Clinical Ophthalmology

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CLINICAL TRIAL REPORT

Evaluation of the Functional Visual Range of a Catenary Curve-Based, Extended Depth-of-Focus Contact Lens for Presbyopia

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Purpose: Employing "relative plus" (Add) power to extend the functional vision range is a primary method to correct presbyopia with contact lenses. Simultaneous vision contact lenses are typically associated with visual disturbances at higher Add powers, often resulting in compromised vision and necessitating specialized fitting methods. Among mature individuals suffering from presbyopia, we evaluated the visual performance of a catenary curve-based extended depth of focus (EDOF) optical profile contact lens with a simplified fitting process.

Methods: Mature individuals suffering from presbyopia with Add requirements of +2.00 D or more were recruited. Monocular and binocular visual acuities were obtained across optical vergences ranging from −4.00 D to +2.00 D to generate defocus curves for best spectacle-corrected distance vision (baseline) and center-distance, catenary curve-based contact lenses (catenary). A subjective questionnaire evaluating the lenses was employed.

Results: Twenty-four mature individuals suffering from presbyopia, average age 59.2 (range: 51–68 years) and average Add requirement of +2.24 D (range +2.00 D to +2.50 D) were enrolled. Under high-contrast conditions, the catenary lens provided functional binocular vision (0.30 logMAR or better) at all optical vergences from distance to −3.50 D (equivalent to 28 cm). Participants demonstrated a significant improvement ($p < 0.05$) in binocular visual acuity while wearing the catenary lens with an imposed defocus of −1.50 D to −4.00 D (equivalent to object distances from 66 cm to 25 cm). Subjective ratings with the catenary lens were equivalent to those documented at baseline.

Conclusion: The catenary curve-based lenses provided a full range of functional vision while maintaining clear distance vision for individuals suffering from advanced presbyopia. Comparison with previous results involving this lens indicates that these findings are also generalizable to wearers with lower Add requirements. This EDOF design provides a universal Add which is sufficient for advanced presbyopia.

Trial Registration: ClinicalTrials.gov. Identifier: NCT05495971.

Keywords: presbyopia, multifocal contact lens designs, catenary optics, defocus curves, extended depth of focus

Introduction

Presbyopia is characterized by an age-related progressive loss of the ability to see near objects clearly.[1–3] Presbyopia negatively impacts everyday tasks such as reading and working at a personal computer. Typically, presbyopia onset occurs around 40 years of age, and progression continues until around 60 years of age, affecting all phakic eyes regardless of refractive status.

Anatomically, presbyopia arises predominantly from stiffening of the crystalline lens of the eye with age. This action results in an inability of the eye to compensate for divergent light rays arising from near objects.

The most common approach to address presbyopia symptoms is to apply an optical solution incorporating "relative plus" power ("Add") corrective lenses for near-visual tasks. This aids the convergence of light rays forward to the retinal surface.[4] An "Add" is prescribed to an individual with reduced accommodative amplitude (ie presbyope); typically, it is

Received: 15 March 2024
Accepted: 10 July 2024
Published: 19 July 2024

the amount of relative plus power needed for a person with reduced accommodative amplitude to comfortably resolve 20/20 (0.0 logMAR) letters at 40 cm. The older the individual, the greater the Add requirement to read the same letters at the same distance. One method to accomplish this action is with bifocal or multifocal contact lenses, which contain relative plus power in addition to full-distance refractive power (sometimes referred to as “simultaneous image” optics).

The designs of multifocal contact lens can be center-near or center-distance, and broadly comprise concentric zonal and aspheric optical profiles. The large majority of multifocal designs utilize a center-near approach. The centermost zone is for near viewing, followed by a rapid transition of optical power towards the distance viewing zone. Concentric zonal designs are impacted by pupil dynamics. As the eye converges and attempts to accommodate, the pupil constricts; whereas when the eye looks at a distant object, the pupil dilates. Center-near designs rely on pupil constriction. When the wearer looks at a near target and the pupil constricts, the wearer will experience better near vision performance. However, the wearer’s distance vision tends to have more compromise than when wearing a center-distance design.[5]

The concentric zonal refractive optical design is regarded as the classic simultaneous-image optic for presbyopia.[6,7] Traditionally, these designs employ one or more concentric distance and “near power” zones to create two foci corresponding to two vergences: one focal point for distant objects and one for near objects. Light rays entering the eye are split into two focal planes. Hence, ~50% of the rays entering the eye will be out-of-focus for any given focal point. These out-of-focus rays will concentrate into rings around the sharp image and create distracting visual disturbances which are often described as “halos”, “ghosting”, or “double images”.[8] The superimposed defocused images reduce the contrast of the image of interest significantly, particularly under low contrast and low illumination. Furthermore, the higher the Add power, the more severe is the deterioration, which results in significant reduction of low-contrast vision and stereopsis.[9–14] As a result, some wearers cannot adapt to a high simultaneous-image bifocal Add.[15] Consequently, practitioners may resort to pushing maximum-plus distance power while employing a lower Add to maximize near vision while retaining acceptable distance vision.[5]

The aspheric optical approach is a simultaneous-image optic designed with gradual power transitions. The lens changes refractive power gradually from the center to periphery and radiates symmetrically, resulting in rays that change focal points more smoothly along the visual axis. Rays that are not focused on the retina create defocus. However, aspheric optics spread defocused light rays out more evenly, so the result is a softer halo and wider range of functional vision.[16–20] Aspheric designs in contact lenses can soften the abrupt power transitions observed with zonal refractive designs, extend the depth of focus (DOF), and reduce spherical aberrations to enhance image sharpness.[21,22]

A “catenary curve” is a highly aspheric shape marked by smooth and rapid transition of curvature. It can be approximated by a free-hanging chain from two points. An optical power profile with a catenary curve-based contact lens design employs a central distance power which transitions rapidly and smoothly to high relative plus power away from the lens center.[23] This smooth transition of power creates an even spread of light across the retinal plane. This action results in a halo which has minimal contrast difference from the background, potentially aiding adaptation.[24] Compared to a center-distance concentric bifocal design, this design has been reported to have a higher Strehl Ratio than a center-distance concentric ring bifocal design.[25]

The extended depth of focus (EDOF) optic is a class of lens design intended to extend the uninterrupted range of acceptable image quality. The American Academy of Ophthalmology defines the EDOF optic as “a single, contiguous, elongated focal point that enhances depth of focus”.[26] The catenary curve-based contact lens design evaluated in the present study was a type of EDOF optic, achieving its elongated focal point via high asphericity. In Figure 1, the optical profile of the lens is characterized via a Hartmann–Shack wavefront sensor (CLAirE, WaveFront Dynamics, New Mexico, USA) with a sampling of 108 µm. Multiple production contact lenses (NaturalVue Multifocal 1 Day, Daily Disposable Soft Contact Lenses, etafilcon A, Visioneering Technologies Inc., Georgia, USA) were shipped from their distribution center with distance power of −1.00 D, −3.00 D and −5.00 D. These lenses were measured repeatedly using a wet cell under the wavefront sensor. Wavefront measurement data were fitted using Zernike polynomials through 10th order over a 6 mm pupil diameter (optical center diameter). Measurements revealed a rotationally symmetric power profile with smooth and rapid power progression that could be decomposed into a high magnitude of primary and secondary spherical aberrations. Around +8.0 µm of spherical aberration was measured with a power difference of +7.81 ± 0.07 D from the center of the lens to the edge of the optical center (6 mm). This high magnitude of asphericity resulted

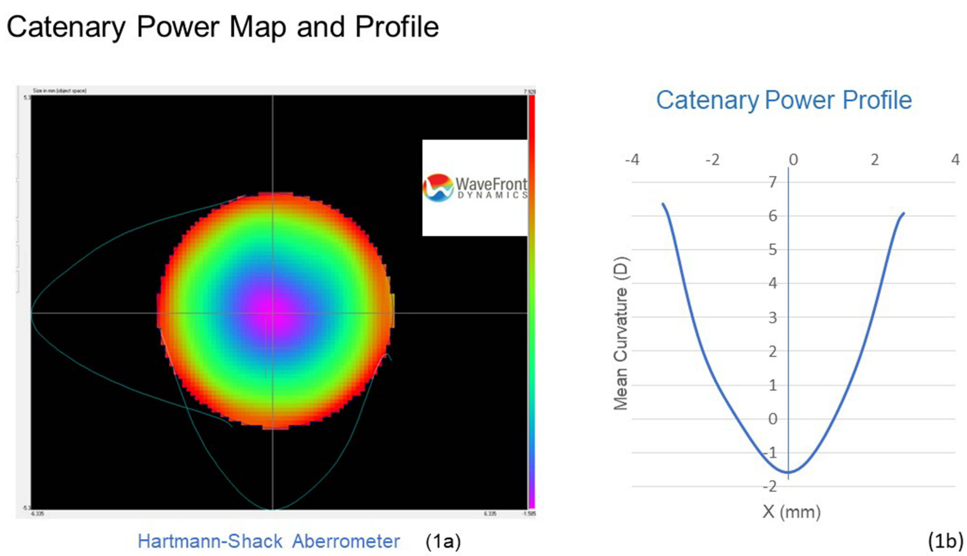

Figure 1 Power map (**1a**) and power profile (**1b**) of the catenary curve-based optic. Hartmann-Shack wavefront sensing revealed a rotationally symmetric wavefront measurement, that can be decomposed into mainly primary and secondary spherical aberrations (**1a**), power conversion resulted in a catenary curve shaped center-distance power profile (**1b**).

in an EDOF (Figure 2). The high degree of relative plus power generated by the lens design enables one universal Add power with a streamlined fitting process in which patients of all ages are fitted with a vertex-corrected spherical equivalent distance power in each eye.

We wished to evaluate the visual performance of the center-distance catenary curve-based optical design across a wide range of vergences (representing the range of viewing distances) in individuals suffering from advanced presbyopia. Functional vision was defined as the range of optical vergences over which monocular and binocular vision achieved visual acuity of ≥0.3 logMAR (20/40). A secondary aim of our study was to understand subjective assessments of visual quality with the lens design via a questionnaire.

Materials and Methods

All procedures conformed to requirements in the Declaration of Helsinki 1963 and its later amendments for research involving humans. The study protocol was approved by the Ethics Committee of Sterling IRB, Atlanta, GA, USA. (FDA/OHRP IRB Registration Number: IRB00001790). The Sterling IRB study number is 10162 for this study. Study investigators were trained at the International Conference on Harmonization guidelines for Good Clinical Practice and study procedures. All participants provided written informed consent. This study is registered under ClinicalTrials.gov (identifier: NCT05495971).

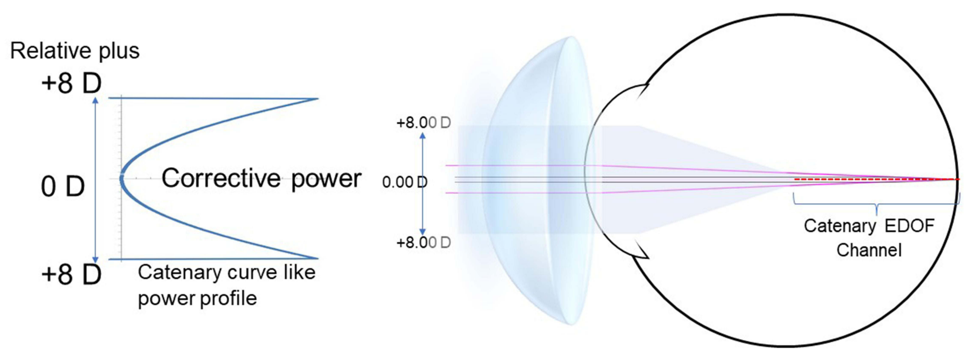

Figure 2 Catenary curve-based optic generates an ultra-elongated depth-of-focus channel. Continuously changing curvature provides a series of focal points along the visual axis, effectively neutralizing vergences from different object distances and elongating the range of clear vision.

https://doi.org/10.2147/OPTH.S468699

A prospective, non-dispensing, single-masked (participant) study was conducted at four clinical sites. Mature individuals (age ≥50 years) suffering from presbyopia (Add requirement > +2.00 D) were recruited to minimize the impact of residual accommodation and better quantify the performance of this EDOF lens design. Refractive astigmatism was limited to ≤1.00 D. Equal inclusion of men and women in this study was desired but not necessary because there are no known differences in the safety or performance of contact lenses based on sex. There were no restrictions on enrollment based on racial/ethnic criteria. The racial/ethnic distribution of participants reflected the racial/ethnic population at study sites.

All participants received a refractive examination and external assessment of ocular health. In the refractive examination, eye dominance was determined via a sensory method. Best spectacle-corrected distance vision (baseline) logMAR acuities under high-contrast, high-illumination (160 cd/m^2), as well as low-contrast (10%), low-illumination (16 cd/m^2) binocular vision at distance, 1 m, and 40 cm were ascertained. Horizontal visible–iris diameter, pupil-size assessment in high and low illuminations, and keratometry were undertaken. Following the fitting guide for the lens, the refractive endpoint was biased to green using the duochrome test binocularly in a darkened room. Catenary curve-based contact-lens diagnostic powers (in spherical equivalent) were calculated for each person and placed on the eye. After a 20-min adaptation period, lens fit was evaluated, followed by assessment of logMAR acuities in high-contrast, high-illumination and low-contrast, low-illumination conditions. A questionnaire regarding subjective visual performance was completed by participants.

Defocus Curves

A defocus curve is a quantitative method for evaluating visual acuity at various viewing distances. It has been adopted as a regulatory outcome measure for intraocular lenses (IOLs) that have an EDOF design.[27,28]

To generate defocus curves for the baseline condition and catenary condition, a logMAR eye chart was placed at a distance (vergence demand of 0.00 D) under standard photopic lighting. A series of positive and negative loose lenses (+2.00 D to −4.00 D in steps of 0.50 D) were imposed to simulate vergences from different viewing distances. For example, a lens of −2.50 D corresponds to an object distance of 40 cm if placed in front of a distance-corrected eye viewing a distance chart. To quantify the range of functional vision from this curve, the DOF is defined by the range of vergences with 0.3 logMAR (20/40) or better visual acuity. Figure 3 demonstrates a series of defocus curves for IOLs from their Summary of Safety and Effectiveness Data (SSED) for the United States Food & Drug Administration.[29–31] The single-vision intraocular lens (SV IOL) curve would be akin to that of a person with presbyopia wearing a single-vision, distance-correcting contact lens, resulting in the need for reading glasses to provide functional intermediate and near vision. The bifocal intraocular lens (MF IOL) curve represented in Figure 3 has two peaks: one optimized at distance (vergence of 0.00 D) and one optimized at ~40 cm (vergence of −2.50 D). The EDOF curves from a refractive (wavefront-shaping) EDOF IOL and a diffractive EDOF IOL in this example demonstrate a smoother transition in visual acuity from distance to near, providing superior intermediate vision but less near vision, than the bifocal design (Figure 3).

Subjective Assessment

A subjective assessment of the catenary lens was conducted after the defocus-curve values were obtained. Scores were given on a scale of 0 to 100 (0 = "extremely poor" and 100 = "extremely good/no problems") with regard to overall comfort, distance vision, intermediate vision, near vision, overall lens performance, and level of difficulty performing normal daily visual activities with only the lenses worn.

Statistical Analyses

Study participants served as their own controls. Baseline data collected using the best distance-corrected spectacle vision of participants was compared with their performance using the catenary curve-based lens. Monocular and binocular measurements were collected from each participant under high-contrast, high-illumination conditions – first at baseline, followed by catenary lenses. Right eyes were used for monocular comparisons. Statistical analyses were undertaken using Excel™ (Microsoft Office®,

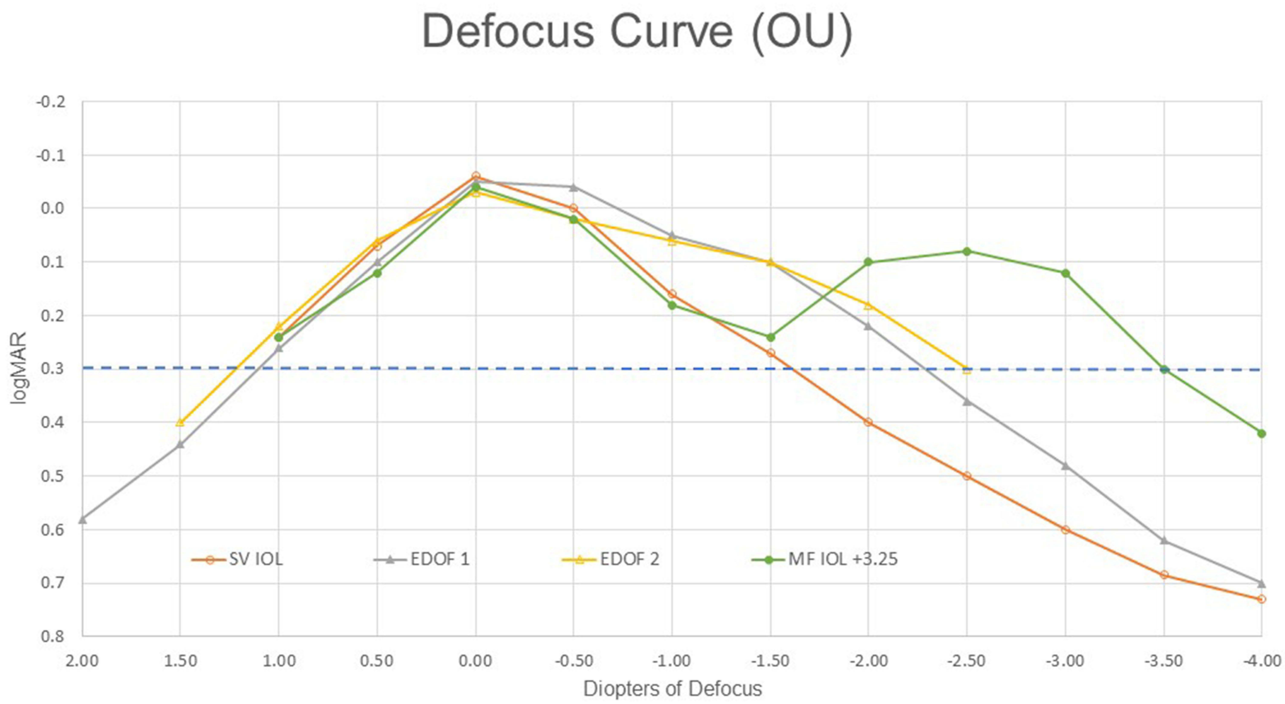

Figure 3 Binocular defocus curve of intraocular lenses. The dioptric value on the x-axis represents the change of vergence from infinity (0.00); where −2.50 D represents 40cm. The dash line represents the threshold of functional vision, 0.30 logMAR (20/40, equivalent to Arial font size 7 at 40 cm). Areas above the line and below the defocus curve is considered to be areas of functional vision. Vergence range with logMAR value 0.30 or better (smaller) is the range of clear vision.

Redmond, WA, USA). Values for the mean and standard deviation were calculated. Paired, two-tailed Student's *t*-tests were conducted to evaluate significance ($p < 0.05$).

Generalizability

This defocus-curve study focused on mature individuals with presbyopia to minimize the impact of residual accommodation. One may assume that the worst-case scenario performance outcomes can also be applied to populations with more accommodative reserve. We wished to evaluate the generalizability of our study findings to people of all ages suffering from presbyopia. Data from the pre-market evaluation trial (PMET) of the manufacturer, who enrolled 55 people aged 50.9 ± 5.2 (range, 43–65) years with a spectrum of Add requirements (+1.00 to +2.50 D), were compared with the defocus-curve study data. Our study followed the same methodology in terms of collecting visual acuities and subjective assessments as that of the PMET.

Results

Individuals were tested at four sites in the USA by four investigators from 9 August 2022 to 12 May 2023. Forty-eight eyes from 24 mature presbyopic, phakic participants were assessed. The study cohort comprised 19 (79%) women and five (21%) men. The mean age of the study cohort was 59.2 (range, 51–68) years. The distance prescriptions of participants ranged from +2.75 D to −9.50 D (mean right eye −2.95 D; left eye −2.70 D) with astigmatism up to −1.50 DC. The requirements for Add power ranged from +2.00 to +2.50 (mean, +2.24 D).

The average pupil size of participants was 3.61 (range, 2.3 to 5.1) mm under high illumination, observed immediately before baseline measurements. The pupil size of the right eye was compared with the monocular logMAR vision from the right eye at a defocus of −2.00 D, −2.50 D, and −3.00 D. Regression analysis showed no correlation between pupil size and near logMAR vision (R^2 = 0.003, 0.016, and 0.025, respectively).

A significant difference between high-contrast, high-illumination or low-contrast, low-illumination visual acuity at distance or intermediate (1 m) was not observed between baseline and catenary conditions. However, significant improvement of near (40 cm) vision with the catenary lens was observed for high-contrast, high-illumination and low-contrast, low-illumination visual acuity (Table 1).

Data for visual acuity from PMET showed no difference in high-contrast, high-illumination visual acuity at distance between PMET data and catenary-lens data from our study. The high-contrast, high-illumination visual-acuity data of the overall PMET cohort were superior to the catenary-lens data from our study at intermediate (1 m) and near (40 cm), but the differences were not clinically significant. Furthermore, when the PMET data were stratified by Add requirement [high (≥ +2.00 D), intermediate (+1.50 to +1.75 D), and low (+1.00 to +1.25 D)], a clinically meaningful difference in visual acuity compared with the catenary-lens data from our study was not found at any distance (Table 1).

The results from defocus curves provide a comprehensive set of high-contrast performance data for different viewing distances under monocular and binocular conditions. The baseline condition represents the natural best-corrected visual capabilities (without the aid of an Add). Negative values for optical vergence where visual acuity is significantly better with the catenary condition represent an expanded visual range provided by the catenary lens. Monocularly, there were no significant differences between vision at baseline and the catenary contact lens for optical vergence from −0.50 D to +2.00 D. This finding indicated that vision with the catenary lens was similar to the best-corrected vision from 2 m and beyond. Monocular vision with the catenary lens was significantly superior (p-value between 0.002 to <0.001) compared with that at baseline from defocus at −1.00 D to −4.00 D, which represented viewing distances between 1 m to 25 cm (Figure 4).

Binocularly, participants demonstrated significant (p-value <0.001) improvement in visual acuity while wearing the catenary contact lens from defocus of −1.50 D to −4.00 D, representing viewing distances from 66 cm to 25 cm, whereas a significant difference was not observed from −1.00 to +2.00 D (Figure 5). The range of clear focus, vergence range within the 0.30 logMAR threshold, expanded by 2.00 D from the baseline to wearing the catenary contact lens.

Clinical defocus curve data from the catenary contact lens design showed a full range of functional binocular vision (0.30 logMAR or better) from distance to 28 cm for mature participants suffering from presbyopia. This corresponds to a functional DOF of 3.50 D with the catenary lens, and an EDOF by 2 D compared with those at baseline. Furthermore, distance and intermediate high-contrast visual acuities were maintained at 20/25 or better with the catenary lens (Figures 4 and 5). The near vergence cutoff of functional vision and the area under the curve compared favorably with commercially available EDOF IOLs (Figures 3 and 5).

Results for subjective assessment with the catenary lens are summarized in Table 2, along with PMET data. Participants reported high scores for comfort and visual performance across distance, intermediate, and near viewing distances. The subjective assessment from the PMET cohort was similar to the catenary cohort from our study. Using the Bonferroni post hoc test to determine pairwise differences, stratified subgroups with high, medium, and low Add requirements reported similar comfort, vision, and performance scores. All three groups reported similar scores regarding the ability of lenses to meet overall daily visual needs and overall performance.

Table 1 Binocular logMAR Scores

Study Cohort		HC Dist	HC Inter	HC Near	LC Dist	LC Inter	LC Near
Baseline (n = 24)	Mean ± SD	−0.07±0.07	0.01±0.13	0.23±0.18	0.10±0.22	0.41±0.14	0.66±0.23
Catenary (n = 24)	Mean ± SD	−0.07±0.07	−0.03±0.13	0.14*±0.13	0.14±0.20	0.37±0.19	0.57*±0.18
PMET (all) (n = 55)		−0.06±0.08	−0.10±0.08	0.08±0.10			
PMET high Add (n = 28)		−0.09±0.08	−0.11±0.09	0.10±0.10			
PMET medium Add (n = 18)		−0.03±0.08	−0.09±0.13	0.09±0.09			
PMET low Add (n = 9)		−0.03±0.08	−0.09±0.13	0.09±0.09			

Notes: Distance = 6 m, Intermediate = 1 m, Near = 40 cm. *Catenary data vs Baseline data, statistically significant (p<0.008).
Abbreviations: HC, high contrast, high illumination; LC, low contrast, low illumination.

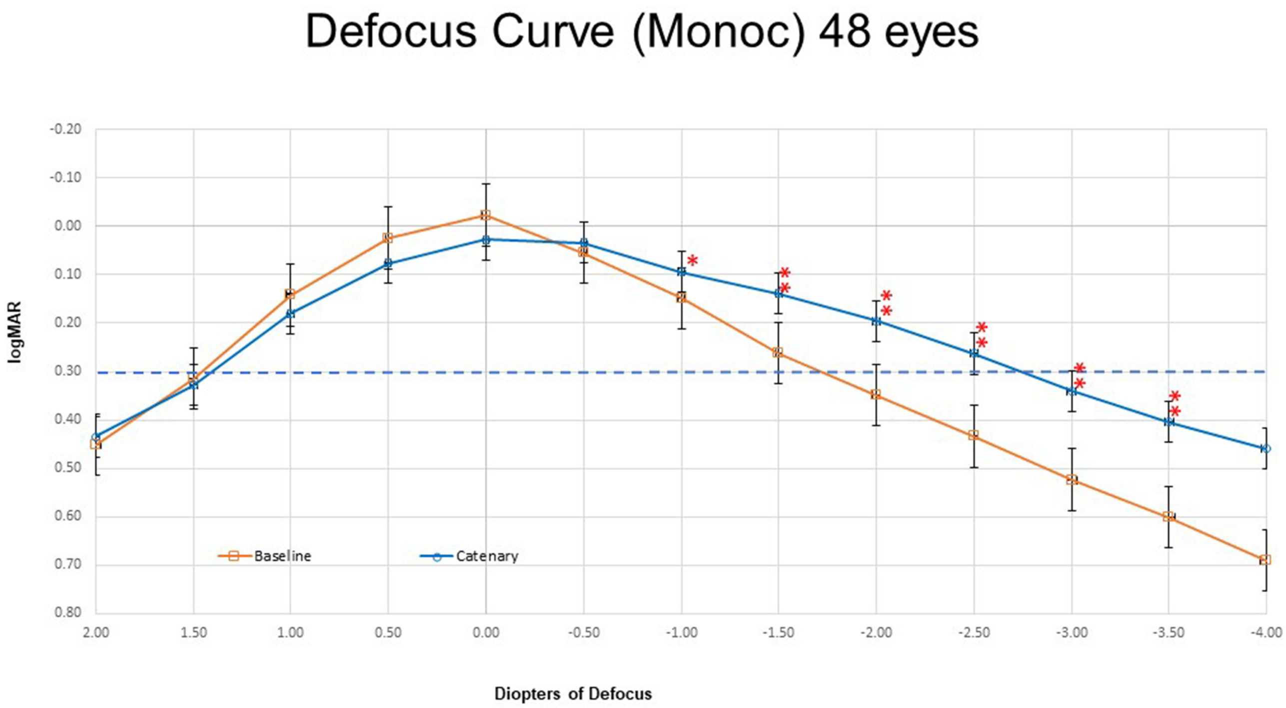

Figure 4 Comparison of monocular defocus curves. Monocular defocus data from the Baseline was collected with sphero-cylindrical correction using trail lenses. Catenary defocus data was collected from the same subjects wearing the catenary curve-based contact lens. Error bar represents standard error. * significance at the P < 0.05; ** significance at the P < 0.001. High illumination/high contrast conditions.

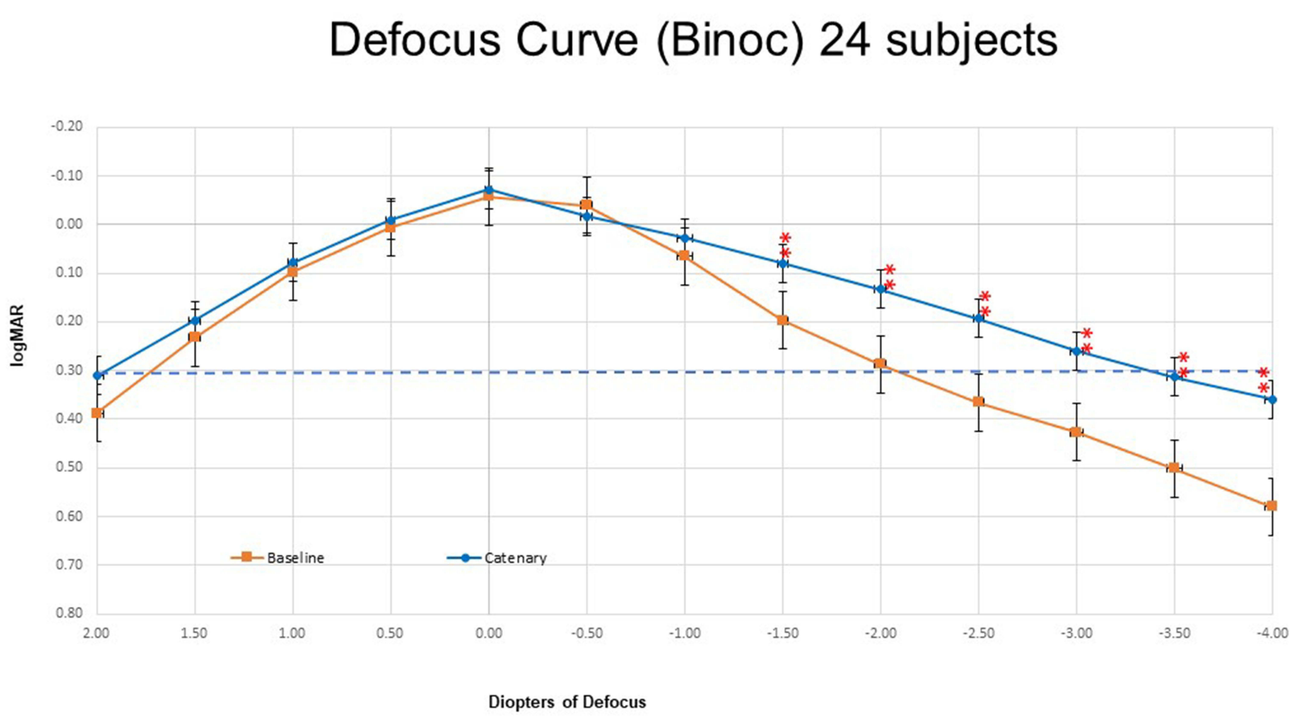

Figure 5 Comparison of binocular defocus curves. Binocular defocus data from the Baseline was collected with sphero-cylindrical correction using trail lenses. Catenary defocus data was collected from the same subjects wearing the catenary curve-based contact lens. Error bar represents standard error. ** significance at the P < 0.001. High illumination/high contrast conditions.

Table 2 Subjective Assessment Scale from the Catenary-Lens Performance

Study Cohort	Overall Comfort	Distance Vision	Intermediate Vision	Near Vision	Overall Performance	Difficulty W/ Daily Visual Activities (y/n)	% of Overall Daily Visual Needs Met W/ Only this Lens
Catenary (n = 24)	94.96 ±7.74	90.21 ±9.61	90.13 ±11.87	87.54 ±9.66	92.25 ±7.29	100% N	
PMET (n = 51)	90.94 ±12.70	89.00 ±12.42	89.73 ±11.66	83.10 ±16.18	84.41 ±14.27		90.47 ±8.34
≥2.00 (n = 26)	92.7 ±9.92	92.58 ±8.86	90.42 ±10.62	82.58 ±14.53	84.69 ±15.25		92.69 ±9.10
1.50–1.75 (n = 16)	89.9 ±15.2	86.69 ±11.2	90.75 ±12.23	79.81 ±20.64	84.69 ±12.58		89.88 ±7.63
1.00–1.25 (n = 9)	87.8 ±15.6	82.78 ±19.7	85.89 ±14.04	90.44 ±9.71	83.11 ±15.72		87.78 ±8.08

Notes: 0= extremely poor and 100= extremely good/no problems.

Discussion

Presbyopia is a progressive condition that eventually impacts everyone, which highlights the importance of optimizing its correction. Spectacles are the most common approach to correction of presbyopia. However, many factors drive patients to seek independence from spectacles, and contact lenses provide such flexibility. With aging populations seeking to remain active,[32] contact lenses prescribed to address presbyopia have seen a steady increase in adoption, with a prevalence that has doubled in the last two decades.[33]

Multifocal contact lenses typically come in low, medium, and high Add powers. Traditional designs for simultaneous vision contact lenses often provide functional vision in early presbyopia when a low relative Add power is usually sufficient to supplement the residual accommodation of patients. However, satisfactory visual outcomes with multifocal lenses are often more challenging to achieve when patients move on to higher Add requirements with age.[5,9] Therefore, there is a common practice among fitters to "push" plus power during distance refraction on presbyopic patients, slightly sacrificing distance vision to gain a small amount of near vision, thereby allowing the fitter to prescribe the lowest possible Add power.[5] The catenary curve-based optical profile of the catenary contact lens is unique due to its application of a large EDOF, which creates a contiguous, elongated visual channel. In the present study, the catenary contact lens provided mature people suffering from presbyopia with uninterrupted functional vision at distance, intermediate, and near viewing distances, ranging from optical infinity to closer than 33 cm. Due to the rapid power progression associated with this design, a significant magnitude of Add is delivered even through smaller pupillary diameters; as such, a correlation was not observed between high illumination pupil size (2.3–4.6 mm) and visual performance in our study. This large EDOF enables a simplified fitting approach without the need to "push" plus, regardless of the age of the patient or the amount of Add requirement needed. Only an accurate distance refraction is needed to ensure the preservation of distance vision, and the full range of functional vision will follow.

All simultaneous-image optics have tradeoffs in image quality in certain environments. The defocus of this rapid and smooth power profile did not result in a reduction of binocular high-contrast, high-illumination vision, but it did show a minimal reduction of image contrast under binocular low-contrast and low-illumination conditions. On average, the low-contrast visual acuity at distance with the catenary contact lens was two-letters less than that with spectacle vision, but this difference was not statistically or clinically significant. The defocus intensity is low, so the benefit of the catenary EDOF optic appears to outweigh the reduction of image contrast at intermediate and near viewing distances.

The data for low-contrast visual acuity from our study corroborated the finding from PMET that stereoacuity was not influenced by the minimal reduction of image contrast. For individuals with presbyopia wearing catenary curve-based contact lenses, at 40 cm, stereoacuity was similar and statistically equivalent compared with the best near-corrected spectacle vision of participants (baseline, 32.97 ± 17.60 vs catenary, 36.90 ± 21.60 s of arc; $p > 0.05$).[24] Other studies have reported on the performance of populations requiring medium-to-high Add powers. Individuals wearing high-EDOF or medium-to-high Add zonal refractive multifocal lenses demonstrated average binocular low-contrast vision (0.17 to 0.31 logMAR) and average stereoacuity (100 to 163 s of arc). These averages were slightly worse than populations with a low Add requirement wearing corresponding low Add EDOF/zonal refractive center-near lens designs (binocular low-contrast vision, 0.15 to 0.22 logMAR; stereopsis, 92 to 155 s of arc).[12–14]

The data from defocus curves from our study cohort wearing the catenary curve-based contact lens were compared with PMET data (which included data from patients with presbyopia who had Add requirements between +1.00 and +2.50 D). This comparison sheds light on the visual performance of a wide range of Add requirements using the same profile of catenary power. Wearing the catenary curve-based contact lens, both cohorts had average distance and intermediate vision better than 20/20 and near vision at 20/25. There was no difference in vision between the high, medium, and low Add subgroups for the PMET cohort. These results suggest that data for defocus curves measured in our study could also represent a population of patients with presbyopia who need less Add requirement.

The data for subjective assessment agreed with the results from defocus curves; participants reported high scores for distance, intermediate, and near vision. They also reported high overall performance and no difficulty with daily visual activities. The subjective assessment from the PMET echoed the data from our cohort, and the stratified subgroups also displayed similar levels of satisfaction. The results for defocus curves appeared to be a good proxy to predict functional visual performance in the real world. In addition, catenary power profile optics may deliver a full range of functional vision that meets most daily visual activity needs for individuals with presbyopia with Add requirements from +1.00 to +2.50 D.

Best-distance spectacle correction was designed to serve as a baseline in the present study. Hence, one limitation of our study design was that the order of conditions was not randomized. All participants had defocus curves generated for baseline and then the catenary lens, so patient fatigue with the procedure might have affected our results. Regardless of this confounding factor, the study aim was to assess distance vision with the catenary lens relative to best-distance correction. Hence, while quantifying improvements to near vision, the objective of our study was met.

There are a few other limitations to this study. Future defocus curve studies could incorporate larger sample sizes and include presbyopic individuals requiring medium or low Add requirements. The goal of this study was to evaluate visual performance in advanced presbyopes, among which the trends for visual performance were strong. The catenary optic studied is highly aspheric, so the decentration of the optic may impact the visual performance. Since lens decentration was not evaluated in this study, we could not quantify the amount of the lens decentration and its impact on visual performance. In addition, since individual eyes demonstrate different amounts of spherical aberration (−0.3 to +0.7 um),[34] the resultant spherical aberration a patient receives from the study lens will vary. These study results reflect a real-world population mean, not necessarily the ideal optical performance of the len's design.

Conclusions

Our clinical data demonstrate that the highly aspheric catenary curve-based multifocal contact lens design extended the functional vision range of mature individuals with presbyopia (Add requirements ≥ +2.00 D) under conditions of naturally varying pupil sizes. The wide range of functional vision and minimal visual degradation observed in individuals with presbyopia with minimal residual accommodation wearing this lens supported their favorable subjective assessments. Our data are generalizable to wearers with medium and low Add requirements. As such, this catenary curve design may benefit individuals with presbyopia of all stages, making it a universal solution for the full spectrum of Add requirements.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author, DPB, upon reasonable request.

Acknowledgments

The authors thank Dr. Kenneth Daniels for serving as a Principal Investigator for this study at his office in Hopewell, NJ, USA. Hartmann–Shack wavefront measurement and power characterization were conducted by Dr Daniel Neal at WaveFront Dynamics Incorporated.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This clinical study was funded by Visioneering Technologies Incorporated.

Disclosure

KAT and DPB are employees of Visioneering Technologies, Incorporated (VTI). BO is a consultant to VTI. The authors report no other conflicts of interest in this work.

References

1. Mishra D, Bhushan P, Singh MK, et al. Prospective clinical study to find out epidemiology of presbyopia in a prepresbyopic population (age group 34–40 years). *J Clin Ophthalmol Res*. 2019;7(2):51–53. doi:10.4103/jcor.jcor_53_18
2. Croft MA, Glasser A, Kaufman PL. Accommodation and presbyopia. *Int Ophthalmol Clin*. 2001;41(2):33–46. doi:10.1097/00004397-200104000-00005
3. Chuck, RS, Jacobs, DS, Lee, JK et al. American Academy of Ophthalmology. Refractive errors and refractive surgery preferred practice pattern. *Ophthalmology*. 2017; 125(1):11. doi:10.1016/j.ophtha.2017.10.003
4. Wolffsohn JS, Davies LN. Presbyopia: effectiveness of correction strategies. *Prog Retin Eye Res*. 2019;68:124–143. doi:10.1016/j.preteyeres.2018.09.004
5. Morgan PB, Efron N, Papas E, et al. BCLA BLEAR presbyopia: management with contact lenses and spectacles. *Cont Lens Anterior Eye*. 2024;16:102158.
6. Montes-Mico R, Madrid-Costa D, Dominquez-Vicent A, et al. *In vitro* power profiles of multifocal simultaneous vision contact lenses. *Contact Lens Anterior Eye*. 2014;37(3):162–167. doi:10.10106/j.clae.2013.09.014
7. Kim E, Bakaraju RC, Ehrmann K. Power profiles of commercial multifocal soft contact lenses. *Optom Vis Sci*. 2017;94(2):183–196. doi:10.1097/OPX.0000000000000998
8. Kollbaum PS, Dietmeier BM, Jansen ME, et al. Quantification of ghosting produced with presbyopic contact lens correction. *Eye Contact Lens*. 2012;38(4):252–259. doi:10.1097/ICL.0b013e31825aa879
9. Fedtke C, Bakaraju RC, Ehrmann K, et al. Visual performance of single vision and multifocal contact lenses in non-presbyopic myopic eyes. *Contact Lens Anterior Eye*. 2016;39(1):38–46. doi:10.1016/j.clae.2015.07.005
10. Madrid-Costa D, Garcia-Lazaro S, Albarran-Diego C, et al. Visual performance of two simultaneous vision multifocal contact lenses. *Ophthalmic Physiol Opt*. 2013;33(1):51–56. doi:10.1111/opo.12008
11. Shah AS, Gundel R. Low-contrast visual acuity measurements in single-vision and bifocal soft lens wearers. *Int Contact Lens Clin*. 2000;27(4):119–123. doi:10.1016/S0892-8967(02)00067-6
12. Sha J, Bakarajiu RC, Tilia D, et al. Short-term visual performance of soft multifocal contact lenses for presbyopia. *Arq Bras Oftalmol*. 2016;79(2):73–77. doi:10.5935/0004-2749.20160023
13. Tilia D, Bakaraju RC, Chung J, et al. Short-term visual performance of novel extended depth-of-focus contact lenses. *Optom Vision Sci*. 2016;93(3):435–444. doi:10.1097/OPX.0000000000000806
14. Tilia D, Munro A, Chung J, et al. Short-term comparison between extended depth-of-focus prototype contact lenses and a commercially available center-near multifocal. *J Optom*. 2017;10(1):14–25. doi:10.1016/j.optom.2016.04.003
15. Dinardo A, Smiley G (2016). Causes of multifocal contact lens dissatisfaction. Presented at the American Academy of Optometry. Program #165109. Available from: http://www.aaopt.org/causes-multifocal-contact-lens-dissatisfaction. Accessed 19, July 2023.
16. Piers PA, Fernandez EJ, Manzanera S, et al. Adaptive optics simulation of intraocular lenses with modified spherical aberration. *Invest Ophthalmol Vis Sci*. 2004;45(12):4601–4610. doi:10.1167/iovs.04-0234
17. Rocha KM, Vabre L, Chateau N, et al. Expanding depth of focus by modifying higher-order aberrations induced by an adaptive optics visual simulator. *J Cataract Refract Surg*. 2009;35(11):1885–1892. doi:10.1016/j.jcrs.2009.05.059
18. Benard Y, Lopez-Gil N, Legras R. Subjective depth of field in presence of 4th-order and 6th-order Zernike spherical aberration using adaptive optics technology. *J Cataract Refract Surg*. 2010;36(12):2129–2138. doi:10.1016/j.jcrs.2010.07.022
19. Benard Y, Lopez-Gil N, Legras R. Optimizing the subjective depth-of-focus with combinations of fourth- and sixth-order spherical aberration. *Vis Res*. 2011;51(23–24):2471–2477. doi:10.1016/j.visres.2011.10.003

20. Yi F, Iskander DR, Collins M. Depth of focus and visual acuity with primary and secondary spherical aberration. *Vis Res*. 2011;51(14):1648–1658. doi:10.1016/j.visres.2011.05.006
21. Bakaraju RC, Ehrmann K, Ho A. Extended depth of focus contact lenses vs. two commercial multifocals: part 1. Optical performance evaluation via computed through-focus retinal image quality metrics. *J Optom*. 2018;11(1):10–20. doi:10.1016/j.optom.2017.04.003
22. McAlinden C, Moore J, McGilligan E, et al. Spherical aberration and higher order aberrations with Balafilcon A (PureVision) and Comfilcon A (Biofinity). *Graefes Arch Clin Exp Ophthalmol*. 2011;249(4):607–612. doi:10.1007/s00417-010-1476-9
23. Griffin RA, Payer RE, Tyson MK, et al. Induced aperture lens and method. US11,630,326. USPTO; 2023.
24. Lee R, Dillehay S, Sommer T. A novel extended depth of focus multifocal contact lens design. *Contact Lens Anterior Eye*. 2018;41(Suppl 1):S47. doi:10.1016/j.clae.2018.03.013
25. Montani G, van der Worp E. *Short-Term Optical and Visual Performance of Soft Contact Lenses for Myopia Management*. Las Vegas, USA: Global Specialty Lens Symposium poster; 2024.
26. Feldman B, Patel A, Masters JS, et al. Extended depth of focus IOLs. EyeWiki, American Academy of Ophthalmology; 2023. Available from: https://eyewiki.aao.org/Extended_Depth_of_Focus_IOLs#:~:text=TECNIS%20Symfony%20IOL-,Definition,that%20enhances%20depth%20of%20focus. Accessed September 5, 2023.
27. Eydelman MF Developing novel endpoints for premium intraocular lenses workshop. Available from: www.fda.gov/media/88701/download. Accessed 5, September 2023.
28. Richman EA FDA update: next-generation IOLs. *EyeNet* Magazine, 2014. Available from: www.aao.org/eyenet/article/fda-update-nextgeneration-iols. Accessed 5, September 2023.
29. US Food & Drug Administration, TECNIS® multifocal 1-piece IOL, ZKB00 and ZLB00. P980040/S049. SSED; 2014.
30. US Food & Drug Administration, TECNIS® symfony extended range of vision IOL. P980040/S065. SSED; 2016.
31. US Food & Drug Administration, AcrySof® IQ vivity™ intraocular lens. P930014/S126. SSED; 2020.
32. Agahi N, Parker MG. Are today's older people more active than their predecessors? Participation in leisure-time activities in Sweden in 1992 and 2002. *Ageing Soc*. 2005;25(6):925–941. doi:10.1017/S0144686X05004058
33. Morgan P, Woods C, Tranoudis I, et al. International contact lens prescribing in 2022, key trends in prescribing highlighted by our 22nd global survey. *Contact Lens Spectr*. 2023;38(1):28–35.
34. Kingston AC, Cox IG. Population spherical aberration: associations with ametropia, age, corneal curvature, and image quality. *Clin Ophthalmol*. 2013;7:933–938. doi:10.2147/OPTH.S44056