ARTICLE

Increasing depth of focus with allogeneic presbyopic inlays: 3-year results

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Purpose: To demonstrate the safety and efficacy of allogenic corneal inlays designed to increase the depth of focus (DoF) in treated eyes.

Settings: Medipol University Hospital, Istanbul, Turkey.

Design: Prospective case series.

Methods: This study includes 50 eyes of 25 patients with a follow-up of 3 years. Emmetropic patients with presbyopia had implantation of allogenic corneal inlays in the nondominant eye. The uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and uncorrected near visual acuity (UNVA) were evaluated in all eyes. A subjective visual acuity test system (Multifocal Lens Analyzer 3.0 application) was used to analyze the DoF by measuring the defocus curves.

Results: No significant difference between the treated and fellow eyes in UDVA and CDVA was found, whereas UNVA was significantly better in the treated eyes ($P = .20$, $P = .07$, $P < .01$, respectively). Comparing to the preoperative CDVA, there was a 1-line decrease in CDVA in 6 (%24) patients. The mean defocus curves reveal a DoF of 1.1 diopters (D) for the untreated eye at the logMAR = 0.2 threshold. By contrast, the mean DoF of the treated eye and binocularly was 2.8 D. The areas under the curve were significantly better in the near, intermediate, and total distances in the treated eyes, whereas it was better for the far distances in the untreated eyes. All values were significant ($P = .023$ total, $P < .01$ others).

Conclusions: Allogenic presbyopic inlay implantation may be safe and provided a clinically and statistically significant increase in the DoF leading to good far, intermediate, and near-visual acuity in emmetropic presbyopic patients.

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Presbyopia is the most common refractive error in the population older than 45 years, affecting 1.8 billion people worldwide and reducing the quality of life.[1] Especially, with the increasing use of personal computers and mobile phones, there has been a dramatic increase in the demand for appropriate presbyopia correction and spectacle independence.[2] Multifocal contact lenses, intraocular lens implantation in different designs, monovision procedures, refractive laser ablation methods, corneal inlays, and various pharmacological agents have been used to ensure patient satisfaction.[3] All of these presbyopia correction options have been used to either enhance the depth of focus (DoF) or attempt to restore accommodation.[4] However, no technique is commonly accepted as the standard for the treatment of presbyopia.

Corneal inlays offer numerous potential benefits as they are minimally invasive and additive, do not require corneal tissue removal, preserve future options for presbyopia correction, are removable in case of complications or patient intolerance, and can be used in combination with laser refractive surgery and/or pseudophakia.[5,6] Various working principles of corneal inlays have been described including changing the refractive index of the cornea (Flexivue Microlens, Presbia Coöperatief U.A.; Icolens, Neoptics AG), corneal reshaping by altering the corneal curvature (Raindrop Near Vision Inlay, Revision Optics, Inc.), or increasing the DoF with small-aperture optics (KAMRA, CorneaGen).[6] All existing corneal inlays are made of synthetic materials and may be associated with complications such as corneal haze caused by stromal inflammatory response and anterior stromal thinning or keratolysis caused by ion transport and metabolic environment changes in the corneal stroma.[7,8] Using biological inlays could solve the tissue reaction problems associated with the placement of synthetic inlays and offers advantages in biocompatibility. A preclinical study published in 2018 used lenticules obtained from lenticule extraction procedures and confirmed this thesis.[9]

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An allograft tissue lenticule was first used in 1949 by Jose Barraquer as a tissue additive method called keratophakia.[10] However, poor predictability because of the lack of a sophisticated technology to create grafts and precise pockets in the recipient's eye did not make this procedure popular in the present circumstances.[11,12] Recently, some authors have suggested that advances in the femtosecond laser technology provide alternative solutions for tissue additive procedures. For example, excimer laser-shaped allograft inlays were used in the treatment of hyperopia and presbyopia and lenticules obtained from lenticule extraction procedures were used in the management of patients with keratoconus and presbyopia correction.[13–16] In addition, allogeneic ring segments were implanted in tunnels created using a femtosecond laser in patients with keratoconus.[17]

Accurately created defocus curves allow exhaustive comparison of visual acuity (VA) at any level of defocus.[18,19] This diagnostic test has been used frequently and successfully to evaluate the efficacy of multifocal and extended depth-of-focus (EDOF) intraocular lenses (IOLs) used in the treatment of presbyopia.[20] Measurements using the third-generation retina display iPad became more efficient than conventional examination methods for time and patient comfort. The validity of this device for psychophysical purposes has been reported elsewhere, and some published studies were using this device.[21–23]

Initial studies of presbyopic allograft implantation have demonstrated safety and efficacy with small sample size and short-term follow-up.[14,16] In this study, we used sterile allograft corneal inlays created using excimer lasers to modify the surface shape of the central cornea. Thus, we aimed to evaluate long-term improvement in the through-focus acuity and visual function provided by an allogeneic corneal inlay by comparing defocus curves of the treated and untreated eyes.

METHODS

This prospective study includes 3-year VA results of 25 patients with presbyopic emmetropia who underwent sterile allograft implantation in our clinic (Department of Ophthalmology, Medipol Mega University Hospital, Istanbul, Turkey).

After giving detailed information about the risks and possible benefits of the surgery, patients signed informed consent forms preoperatively and permission was obtained to share their medical records in scientific studies. The tenets of the Declaration of Helsinki were followed, and permissions were obtained from the institutional review board/ethics committee of Istanbul Medipol University (document no: 10840098-772.02-219).

The inclusion criteria were stable refraction (no more than 0.50-diopter [D] increase in manifest refractive spherical equivalent [MRSE] during the previous 12 months) and a difference between cycloplegic and MRSE not greater than 0.75 D. An uncorrected near VA (UNVA) of less than 20/40, need for an addition between +1.5 D and +2.5 D for reading, MRSE between −0.75 D and +1.00 D, and astigmatism less than 0.75 D were required.

The exclusion criteria were corneal anomalies (endothelial dystrophies and recurrent corneal erosion), previous corneal surgery, topographic findings of keratoconus or other ectatic corneal disorders, severe eye dryness, history of viral keratitis, glaucoma, systemic treatment with side effects in the eye, anterior segment pathology, cataract, any retinal pathology, pregnancy, breastfeeding, and hypersensitivity to planned treatment postoperatively.

Allograft inlays with 2.5-D refractive power were implanted in all nondominant eyes by the same experienced surgeon (A.K.). In this case series, all inlays were obtained from human corneas and each donor cornea was prepared for use by an approved eye bank (Lions Vision Gift). The process was managed, and inlays were delivered to us in sterilized, ready-to-use packages with a shelf life of 2 years by the manufacturer (Allotex Inc.). The inlay was designed to increase the DoF by increasing spherical aberration of fourth and sixth orders to allow a near vision increase at 40 cm. The central thickness was approximately 20 μm with a diameter of 2.8 mm. The edge of the lenticule was designed without a step.

A flap with an 80-degree superior hinge and of 8.8-mm diameter was created at a depth of 110 μm using a 150-kHz femtosecond laser platform (iFS 150 kH, Intralase, Abbott Medical Optics, Inc.), and the corneal inlay was meticulously placed onto the exposed stromal bed. After the lenticule was aligned with the center of the pupil, the flap was repositioned on the stromal bed. Postoperative artificial tears and anti-inflammatory eyedrops were used for 2 months, and antibiotic drops were used for 1 month.

The patients were followed up for 3 years postoperatively. The uncorrected distance VA (UDVA), corrected distance VA (CDVA), UNVA, slitlamp biomicroscopy, and detailed fundus examinations were performed at all visits. In addition, anterior segment optical coherence tomography (Spectralis, Heidelberg Engineering GmbH), corneal tomography (Pentacam, Oculus Optikgeräte GmbH), and wavefront aberrometry (iDesign, Abbott Medical Optics, Inc.) measurements were obtained.

The patients were invited for the examination at the third postoperative year for long-term visual quality and satisfaction evaluation. Patients' visual functions were assessed by the measurement of VA and VA defocus curve. VA was evaluated with the Snellen chart and then converted to logMAR for statistical analysis. VA defocus curve measurements were obtained with a third-generation retina display iPad (Apple Inc.). The Multifocal Lens Analyzer 3.0 application (Q Vision Academy) was used to analyze the DoF. All readings were obtained by the same clinician at 0.50-D intervals in the +1.50 to −4.00 D range. The area under the curve (AUC) in the total, far, intermediate, and near distances was calculated for each defocus curve by the system. The VAs and AUCs for all distances and preoperative and postoperative spherical equivalents were compared between the 2 eyes of every patient.

Statistical Analysis

In this study, IBM SPSS Statistics for Windows (v. 22, IBM Corp.) was used for statistical analysis. The Shapiro-Wilk test was used to determine the normal distribution. The independent *t* test was used in groups with normal distribution, and the Mann-Whitney *U* test was used in groups that were not normally distributed. A *P* value below 0.05 was considered significant.

RESULTS

A total of 25 patients (19 male and 6 female) were included in this study. The mean age of the study patients was 53.52 ± 4.04 (median, 52; range, 48-62) years. Nine right eyes and 16 left eyes were treated.

In the treated eyes, the UDVA, CDVA, and UNVA were 0.07 ± 0.10 logMAR, 0.01 ± 0.04 logMAR, and 0.10 ± 0.15 logMAR, respectively, whereas in the untreated eyes, they were 0.03 ± 0.06 logMAR, 0.00 ± 0.01 logMAR, and 0.56 ± 0.24 logMAR, respectively. No significant difference was found between the treated and untreated eyes in UDVA and CDVA, whereas the improvement in UNVA was highly significant in the treated eyes ($P = .20$, $P = .07$, $P < .01$, respectively) (Table 1). All patients had better near VA in the treated eye than in the untreated eye.

Table 1. Visual acuity and defocus curve data of the patients included in the study

Parameter	Treated eye	Fellow eye	*P* value
Preop-SE (D)	0.26 ± 0.25	0.18 ± 0.26	.1
Postop-SE (D)	−0.22 ± 0.31	0.10 ± 0.30	<.01
UDVA (logMAR)	0.07 ± 0.10	0.03 ± 0.06	.20
CDVA (logMAR)	0.01 ± 0.04	0.00 ± 0.01	.07
UNVA (logMAR)	0.10 ± 0.15	0.56 ± 0.24	<.01
AUCT	1.83 ± 0.74	1.43 ± 0.55	.023
AUCF	0.38 ± 0.22	0.66 ± 0.13	<.01
AUCI	0.90 ± 0.32	0.36 ± 0.30	<.01
AUCN	0.53 ± 0.43	0.02 ± 0.06	<.01

AUCF = area under the curve—far; AUCI = area under the curve—intermediate; AUCN = area under the curve—near; AUCT = area under the curve—total; SE = spherical equivalent

In this study, 72% (18/25) of the treated eyes had UDVA of 0.1 logMAR or better, whereas 84% (21/25) of the untreated eyes had UDVA of 0.1 logMAR or better. UDVA was 0.2 logMAR or better in 92% (23/25) of the treated eyes and 96% (24/25) of the untreated eyes. CDVAs were 0.1 logMAR or better in both eyes. Comparing with the preoperative CDVA value, there was a 1-line decrease in 24% (6/25) of the treated eyes. Four of these patients had severe dry-eye findings. UNVA was 0.2 logMAR or better in 92% (23/25) of the treated eyes and 4% (1/25) of the untreated eyes. Moreover, 22 patients stated that they were completely independent of spectacles. One patient with a binocular UNVA of 0.2 logMAR reported needing spectacles sometimes at a close range when reading for too long. Two patients with a binocular UNVA of 0.3 logMAR could manage without spectacles for 2 years after the operation; however, they could not do near work without spectacles for the past 1 year. To better analyze the visual results of the surgical procedure, the standard refractive surgery graphs, as demonstrated in Figure 4, were created. However, a scatterplot of achieved vs attempted refractive change was not included in the standard refractive surgery graphs for these data because the intent of the procedure is not to produce a particular spherical equivalent refractive change but to increase the DoF by increasing the fourth and sixth-order spherical aberrations. Haze, rejection reaction, or epithelial ingrowth was not detected in any of the inlay-implanted eyes, and no situation requiring inlay explantation was encountered at the end of 3 years.

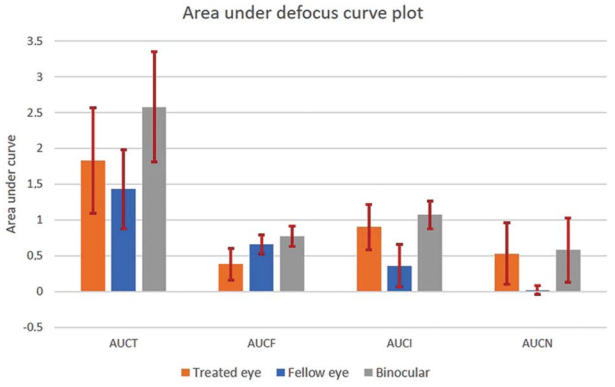

Figure 2. Area under the defocus curve. AUCF = area under the curve—far (from +0.50 to −0.50 D); AUCI = area under the curve—intermediate (from −0.50 to −2.00 D); AUCN = area under the curve—near (from −2.00 to −4.00 D); AUCT = area under the curve—total (from +1.00 to −4.00 D)

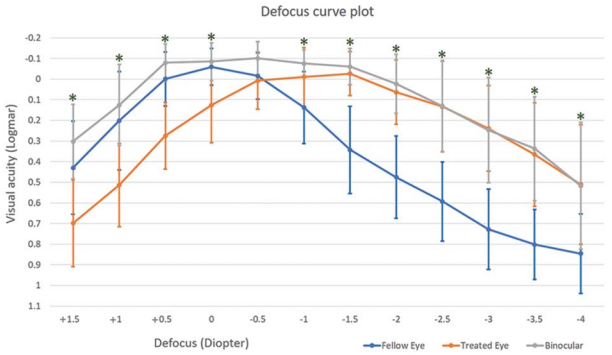

Figure 1. Defocus curves of treated eye, fellow eye, and binocularly.

According to the defocus curves, the mean VA of the untreated eyes was 1.7 lines better at far distances and the VAs of the treated eyes were 3.7 and 4.9 lines better at intermediate (67 cm) and near (33 cm) distances, respectively (Figure 1). In addition, the areas under the curve were better in the near, intermediate, and total distances in the treated eyes, whereas they were better in far distances in the untreated eyes (Figure 2). All values were significant ($P = .023$ total, $P < .01$ others, Table 1). The DoF range of the treated eyes was 3.8 D, whereas in the untreated eyes, it was 2.6 D (Figure 3, a).

DISCUSSION

This study aimed to compare the focus performance between the treated and untreated eyes of patients who underwent allogeneic presbyopic inlay implantation. This study shows that presbyopic allograft inlay implantation provides a significant increase in near VA with a focal depth of approximately 4 D without decreasing the distance VA. No significant difference was found between treated and untreated eyes in UDVA and CDVA, whereas UNVA was significantly increased in treated eyes. When analyzing the defocus curves in detail, although the treated eye was better at near and intermediate distances, it was associated with worse visual outcomes at far distances. This may be because of induced myopia and increased spherical aberrations in the treated eye. A myopic shift of −0.50 D in spherical equivalent was observed in the treated eyes (Table 1). Moreover, the peak of the defocus curve of the treated eyes shifted to the right, plateauing between −0.5 D and −1.5 D (Figure 1).

Compared with preoperative data, there was no difference in the cylindrical refractions while the spherical refraction shifted toward myopia. While no significant difference was found in UDVA, 24% (6/25) of eyes lost 1 line of CDVA. The decline in CDVA was statistically significant, but no patient had more than 1-line decrease (Figure 4). We may speculate that the decline in CDVA

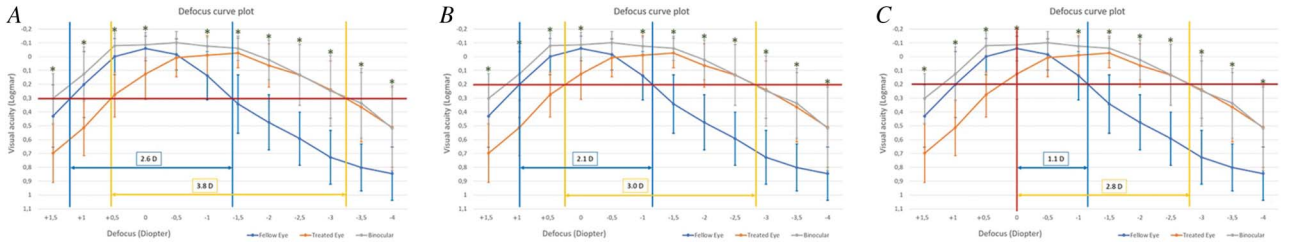

Figure 3. Depth of focus. *A*. Full range of DoF at 0.3 logMAR VA. *B*. Full range of DoF at 0.2 logMAR VA. *C*. Useable range of DoF at 0.2 logMAR VA.

may be associated with dry eye. The increase in postoperative UNVA was obvious (Table 2).

Jacob et al. reported similar results. They described the treatment of presbyopia with allogeneic lenticule (obtained from lenticule extraction procedures) implantation and reported 6-month refractive results of 4 patients with emmetropic presbyopia: The UNVA (33 cm) in 1 patient increased from J8 to J3 while in the other 3 patients, the UNVA increased from J5, J6, and J7 to J2, respectively. The UDVA was 20/20 for all patients, with no postoperative decline. In this study, VA was measured only for specified distances. However, the defocus curve, which gives more information about visual performance, is not included.[16]

In this study, the AUCs were calculated with 0.3 logMAR as a threshold. This cutoff value was suggested by Wolffsohn et al. arguing that this level of VA is widely accepted in Europe to meet the driving standard.[24] When the AUCs based on the 0.3-logMAR visual level were compared, the AUC of the untreated eye was approximately 2 times larger at far distances, whereas the area for the treated eye was approximately 3 times larger at intermediate distances and 25 times larger at the near range (Figure 2). According to these criteria, approximately 1.2 D of difference was found between the treated and untreated eyes in the full range of DoF (3.8 D and 2.6 D, respectively) (Figure 3, a). In a study of VA and contrast sensitivity involving 2520 participants, West et al. found that approximately 50% of the studied population with VA worse than 0.2 logMAR had reading difficulties.[25] Similarly, Yi et al. and Collins et al. adopted the level of 0.2-logMAR VA to measure the DoF.[26,27] In the present study, a VA level of 0.2 logMAR, which has been adopted as a preset image quality threshold that must be maintained while extending the DoF of the eye, was also used to better evaluate allograft inlay performance. Based on 0.2 logMAR, approximately 0.9 D of difference was found between the treated and untreated eyes in the full

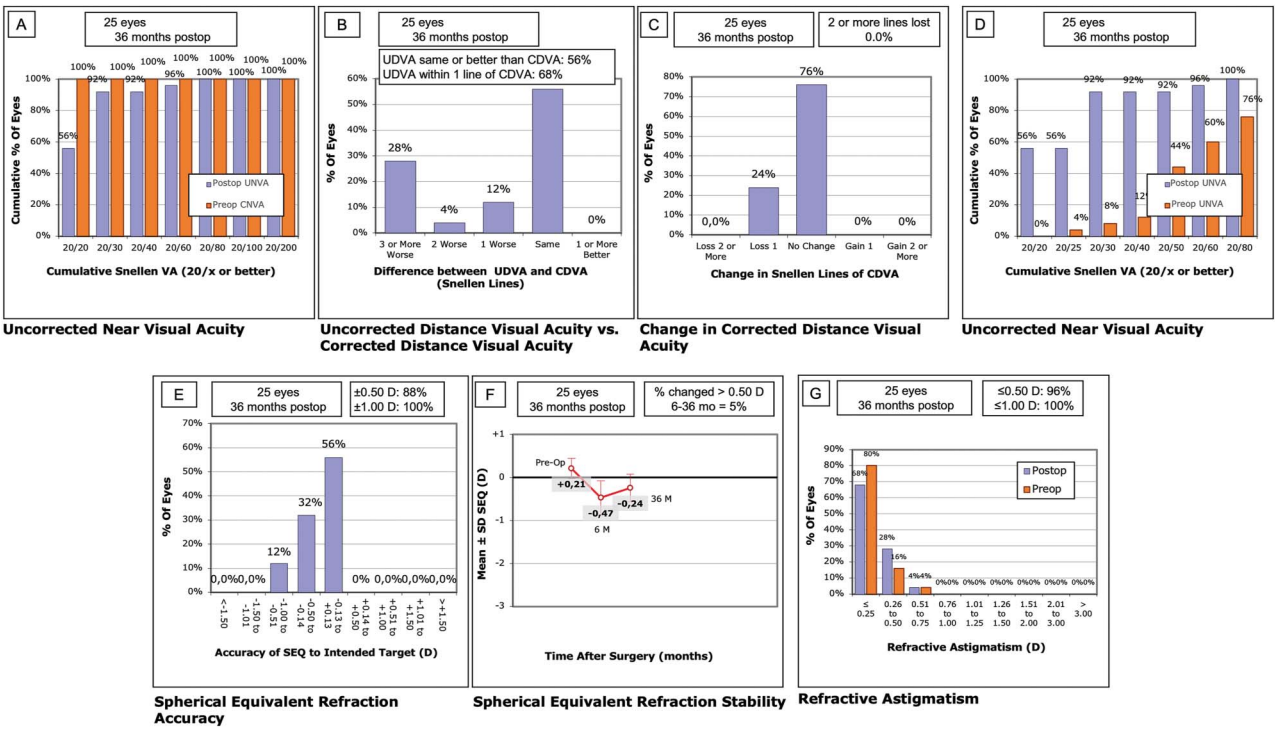

Figure 4. Standard graphs of refractive surgery. *A*. Preop CNVA and postop UNVA. *B*. Difference between UDVA and CDVA *C*. Change of CDVA *D*. Preop and postop UNVA *E*. SE refraction accuracy *F*. SE refraction stability *G*. Refractive astigmatism.

Table 2. Comparison of preoperative and postoperative values

Parameter	Preop	Postop	*P* value
Sphere (D)	0.32 ± 0.25	−0.15 ± 0.28	<.01
Cylinder (D)	−0.12 ± 0.22	−0.16 ± 0.25	.31
UDVA (logMAR)	0.02 ± 0.04	0.07 ± 0.10	.052
CDVA (logMAR)	−0.00 ± 0.01	0.01 ± 0.04	.01
UNVA (logMAR)	0.50 ± 0.18	0.10 ± 0.15	<.01
SA (μm)	0.04 ± 0.03	−0.06 ± 0.07	<.01

Cylinder = manifest cylinder refraction; SA = spherical aberration; Sphere = manifest sphere refraction

range of DoF (Figure 3, b). The difference between 0.0 D and negative diopters where the curve cuts the 0.2-logMAR line was used to calculate the useable DoF, that is, the uninterrupted vision from infinity to the near point of the person. A 1.7-D difference exists between the treated and untreated eyes in the useable range of DoF (2.8 D vs 1.1 D, respectively) (Figure 3, c).

Several studies have used synthetic material inlays in the treatment of presbyopia, but no defocus study with allograft inlays was conducted. A defocus study by Whitman et al. using a corneal shape-changing inlay (Raindrop) showed a 1-line decrease in distance, a 1-line increase in intermediate (67 cm) distance, and a 3-line increase in near (40 cm) distance across a 3.50-D range of defocus at 1 year postoperatively. Although the present study did not include preoperative defocus curve data, direct comparison is not very meaningful as the VA of the treated eyes was 1.5 lines less at far distances, whereas the 3.5 and 4.5 lines were better at intermediate (67 cm) and near (33 cm) distances, respectively, with a 4-D focus range.[28] Vilupuru et al. compared the defocus curves of small-aperture corneal inlays (Kamra) and different design multifocal IOLs and found a 3.5-D range for the inlays.[29] In another study with model eyes, the focus ranges of small-aperture corneal inlays (Kamra) implanted in pseudophakic eyes and small-aperture IOLs (IC-8) were compared and simulated as 3.0 D and 3.3 D, respectively.[30] In a study with refractive corneal inlays (Flexivue), by Han et al., the focus range was similarly 3.5 D; however, a serious decrease was found in UDVA.[31] The gains in intermediate and near vision of all previous studies are comparable with the current one. Nonetheless, the use of synthetic corneal inlays in the treatment of presbyopia has not become a preferred option today because of wound-healing concerns, unpredictable refractive outcomes, shifts in refractive errors, implant decentrations, and various optical side effects due to impaired corneal nutrient and oxygen diffusion or foreign body reaction.[32]

Currently, clear lens exchange and multifocal or EDOF IOL implantation in different designs are the most preferred methods to ensure the independence of presbyopes from spectacles. These IOLs provide satisfactory vision at certain distances according to their design. In a recent study by Ferreira et al., the binocular defocus curve of a diffractive trifocal IOL (Acrysof IQ PanOptix TFNT00) was examined and visual acuities were measured as 0 logMAR at distance, 0.05 logMAR at 67 cm, and 0 logMAR at 33 cm. Compared with the binocular defocus curve in the current study, the VA of the allograft inlay is better at the far and intermediate distances, whereas this IOL has a better VA at near distances. Potential disadvantages of this diffractive optic design include reduction in contrast sensitivity, degraded image quality, and increased visual symptoms such as glare, halos, and focusing difficulties.[33] It should be investigated whether allograft inlays can provide an advantage for these side effects. According to the results of the studies by Bautista et al. and Böhm et al., the VA of an IOL with the EDOF technology (TECNIS Symfony, Johnson & Johnson Vision) was 0 logMAR at far distances, 0.1 logMAR at 67 cm, and 0.5 logMAR at 33 cm. Compared with the current study, the inlays provided better vision at all distances.[20,34] The authors argue that a corneal approach rather than lens exchange would be judicious to protect the existing accommodation reserve, especially in patients with early-stage emmetropic presbyopia. Other advantages of allograft corneal inlays include suitability for a single-eye approach.

The limitations of this study include its small sample size, single-center setting, and noninclusion of preoperative defocus curves. Furthermore, these results are valid only in the age and emmetropia conditions detailed in the inclusion criteria. The effect of inlays in patients with concomitant refractive errors is unknown. In addition, other conditions affecting visual quality such as contrast sensitivity, halo, and glare should also be investigated to compare current treatment methods. To our knowledge, this study is the first defocus study and long-term follow-up study with allograft presbyopic inlays. Multicenter studies with more volunteers are needed in the future.

At 3 years, allogeneic presbyopic lenticule implantation was safe and provided a clinically significant increase in the DoF by expanding the width of the plateau in the defocus curve. The increase in the DoF was only present in the treated eyes, whereas the untreated eye remained presbyopic.

WHAT WAS KNOWN

- Different designs of corneal inlays have been used in the treatment of presbyopia. These inlays made of synthetic material have caused some complications such as corneal haze.
- Allograft inlay implantation was described in small case series in patients with presbyopia, and early results were published.
- There is no study in the literature that includes long-term visual results and defocus curves of patients who underwent allograft corneal inlay implantation.

WHAT THIS PAPER ADDS

- To our knowledge, this is the longest follow-up study with allograft corneal inlay.
- The defocus curve gives information about uninterrupted visual acuity. Patients who underwent allograft corneal inlay implantation had satisfactory visual results at near, intermediate, and distance.
- Although allograft corneal rings seem safe, 1-line loss in CDVA in 24% of eyes is the main limitation. In the future, this problem should be focused on.

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