• Investigation •

Comparison of FDA safety and efficacy data for KAMRA and Raindrop corneal inlays

Majid Moshirfar[1,2], Jordan D Desautels[1,3], Ryan T Wallace[4], Nicholas Koen[5], Phillip C. Hoopes[1]

[1]HDR Research Center, Hoopes Vision, Draper, Utah 84020, United States
[2]John A. Moran Eye Center, Department of Ophthalmology and Visual Sciences, University of Utah School of Medicine, Salt Lake City, Utah 84132, United States
[3]Tufts University School of Medicine, Boston, Massachusetts 02111, United States
[4]Brigham Young University, Provo, Utah 84602, United States
[5]Brown University Alpert School of Medicine, Providence, Rhode Island 02906, United States
Correspondence to: Majid Moshirfar. HDR Research Center, Hoopes Vision, 11820 S. State Street Suite #200, Draper, Utah 84020, United States. cornea2020@me.com
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Abstract

• AIM: To provide a side-by-side analysis of the summary of safety and effectiveness data (SSED) submitted to the FDA for the KAMRA and Raindrop corneal inlays for the correction of presbyopia.

• METHODS: SSED reports submitted to the FDA for KAMRA and Raindrop were compared with respect to loss of corrected distance visual acuity (CDVA), adverse event rates, induction of astigmatism, retention of contrast sensitivity, stability of manifest refractive spherical equivalent (MRSE), and achieved monocular uncorrected near visual acuity (UNVA) at 24mo.

• RESULTS: Totally 442/508 of KAMRA patients and 344/373 Raindrop patients remained enrolled in the clinical trials at 24mo. The proportion of KAMRA and Raindrop patients who lost ≥2 lines of CDVA at 24mo was 3.4% and 1%, respectively. The adverse event rate was comparable between the devices. No significant inductions of astigmatism were noted. Both technologies induced a transient myopic shift in MRSE followed by a hyperopic shift and subsequent stabilization. Totally 87% of KAMRA and 98% of Raindrop patients attained a monocular UNVA of J5 (20/40) or better at 24mo, 28% of KAMRA and 67% of Raindrop patients attained a monocular UNVA of J1 (20/20) or better at 24mo.

• CONCLUSION: Both devices can be considered safe and effective, however, the results of corneal inlay implantation are mixed, and long-term patient satisfaction will likely depend on subjective expectations about the capabilities of the inlays. Variability in surgical technique and postoperative care within and between the two clinical trials diminishes the comparative power of this article.

• KEYWORDS: KAMRA; Raindrop; presbyopia; corneal inlay
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INTRODUCTION

Presbyopia describes an age related loss of near visual acuity with preserved distance visual acuity. Although the exact mechanism of presbyopia has yet to be elucidated, it is supposed that decreased compliance of the crystalline lens, reduced function of extralenticular structures, and altered zonular tension due to increases in lens diameter contribute to its occurrence[1-3]. It is estimated that by the year 2020, the worldwide prevalence of presbyopia will rise to 1.4 billion[4]. Correspondingly, surgical alternatives to spectacle correction, such as the implantation of Raindrop (ReVision Optics, Lake Forest, CA, USA) and KAMRA (AcuFocus Inc., Irvine, CA, USA) corneal inlays, are expected to attain a broader presence. Relevant material properties, mechanisms of action, and surgical indications for both devices have been previously described, and are summarily presented in Tables 1 and 2[5]. In brief, the volume of the Raindrop inlay displaces anterior corneal tissue into a steeper configuration that yields +1.5 to +2.5 diopters (D) of near vision add. By contrast, the KAMRA inlay operates as a small aperture that filters defocused peripheral rays to reduce the size of the retinal blur spot in patients lacking sufficient accommodative amplitude.

Going forward, it is important for refractive surgeons to have a comprehensive understanding of the comparative safety and efficacy profiles of these devices before offering them as treatment options. Although the summary of safety and effectiveness data (SSED) reports from the pivotal FDA clinical trials are available for both devices, these reports cannot be expediently compared due to the use of differing outcome measures and data presentation[6-7]. A brief demographic comparison of the KAMRA and Raindrop SSED reports is presented in Table 3. In this article, we seek to

Table 1 Device properties and mechanisms of action

Property	KAMRA	Raindrop
Material	Polyvinylidine difluoride	Proprietary hydrogel
Dimensions	Inner diameter=1.6 mm; outer diameter=3.8 mm; thickness=6 μm	Diameter=2 mm; thickness=32 μm
Optical properties	Opaque, no power	Transparent, no power
Implantation technique	Lamellar pocket or flap	Lamellar flap
Mechanism of action	Improves depth of focus using pinhole effect	Steepens anterior corneal topography

Table 2 Surgical indications

Parameters	KAMRA	Raindrop
Age (a)	45-60	41-65
Refraction	+0.50 D to -0.75 D of cycloplegic refraction	+1.00 D to -0.50 D MRSE
Refractive cylinder (D)	⩽ 0.75	⩽ 0.75
Reading add (D)	+1.00 to +2.50	+1.50 to +2.50
Minimum placement depth (μm)	200	150
Residual stromal bed	>250 μm below the pocket	>30 μm below the flap

Table 3 Trial demographics

Parameters	KAMRA	Raindrop
No. of eyes	508	373
Male	240	169
Female	268	204
Mean (SD) age (a)	52 (4)	51.3 (4.3)
Mean (SD) MRSE (D)	0.074 (0.291)	0.242 (0.344)
Preop MRSE range (D)	-0.75 to +0.75	-.50 to +1.00

compile the relevant safety and efficacy data for the KAMRA and Raindrop corneal inlays in a standardized manner that eases comparison and facilitates discussion with patients regarding surgical options for their presbyopia.

SUBJECTS AND METHODS

This is a comparative retrospective analysis of SSED reports pertaining to the pivotal FDA clinical trials for the KAMRA and Raindrop corneal inlays. When possible, safety and effectiveness outcomes were compared at 24mo postoperatively due to sample size deterioration in both reports at 36mo and beyond. Cumulative data pertaining to adverse event rates is presented through 36mo for both studies. Comparative categories are as follows: obtainment of primary safety outcomes, obtainment of secondary safety outcomes, stability, and efficacy.

We treat having less than 5% of patients losing ≥2 lines of corrected distance visual acuity (CDVA) 2y after inlay implantation, and at all subsequent visits, as the primary safety criterion. Our secondary safety criteria include that less than 1% of eyes with a preoperative CDVA of 20/20 or better should have a CDVA worse than 20/40 2y after surgery and beyond, less than 5% of eyes should have an increase in manifest refractive astigmatism greater than 2.00 D from their preoperative astigmatism at 2y and beyond, and the cumulative number of surgically induced adverse events should be limited to 5% of eyes, with no more than 1% of eyes experiencing any single surgically related adverse event over the lifetime of the study. Adverse events with a clear causal link to inlay implantation, such as significant loss of visual acuity, need for surgical reintervention, and complications related to the implantation interface are regarded as surgically induced adverse events. Although only the Raindrop report treats refractive stability as a safety parameter, we include refractive stability in our safety analysis due to its linkage to corneal changes. To be considered stable, at least 95% of eyes should have ≤1.0 D of change in manifest refractive spherical equivalent (MRSE) between any two refractions performed at least 3mo apart. Moreover, the annualized mean rate of change in MRSE should be ≤0.5 D (0.04 D/mo) between two refractions performed at least 3mo apart, and the mean rate of change in MRSE should level out to a rate that is either explained by aging, or has a 95% confidence interval (CI) that includes zero. Our standardized effectiveness criteria is related to the change in monocular uncorrected near visual acuity (UNVA) in the implanted eye, and is considered met when at least 75% of eyes achieve a CDVA of 20/40 (J5) or better at 24mo and all subsequent visits.

It should be noted that some data on MRSE change derived from the pivotal clinical trials for each device was withheld from the SSED reports and was instead published in the professional use information guides. Professional use data may not undergo the same degree of vetting as FDA-reviewed SSED data.

RESULTS

Both KAMRA and Raindrop meet the targeted safety parameter of having less than 5% of patients losing ≥2 lines of CDVA 2y after implantation and beyond (Figure 1). Overall, the incidence of ≥2 lines of CDVA loss is lower for the Raindrop inlay than for the KAMRA inlay. Although both

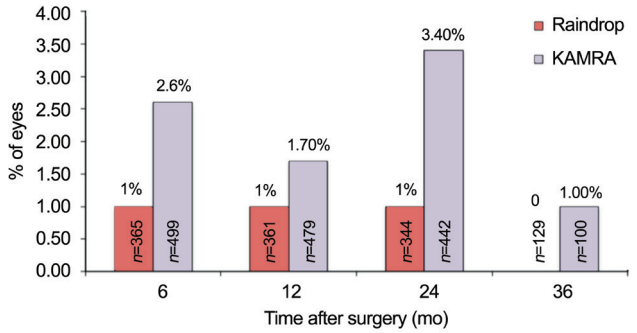

Figure 1 Percent of eyes showing a loss of two or more lines of CDVA at the given postoperative time points Of note, the sample size diminishes throughout the course of follow up visits for both devices.

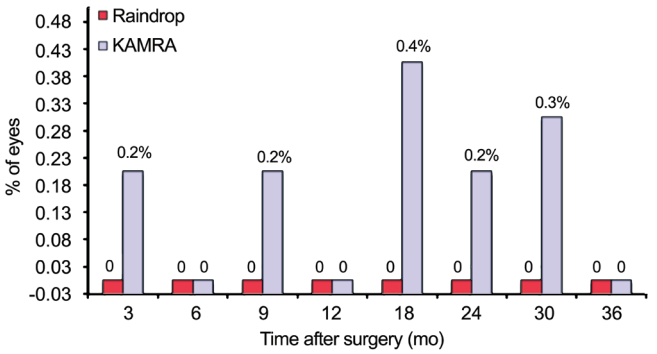

Figure 2 Percent of eyes with a preoperative CDVA of 20/40 or better that became worse than 20/40 postoperatively.

devices meet the safety criteria for loss of CDVA, it should be noted that at 36mo, 13% of Raindrop patients and 18% of KAMRA patients still experienced a loss of >1 line of CDVA. Instances of eyes that were 20/20 preoperatively becoming 20/40 or worse postoperatively were well below the 5% occurrence threshold for the KAMRA cohort, and nonexistent for the Raindrop patients (Figure 2).

No patients in the Raindrop study experienced an induction of >2.00 D of manifest refractive astigmatism at any time point. The percentage of KAMRA patients with >2.00 D of induced manifest refractive astigmatism reached a maximum of 0.4% at 9mo postoperatively before declining to 0.2% at 24mo, and 0.0% by 36mo.

The overall adverse event rate is comparable for both devices (Table 4). Raindrop violated the safety parameter that the cumulative surgically induced adverse event rate should be less than 5% in that 44/373 (12%) eyes required secondary surgical intervention (SSI) at some point at 3y following implantation. SSI's include recentration, explantation, additional refractive correction, epithelial ingrowth removal, and lamellar interface rinse for diffuse lamellar keratitis (DLK). Totally 18/373 (5%) of Raindrop SSI's were due to inlay exchange and 27/373 (7%) were due to inlay explant. The predominant contributing factors to inlay explant were corneal haze 10/27 (37%) and dissatisfaction with visual outcomes 10/27 (37%). The total incidence of corneal haze was 62/373 (17%) of eyes following surgery. Therefore, approximately 16% of the experienced corneal haze was severe enough to warrant explant. At the last available visit prior to explant, the incidence of >1 line, ≥2 lines, and ≥3 lines of monocular UDVA loss compared to baseline was 20/27 (74%), 16/27 (59%), and 11/27(41%) respectively. Six months after explant, 5/18 (28%) eyes had persistent loss of >1 line, 3/18 (17%) eyes had a persistent loss of ≥2 lines, and no eyes had a persistent loss of ≥3 lines of monocular UDVA. All patients had a CDVA of 20/20 or better after explant. Decentration 2/27 (7%), epithelial ingrowth 2/27 (7%), and patient request 3/27 (11%) were additional causes

Table 4 Overall adverse event comparison between KAMRA and Raindrop *n* (%)

Adverse event	KAMRA (*n*=508)	Raindrop (*n*=373)
Ocular infection	Not given	7 (2)
Epithelial ingrowth	3 (0.6)	10 (3)
Loss of CDVA >2 lines at 3mo or later	30 (6)	11 (3)
Increase in IOP of >10 mm Hg above baseline	16 (3)	6 (2)
DLK	6 (1)	6 (2)
Inlay exchange	Not given	18 (5)
Inlay repositioning	6 (1)	Not given
Inlay explant	43 (8)	27 (7)

of inlay removal. Furthermore, Raindrop exceeds the 1% occurrence threshold for singular adverse events with regards to the rate of ocular infection 7/373 (2%), epithelial ingrowth 10/373 (3%), cumulative loss of CDVA >2 lines at 3mo or later 11/373 (3%), increase in IOP >10 mm Hg above baseline 6/373 (2%), and DLK 6/373 (2%).

The KAMRA inlay broke the 5% cumulative adverse event safety threshold in that 30/508 (6%) eyes experienced a loss of >2 lines of CDVA at 3mo or later and 55/508 (11%) eyes required SSI. SSI's included epithelial ingrowth removal 3/508 (0.6%), lamellar interface rinse for DLK 1/508 (0.2%), explant 43/508 (8%), recentration 6/508 (1%), and additional refractive correction 3/508 (0.6%). Of the 43 inlays removed, 34/43 (79%) were prompted by visual complaints, with hyperopic shift 24/34 (71%) being more common than myopic shift 2/34 (6%). Totally 7/34 (20%) reported inadequate benefit, and 1/34 (3%) experienced induced cylinder. An additional 2/43 (5%) of inlays were removed due to cosmetic dissatisfaction. Totally 7/43 (16%) were removed secondary to medical indications such as poor centration, persistant stromal opacity causing sustained CDVA loss, inlay folding during implantation, stromal thinning due to foreign body trauma, and posterior vitreous detachment and floaters in the visual axis. KAMRA explantation did not shift CDVA by greater than one line from baseline for any patients at the time of the last available follow up visit. No data is available regarding monocular UDVA loss following explant. KAMRA exceeds the 1% threshold for the

occurrence of singular adverse events in that 16/508 (3%) eyes experienced an increase in IOP >10 mm Hg from baseline and 6/508 (1%) had postoperative DLK.

Monocular contrast sensitivity with and without glare is mildly reduced after implantation of both KAMRA and Raindrop, whereas binocular contrast sensitivity is not appreciably affected. Although exact log contrast sensitivity values are not supplied in either SSED report, the graphical data in each report supports the notion that neither device provides a distinct advantage with respect to the retention of contrast sensitivity.

Safety data indicating the change in mean MRSE at the reported postoperative intervals is shown in Figure 3. The Raindrop SSED report claims that >98% of eyes experienced ≤1.00 D of MRSE change between all consecutive postoperative time points. However, Raindrop MRSE change data is absent for the zero to 1mo interval. KAMRA does not achieve a ≤1.00 D change in MRSE in ≥95% of patients until the 9-12mo interval. This proportion then dips below the ≥95% threshold until the 18-24mo interval.

Approximate changes in MRSE are shown in Figure 4 for qualitative purposes. The Raindrop report presents a plot of mean MRSE between postoperative time points rather than a list of the actual values, whereas the KAMRA report states all mean MRSE values. As such, the mean change in MRSE for Raindrop can only be presented as a near approximation. Overall, both devices experience a transient myopic shift between zero and 3mo followed by a hyperopic shift and subsequent stabilization. The magnitude of the zero to 1mo myopic shift is larger for raindrop. Apparent stability is reached earlier for Raindrop (3 to 6mo) than for KAMRA (6 to 9mo) as indicated by the fact that the 95% CI does not include zero until the 9-12mo interval for KAMRA. The 95% CI includes zero at the three-month time point and beyond for Raindrop. Raindrop data is not provided beyond 24mo, however, KAMRA experiences a minor loss in MRSE in the 30-36mo interval.

Exact values for the annualized mean rate of MRSE change between 3mo postoperative intervals cannot be determined for Raindrop based on the provided study data. However, the SSED data reports that the mean rate of MRSE change does not reach or exceed 0.5 D/y between 3 and 24mo. The annualized mean rate of MRSE change for KAMRA exceeds the ≤0.5 D/y threshold between the three and 6mo refractions, but stabilizes below this threshold until the 30 to 36mo postoperative interval, where the rate of MRSE change becomes -0.52 D/y (-0.043 D/mo).

Preoperatively, 0.3% (1/373) of Raindrop patients and 0 (0/508) of KAMRA patients had a UNVA of J5 (20/40) or better. The results at 24mo for the KAMRA and Raindrop inlays are shown in Figure 5. At 24mo, 87% (380/436) of KAMRA inlay

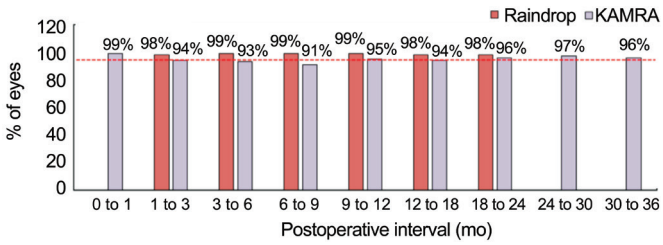

Figure 3 Percent of eyes experiencing a change in mean MRSE less than or equal to 1.0 D between 3mo intervals up to 24mo Raindrop did not include data in the ranges: 0-1mo and >24mo.

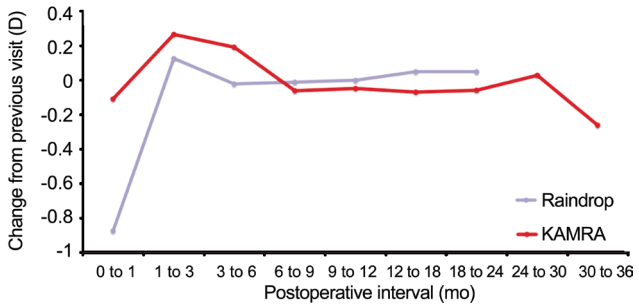

Figure 4 Change in MRSE between specified postoperative intervals.

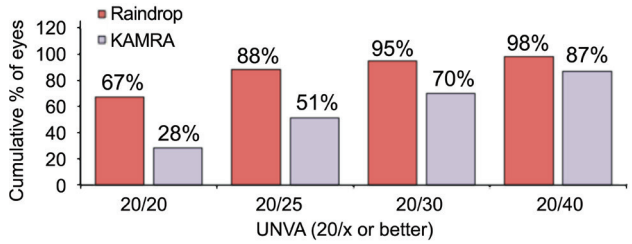

Figure 5 Efficacy results for monocular UNVA at 24mo.

patients and 92% (336/364) of Raindrop patients achieved a UDVA of J5 (20/40) or better. Totally 120/432 (28%) of KAMRA and 230/344 (67%) of Raindrop patients had a UNVA of J1 (20/20) or better.

DISCUSSION

Both devices met the safety criteria for postoperative loss of CDVA. Although the comparative data cannot be statistically analyzed due to the inaccessibility of the raw data, Raindrop does moderately outperform KAMRA in terms of the percentage of patients who met the primary CDVA-loss safety parameter. It should be noted, however, that CDVA loss after KAMRA is generally transient, and that only 5/442 (1%) of implanted eyes experienced a ≥2 lines CDVA loss that had persisted for at least two consecutive visits by 24mo postoperatively. Additional studies have corroborated high CDVA retention rates after KAMRA and Raindrop implantation. In a prospective study of 57 KAMRA eyes, Moshirfar *et al*[8] report that no eyes lost 2 or more lines of CDVA when implanting in an FS-laser pocket generated with a 4×4 spot/line separation. Yilmaz *et al*[9] reported that 1/39 (3%) of eyes lost ≥2 lines of CDVA 6mo after KAMRA implantation under a microkeratome flap. In a similar analysis of the raindrop inlay, Garza *et al*[10] showed that 0/20 Raindrop eyes experienced a loss of ≥2 lines of CDVA.

While tissue healing responses and changes to the tear film are likely responsible for early postoperative CDVA loss, the incidence peak at 24mo implicates other causes related to mechanism of action, operative technique, and patient demographics. One major mechanistic difference that likely yields better CDVA safety outcomes for the Raindrop device is the multifocal effect imparted by the selective steepening of the central cornea[10]. By contrast, defocused peripheral light rays are either entirely excluded by the KAMRA inlay, or pass around the outer inlay edge. A theoretical modeling study of KAMRA implanted eyes by Langenbucher *et al*[11] describes how peripheral rays that pass through and around the inlay may cast retinal shadows that lead to reductions in contrast sensitivity and visual acuity. However, neither the KAMRA nor Raindrop studies show significant reductions in contrast sensitivity. Other authors have reported significant improvements in binocular contrast sensitivity for near vision following KAMRA implantation[12]. Baseline pupil diameter may also contribute to visual outcomes. Presumably, any pupil with a diameter smaller than the outer KAMRA diameter (3.8 mm) will result in passage of defocused peripheral light. A report by Tomita *et al*[13] regarding visual acuity in 584 KAMRA implanted eyes showed that eyes with pupil diameters >6.0 mm had significantly worse CDVA outcomes under mesopic conditions at 6mo postoperatively.

The higher percentage of KAMRA inlay patients experiencing a loss of 2 or more lines of CDVA could also stem from systematic and demographic differences within and between the studies. MRSE, change in MRSE, and UNVA data from the KAMRA SSED report that was stratified into 6×6 μm, 7×7 μm, 8×8 μm spot/line separtation, or mechanical microkeratome lamellar resection methods revealed markedly better outcomes in the 6×6 μm spot/line separation group. These results were further confirmed by a follow up study that was appended to the SSED report. Although subgroup specific data is not provided for CDVA, the correlation between lamellar resection method and other visual outcome metrics implicates surgical technique as a potential predictor of CDVA loss. Moreover, the Raindrop study was performed on a group of eyes with a slightly hyperopic mean preoperative MRSE (0.242±0.344). The steepening effect of the Raindrop may result in a higher proportion of preoperative hyperopes becoming emmetropic postoperatively than if the implant was placed in a group of eyes that was myopic on average.

The overall adverse event rate is comparable for both technologies. Some effects, such as elevated epithelial ingrowth following Raindrop compared to KAMRA, postoperative intraocular pressure increases, and ocular infection are not intrinsic to the devices, but rather to variability in implantation techniques and postoperative management. Although we expect the creation of a flap for Raindrop implantation to be associated with more corneal nerve damage and subsequent dryness, KAMRA does not seem to produce any appreciable benefit in terms of the occurrence of postoperative dry eye. Across both studies, only 1/373 (0.3%) Raindrop implanted eyes had severe persistent dry eye beyond 6mo and 2/508 (0.4%) of KAMRA implanted eyes experienced diagnosable dry eye. Garza *et al*[10] present similarly minimal dry eye findings following Raindrop implantation, and even showed improvement of dry eye in several eyes after Raindrop. The relatively deep stromal placement depths for these devices may also limit damage to the more anteriorly positioned sub-basal nerves.

SSI resulting in inlay explantation is perhaps the most relevant adverse event from a patient perspective. A crucial component of the decision making process for inlay candidates should be an awareness that the overall SSI rate is near 10% for both devices, and that approximately 8% (42/508) of KAMRA inlays and 7% (27/373) of Raindrop inlays will require removal for various reasons. Explant rates may have been particularly sensitive to individual trial sites that had low thresholds for removal. This is particularly relevant for the KAMRA trials, as they were performed across a larger variety of sites. It is further possible that some inlay removals occurred outside of the study window. A large fraction of removals will be prompted either by visual dissatisfaction resulting from an induced loss of distance visual acuity or insignificant improvements in near vision. Although the Raindrop report does not specify whether myopic or hyperopic shift was a larger contributor to visual dissatisfaction, a large majority of KAMRA patients had their inlays removed following a hyperopic shift. Given that the KAMRA inlay has no refractive power, progressive presbyopia will ultimately lead to hyperopic regression. By contrast, the Raindrop inlay may provide a small buffer against presbyopic progression by steepening the cornea to make patients slightly myopic. Prior data derived from a limited subset of 10 KAMRA patients indicates that removal should occur within the first 6mo to maximize visual and topographic outcomes[14]. Patients should, however, expect fluctuations in visual acuity in the early postoperative phase. Overall, the KAMRA data was more complete and transparent in terms of providing the raw MRSE change data. As is expected based on the corneal steepening effect, Raindrop patients are likely to experience a larger myopic shift in the zero to one-month time frame, despite reaching refractive stability earlier than KAMRA. Current literature regarding MRSE stability after implantation is lacking for both inlays.

Both devices met the efficacy benchmark of having at least 75% of eyes achieve a monocular UNVA of 20/40 or better at 24mo. Although Raindrop appears to be more effective in improving monocular UNVA, this metric may be more sensitive than any other to surgical implantation technique

and baseline patient characteristics. Moshirfar *et al*[8] reported that KAMRA inlays implanted at depths ≥250 μm resulted in 71% of patients attaining a UNVA of 20/20 or better, whereas only 22% of patients with inlays placed shallower than 250 μm experienced a UNVA of 20/20 or better. Centration of the KAMRA inlay is also a subject of ongoing debate, and it is not yet clear to what extent centering on the Purkinje reflex, pupil center, or a point between affects visual outcomes. With regards to patient characteristics, it has been shown that moderate baseline myopia is associated with better visual outcomes after KAMRA implantation[15]. The KAMRA cohort involved in the FDA trial had a mean refraction that was mildly hyperopic preoperatively (0.074±0.291 D).

In summary, although both inlays adequately met standardized measures of safety and efficacy, patients should be presented with a realistic picture of the overall rates of SSI, CDVA loss, and UDVA improvement. Differences in subject demographics and surgical techniques diminish the comparative power of this article, and emphasize the notion that results will likely be surgeon specific.

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Conflicts of Interest: Moshirfar M, None; **Desautels JD,** None; **Wallace RT,** None; **Koen N,** None; **Hoopes PC,** holds shares in Acufocus Inc.

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