sup>6</sup> establishing the contributions from epithelial and stromal remodeling. In another publication, the induced add-power changes from wavefront measurements combined with theoretical optical simulations were used to establish the inlay's mechanism of action and explain the range of depth of focus.<sup>7</sup>

Surgeons intended to deliver the Raindrop Near Vision Inlay at the center of the light-constricted (photopic) pupil, which was qualitatively between 3 and 3.5 mm in diameter in most cases. However, the postoperative inlay position measurements by wavefront techniques were recorded at mesopic pupil sizes (4.7  $\pm$  0.39 mm). On average, the center of the inlay effect was decentered inferiorly only slightly (-0.19  $\pm$  0.25 mm; Figure 1). In a group of 130 eyes (70 patients), Yang et al.<sup>11</sup> found a mean nasal shift of  $0.13 \pm 0.07$ mm as the pupil size changed from a mesopic to photopic lighting condition. Both of these shifts are close to the step-resolution (0.1 mm) of the inlay position measurement. Thus, the intended inlay centration on the light-constricted pupil was achieved on average to within measurement accuracy. Nevertheless, the inlay's mean radial decentration with respect to the pupil center was 0.31 ± 0.21 mm, suggesting that some patients were radially decentered 0.5 mm or more with respect to the pupil center.

Figure 2 confirms that, as expected, the CSCLR, which is an estimate of the location where the visual axis passes through the cornea, is on average decentered nasally  $(0.28 \pm 0.14 \text{ mm})$  with respect to the pupil center. This is consistent with other measurements.<sup>11,12</sup> Therefore, when targeting inlay centration on the pupil center, the inlay effects were decentered with respect to the CSCLR slightly temporal (-0.30 ± 0.26 mm) and slightly inferior (-0.20 ± 0.27 mm) (Figure 3).

A multivariate statistical analysis demonstrated that radial decentration of the inlay had no effect (P > .05) on UDVA (**Figure 4**), near or distance task performance (**Figures 5-6**), or satisfaction with either near or distance vision (**Figure 7**). The analysis showed a statistically significant (P = .000) decrease of 1.4 and 1.2 lines of UNVA with each millimeter of radial decentration with reference to either the pupil center or CSCLR, respectively. However, **Figure 4** demonstrates that the decrease is only effective for radial decentration of approximately more than 0.75 mm.

Because placement of the Raindrop Near Vision Inlay was targeted on the pupil center for all implanted patients, it is not possible to accurately address the question of which provides better outcomes: centration on the pupil or CSCLR. Nevertheless, given the similar insensitivity of monocular UNVA to radial decentration of less than 0.75 mm with respect to either the pupil center or CSCLR, either method of centration appears to be clinically acceptable.

Limitations of our study included: (1) only 4 (3%) of the 115 eyes had a decentration of more than 0.75 mm; (2) we could only evaluate the centration of the induced inlay effect by wavefront methods and not the actual centration of the device, although presumably they must be similar; and (3) our study did not include

other methods of analyzing visual outcomes, such as contrast sensitivity.

There is ongoing debate regarding which method of centration is optimal for ablative corneal procedures. Recent studies suggest that centration over the CSCLR is preferable.<sup>1,13</sup> However, for wavefront-guided treatments, centration should be on the pupil center at the time of wavefront measurement, as is done when the iris registration occurs.<sup>14,15</sup> For the FDA-approved KAMRA small-aperture inlay, the physician's labeling indicates the need to center either on the CSCLR or midway between the CSCLR and pupil center when the distance between the two exceeds 300 µm. In a case report,<sup>16</sup> two patients implanted with the KAMRA inlay improved their visual outcomes with re-centration to the midpoint between the pupil center and CSCLR. However, when the KAMRA inlays were combined with LASIK,17 the postoperative UDVA and UNVA were independent of inlay decentration up to 400 µm. The effects of ablation centration were not assessed.

Our analysis suggests that visual outcomes with the Raindrop Near Vision Inlay remain unchanged with up to 0.75 mm radial inlay decentration with respect to the light-constricted pupil center, thereby validating this relatively simple surgical approach that does not require additional diagnostic instrumentation for centration.

### **AUTHOR CONTRIBUTIONS**

Study concept and design (EB-G, DDK, LGV, AL); data collection (EB-G); analysis and interpretation of data (DDK, LGV, AL, AR); writing the manuscript (AL); critical revision of the manuscript (EB-G, DDK, LGV, AR)

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