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Visual Performance and Binocular/Accommodative Function of S.T.O.P. Contact Lenses Compared With MiSight

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Objectives: The objective of this study was to compare the visual performance and binocular/accommodative function of two novel S.T.O.P. design (F2 and DT) contact lenses against MiSight when worn by myopic, young adults.
Method: This was a prospective, randomized, cross-over, single-masked study. Each lens was worn daily wear with overnight peroxide disinfection for approximately 7 days. Visual performance was assessed with subjective ratings (0–100): clarity of vision and lack of ghosting (far away, intermediate, and near), vision when driving, overall vision satisfaction, and with monocular high-contrast and low-contrast visual acuity (HCVA/LCVA) at 6 m, binocular HCVA (6 m, 70 cm, 50 cm, and 40 cm), binocular LCVA (6 m and 70 cm). Binocular function was assessed with heterophorias (3 m and 40 cm). Accommodative function was assessed with monocular accommodative facility (AF: 40 cm) and dynamic monocular accommodative response (AR: 6 m, 70 cm, and 40 cm).
Results: F2 was rated higher than MiSight for clarity of vision (near and intermediate) and lack-of-ghosting ($P<0.001$), while MiSight was rated higher than DT for clarity of vision (near, $P<0.001$). MiSight was better than F2 and DT for monocular HCVA (6 m) and binocular HCVA (6 m and 40 cm, $P\leq0.02$), but the maximum difference was ≤2 letters. There were no differences between designs for heterophoria ($P=0.61$) nor were there any differences between DT and MiSight for any accommodative measure ($P>0.1$). F2 was higher for monocular-AF ($P=0.007$) and lower for AR (70 cm and 40 cm; $P\leq0.007$) compared with MiSight.
Conclusions: The visual performance and binocular/accommodative function of S.T.O.P. designs F2 and DT were comparable with MiSight. F2 outperformed MiSight in some aspects of subjective visual performance and monocular accommodative function.

Key Words: Myopia—Contact lens—Dynamic optical cue—Visual performance—Binocular function—Accommodative function—S.T.O.P.—MiSight.

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An often quoted statistic in the field of myopia is approximately 50% of the world's population is expected to be myopic by 2050.[1] This potential prevalence is alarmingly high, given the associations between the increased risk of serious ocular pathology[2–4] and increased economic burden[5,6] with myopia. Optical strategies currently available for myopia management include spectacles,[7,8] orthokeratology,[9] and soft contact lenses (CLs).[10–14]

Soft CLs are safe to wear and easy to fit.[15–17] Several designs are effective in reducing myopia progression,[10–14] and MiSight (omafilcon A: CooperVision, Pleasanton, CA) is the only CL currently approved by the FDA for myopia management.[18] The mechanism for reducing myopia progression is most commonly an optical cue induced by peripheral myopic defocus,[10,11,14] while other designs induce relative defocus posterior to the retina.[13] All these soft CL designs have a rotationally symmetrical power profile[11,19] with no stabilization features, and thus, the optical cue is static, that is, the areas of induced defocus do not change even when the lens rotates on eye.

Soft CLs used for myopia management often show an initial period of high efficacy in reducing myopia progression followed by a decayed efficacy with time[10–14,20] (Fig. 1). Both initial high efficacy and subsequent decay are independent of age,[20] suggesting an adaptation effect, possibly because of the static optical cue, may be a factor. If true, then minimizing any adaptation effect, either by changing treatments[20] or providing a dynamic optical cue, may improve efficacy over time.

Contact lenses using the Spatio-Temporal Optical Phase (S.T.O.P.) technology aim to provide a dynamic optical cue through the combination of optical and peripheral carrier zones. The optical zone contains rotationally asymmetric power maps designed to have meridionally and azimuthally varying power distributions (Fig. 2), which introduces a conoid of Sturm on the retina that creates a type of astigmatic blur that may have efficacy in reducing myopia

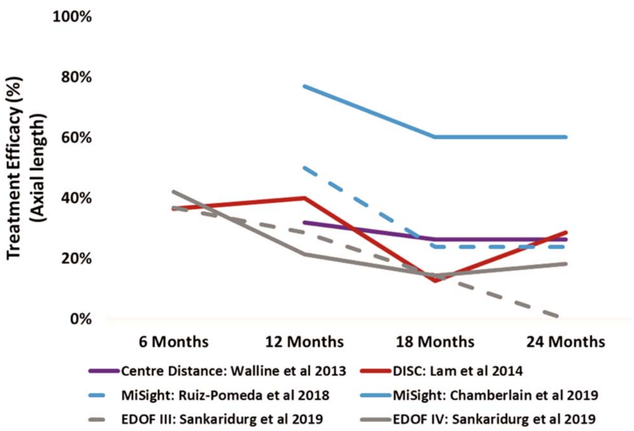

FIG. 1. Myopia management efficacy over a two-year period for five different contact lens designs.[11–14] Efficacy is based on change in axial length relative to each design's respective control.

progression.[21] The lens fit, including the peripheral carrier zone, is configured to facilitate free on-eye rotation. The combination of asymmetric design and free on-eye rotation provides an optical cue that is dynamic, that is, the areas of induced astigmatic blur change as the lens rotates on eye, rather than static.

Soft CLs used for myopia management can adversely affect visual performance[19,22,23] and binocular/accommodative function.[19,23] However, these designs can be successfully worn if effects are within the wearer's tolerance.[10,19,22,23] The aims of this study were to compare the visual performance (subjective, visual acuity [VA]) and binocular/accommodative function of two designs incorporating the S.T.O.P. technology (F2 and DT) against MiSight.

MATERIALS AND METHODS

Participants

Participants were required to be healthy, myopic, experienced soft CL wearers with ≤1.00 D of astigmatism and a CL prescription between −0.75 and −6.00 DS. Participants were also required to be nonpresbyopic (18 years or older and younger than 40 years), have best-corrected high-contrast visual acuity (HCVA) of at least 6/7.6 in each eye at 6 m, not be pregnant, have had no refractive surgery, and have no systemic or ocular conditions that may adversely affect CL wear.

Contact Lens Designs

The control lens was MiSight (base curve=8.7 mm and diameter=14.2 mm). Test lenses comprised investigational S.T.O.P. designs F2 and DT (Contaflex 42; Brighten Optix Corporation: New Taipei City, Taiwan: base curve=8.6 mm and diameter=14.0 mm). Power profiles of MiSight, F2, and DT were measured using NIMO^{evo} (Lambda-X, Nivelles, Belgium), and power maps are shown in Figure 2. A video-assisted pilot study conducted at nthalmic Pty Ltd, Sydney, Australia, observed that S.T.O.P. designs consistently rotated on-eye, with up to four complete rotations within 30 min of lens wear. Proclear 1 day (omafilcon A, CooperVision: base curve=8.7 mm and diameter=14.2 mm) was fitted to participants at baseline so that a spherical lens could be used as a reference against control and test lenses for VA and binocular/accommodative measurements.

Study Design

This was a prospective, randomized, single-masked (participant), cross-over study conducted at nthalmic. This study was reviewed and approved by a local Human Research Ethics Committee, prospectively registered on the Australia New Zealand Clinical Trials Registry (ACTRN12620001034921), and followed the tenets of the Declaration of Helsinki. Potential participants attended a screening visit, which comprised a routine optometric examination, to determine eligibility for this study. Eligible participants were invited to attend a baseline visit, followed by three fitting and assessment visits (Fig. 3). All participants gave written informed consent before any study procedures.

Study Visits

Baseline

Demographic data (age, sex, and ethnicity) were collected. Open-field autorefraction/keratometry (Grand Seiko WAM-5500: Shigiya Machinery Works Ltd, Hiroshima, Japan) was measured, subjective distance refraction was performed, and the ocular surface was assessed with slitlamp biomicroscopy (KSL-H5: Keeler, Windsor, United Kingdom). Eligibility was confirmed before fitting with Proclear, and the initial power was chosen based on the spherical equivalent subjective distance refraction. A monocular spherical overrefraction with a trial frame was performed, with an end point of the least minus power to achieve maximum HCVA at 6 m, and a new lens power was fitted if required. The final power Proclear lens was worn for VA and

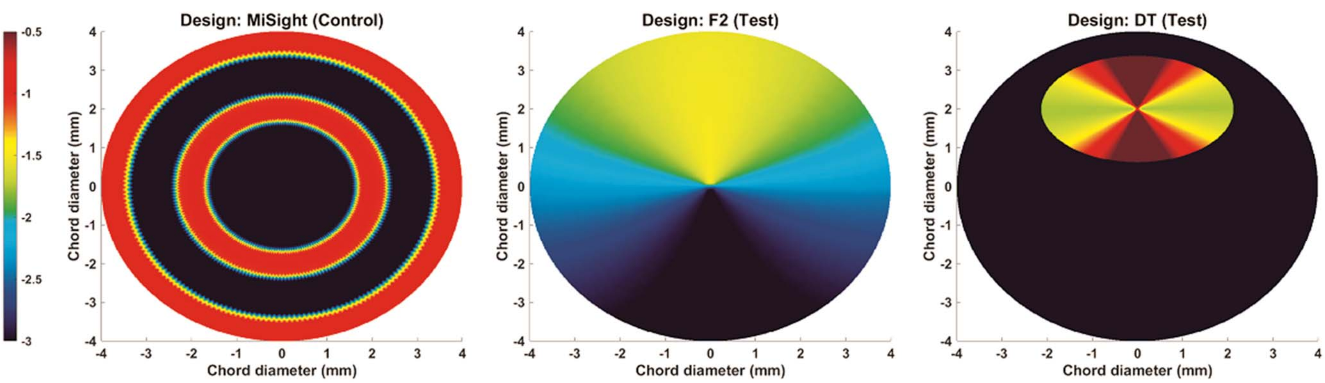

FIG. 2. Power maps for MiSight, F2, and DT. The labeled distance power for each design is −3.00 D.

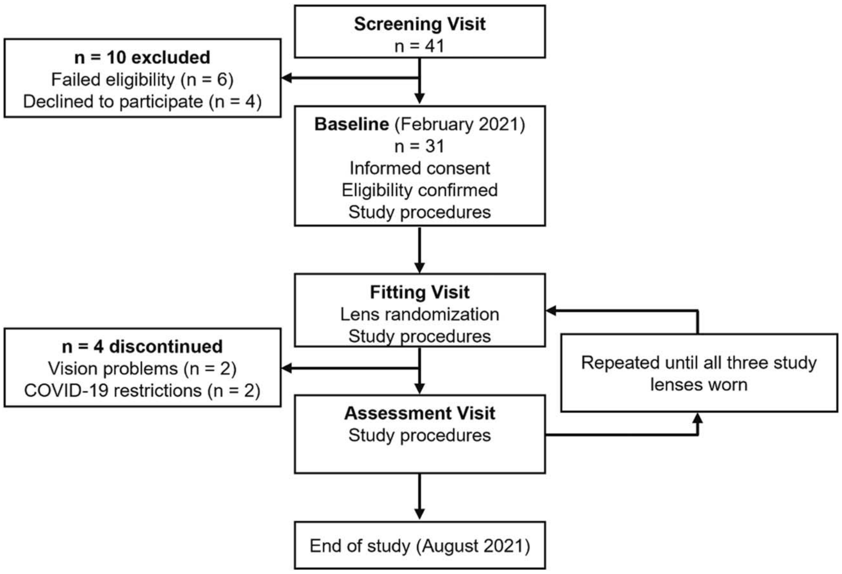

FIG. 3. Participant flowchart.

binocular/accommodative function measurements. Proclear lenses were removed and discarded at the completion of baseline.

Fitting Visits

The first fitting visit occurred at the completion of baseline, and the second and third fitting visits occurred at the completion of the first and second assessment visits, respectively (Fig. 3). Participants were fitted with one of three, randomly allocated lenses (MiSight, F2, and DT). An overrefraction was performed as described for Proclear, and a new lens power trialed if required. The dispensed lenses were worn for VA and lens fitting measurements and lens surface assessment. Participants were instructed to wear lenses daily wear with overnight disinfection in AOSEPT PLUS (CLEARCARE) with HYDRAGLYDE (Alcon: Sydney, Australia) and return for the assessment visit approximately 7 days (6–14 days) after the fitting visit.

Assessment Visits

Study lenses were worn while completing questionnaires for VA, binocular/accommodative function, and lens fitting measurements and lens surface assessment. Bulbar and limbal hyperemias were assessed before lens removal, and the remainder of the ocular surface assessment was performed after lens removal.

Study Procedures

All data were collected using direct data entry on an internet-based database (Castor EDC: https://au.castoredc.com/).

Questionnaires

Subjective ratings were assessed with a nonvalidated, combination visual analog/numeric rating scale. Participants entered data directly into the Castor database using a sliding scale with the numeric value of each rating visible. Ratings were scored from 0 to 100 in 1-point steps and comprised clarity of vision and vision when driving (0=blurred and 100=clear), ghosting (0=none and 100=severe), overall vision satisfaction (0=not satisfied and 100=satisfied), and comfort (0=uncomfortable and 100=comfortable). Participants were asked about their willingness to purchase lenses by answering the question “Would you purchase these lenses if they cost the same as your normal correction and they helped to slow down your rate of becoming short-sighted?” with a yes/no response.

Clarity of vision and vision when driving were rated for time (daytime and night time) and performance extreme (at best and at worst). The rating of performance extreme was used to assess variability in vision. Clarity of vision was additionally assessed for viewing distance (far away, intermediate, and near).

Ghosting was also rated for viewing distance. The ghosting scale consisted of three progressively ghosted letter “R’s”[24] (0=no ghosting, 50=moderate, and 100=severe) with a size of approximately 6/38 at 6 m. Participants were shown this scale at 6 m while wearing Proclear lenses at baseline. Subsequent ghosting ratings while wearing study lenses were made relative to Proclear. Overall vision satisfaction was rated as a single metric that considered all subjective aspects of visual performance. Comfort was rated for time of day (on lens application, during the day, and before lens removal).

Visual Acuity

Monocular and binocular HCVA and low-contrast visual acuity (LCVA) at 6 m were measured with a computerized logMAR letter chart. Binocular HCVA at 70 cm, 50 cm, and 40 cm was measured with a Lighthouse Near Visual Acuity Test (Precision Vision; Woodstock, IL) and binocular LCVA at 70 cm with a Logarithmic Low-Contrast Acuity Chart-2000 “New-ETDRS” (Precision Vision). Both near letter charts are calibrated to 40 cm, and thus, measurements at 70 cm and 50 cm were converted to equivalent values in logMAR[25] before statistical analyses. Low-contrast visual acuity at 6 m was measured under low illumination (<5 lux), and all other VAs were measured under high illumination (275–325 lux).

Binocular/Accommodative Function

Binocular function assessment comprised heterophoria (phoria), and accommodative function assessments comprised monocular accommodative facility (AF) and dynamic monocular accommodative response (AR) measurements. Phorias and monocular-AF

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were measured under high illumination as previously described.[26] In brief, phorias were measured at 3 m and 40 cm using the modified Thorington technique and monocular-AF at 40 cm with a ±2.00 D flipper.[26]

Accommodative response was calculated from autorefraction measurements taken with an open-field Grand Seiko WAM-5500. A consensual method was used as previously described.[27] In brief, the left lens was removed, and the left eye occluded under black cardboard placed on the tilted hot mirror of the autorefractor. The participant viewed targets with the right eye wearing a lens, and autorefraction measurements were taken on the left eye not wearing a lens (see Supplemental Digital Content 1A, http://links.lww.com/ICL/A241).

Accommodation targets comprised illuminated Maltese crosses at 6 m, 70 cm, and 40 cm, giving accommodative demands of 0.17 D, 1.43 D, and 2.50 D, respectively. Each cross was of equal apparent size. All Maltese crosses (see Supplemental Digital Content 1B, http://links.lww.com/ICL/A241) and plastic components (see Supplemental Digital Content 1A, http://links.lww.com/ICL/A241) were 3D printed. Customized hardware was used to automatically control targets each distance, with only one target illuminated during each testing sequence. Autorefraction measurements were recorded using Grand Seiko WCS-1 software. Measurements were taken in a dark room (<1 lux) to maximize visibility of the illuminated target and to minimize visibility of surrounding objects.

The autorefractor was placed in high-speed mode, and the testing sequence began at 6 m, followed by 70 cm and then 40 cm. Six autorefraction measurements were taken every second, each target was visible for 8 s, and each testing sequence lasted 24 s. Participants were instructed to always keep the visible target clear. Each testing sequence was repeated five times.

For any testing sequence, the minimum amount of accommodation occurred when the least minus autorefraction measurement at 6 m was taken. This measurement was used as the reference point, AR was calculated by subtracting each autorefraction measurement from the reference point,[28] and the mean AR was determined for each distance. Accommodative response calculations were also used to determine the SD (AR_{SD}) at each distance.

Lens Fitting, Lens Surface, and Ocular Surface

All variables were assessed with slitlamp biomicroscopy. Lens fitting comprised horizontal and vertical centration (mm), primary gaze movement and lag (mm), and tightness (%). Lens surface comprised wettability and front surface deposition, graded on a 0–4 scale[29] in 0.5 steps (0=fully wetting/no deposition and 4=poor wetting/high deposition). Ocular surface assessment comprised bulbar, limbal, and palpebral hyperemia; corneal and conjunctival staining; and palpebral roughness, graded on the Efron scale[30] (0–4 scale in 0.5-steps: 0=normal and 4=severe).

Statistical Analysis

A minimum sample of 27 participants were required to complete this study to demonstrate a statistically significant difference±SD of 10±18 units between control and each test design for subjective ratings at the 5% level of significance and with 80% power. This sample size also had 90% power to detect a difference in VA of 0.1±0.15 logMAR. A 10% drop-out rate was assumed, and thus, this study aimed to enroll 31 participants. All data analyses were performed with SPSS 28 (IBM, Armonk, NY), and significance was set at 5%. Post hoc multiple comparisons were adjusted with Bonferroni correction.

The ghosting ratings have been reversed to be consistent with other ratings so that a higher rating indicates better performance. The ghosting variable will therefore be referred to as "lack of ghosting." Data were summarized as mean±SD for variables measured on an interval scale and percentages for willingness to purchase. Raw data measured on an interval scale were assessed by observing Q-Q plots, and if observed values deviated from expected normal values, an appropriate transformation was applied before statistical analysis.

A linear mixed model with subject random intercepts was used to assess differences between MiSight and F2/DT for variables measured on an interval scale. This model accounts for within-participant correlation from two-eyed data and repeated measures. All models included lens (MiSight, F2, and DT) as a fixed factor. The other fixed factors comprised distance measured, visit, viewing distance, time, time of day, performance extremes, and repeatability, as applicable for each variable. Interactions between lens and all other fixed factors were tested, and if significant at the 10% level, the effects were assessed at each level of the interacting term at the 5% level. Willingness to purchase was analyzed with the χ^2 test.

Proclear lenses were not included in these analyses because they were not randomly allocated and were only worn at baseline. The results while wearing Proclear are presented for reference purposes only.

RESULTS

Demographics

A total of 41 participants were screened, 31 were enrolled and fitted with Proclear at baseline, and four discontinued during this study (Fig. 3). Two of the discontinuations were because of vision problems with study lenses (one MiSight and one DT), and two were because of a lockdown ordered by the NSW state government in May 2021 in response to an outbreak of the delta variant of COVID-19. Participants were included in the final analysis if they were fitted with at least one study lens and attended the subsequent assessment visit. Three participants discontinued after their first fitting visit, and one discontinued after their second fitting visit. The final data set comprised 28 participants (27 wore MiSight and F2 and 28 wore DT). Of the final data set, 67.9% were women, the mean age±SD was 27.5±6.0 years, 50.0% were Asian, 42.9% were White, and 7.1% were "other" ethnicity. No significant adverse events resulted from lens wear, and there were no instances where a lens fit was unacceptable.

Subjective Data

Differences between lenses for subjective ratings are presented in Table 1. F2 was rated higher than MiSight for clarity of vision (intermediate $P<0.001$ and near $P<0.001$) and for lack of ghosting ($P<0.001$). MiSight was rated higher than DT for clarity of vision at near ($P<0.001$), whereas there was no difference for clarity of vision at intermediate ($P=0.09$) or lack of ghosting ($P>0.99$). There were no differences between lenses for clarity of vision at far away ($P=0.16$), vision when driving ($P=0.06$), or overall vision satisfaction ($P=0.13$). As expected, clarity of vision and

TABLE 1. *Differences in Subjective Ratings of Visual Performance and Comfort Between Control (MiSight) and Test (F2 and DT)*

	Visual Performance Shows Distance-Viewed, and Comfort Shows Time of Day		Lens Design × Distance or Time	MiSight	F2		DT	
Variable	Rated for:	*P*	*P*	Mean±SD (95% CI)	Mean±SD (95% CI)	P^a	Mean±SD (95% CI)	P^a
Visual performance: subjective ratings (0–100 units)								
	Far away			63±23 (59–67)	67±19 (63–71)	—	64±22 (60–68)	—
				5.8 ± 2.0^b (5.5–6.2)	5.5 ± 1.8^b (5.2–5.9)	0.16	5.8 ± 1.8^b (5.5–6.2)	0.16
Clarity of vision	Intermediate	***0.003***	<***0.001***	61±24 (57–65)	71±18 (68–74)	—	57±23 (52–61)	—
				6.0 ± 2.0^b (5.6–6.4)	5.2±1.8 (4.8–5.5)	<***0.001***	6.4 ± 1.8^b (6.1–6.7)	0.09
	Near			64±28 (58–69)	78±16 (75–81)	—	56±26 (51–61)	—
				5.6±2.4 (5.2–6.1)	4.4±1.8 (4.1–4.8)	<***0.001***	6.4±2.0 (6.1–6.8)	<***0.001***
Vision when driving	—	0.06	0.13	58±25 (51–65)	64±23 (58–72)	0.06	64±23 **(58–72)**	0.06
Lack of ghosting	Far away Intermediate Near	0.37	0.13	64±30 (58–71)	79±24 (73–84)	<***0.001***	64±29 (58–70)	>0.99
Overall vision satisfaction	—	—	—	61±25 (51–70)	71±18 (64–78)	0.13	62±21 (54–69)	0.13
Comfort: subjective ratings (0–100 units)								
	On lens application			68±24 (59–77)	75±17 (69–82)	0.70	72±24 (63–81)	0.70
Comfort	During the day	***0.001***	0.29	77±17 (70–83)	70±18 (63–77)		71±18 (64–78)	
	Before lens removal			66±24 (57–75)	62±21 (54–70)		61±23 (52–70)	

Clarity of vision ratings are square root transformed (√[101-score]) before analysis because of negative skew. *P* values significant at the 5% level are shown in bold, italic font.

[a] *P* value is relative to MiSight.

[b] √units.

vision when driving were rated higher at daytime ($P \leq 0.002$) and "at best" ($P<0.001$), but both effects were independent of lens ($P>0.1$).

There was no difference between lenses for comfort ($P=0.70$). Comfort on lens application and during the day were rated significantly higher than comfort before lens removal ($P \leq 0.007$), and the effect was independent of lens ($P=0.29$). The proportion of those willing to purchase MiSight, F2, and DT was 57.1%, 74.1%, and 57.1%, respectively, but there was no difference between lenses ($P=0.30$).

Visual Acuities and Binocular/Accommodative Function

Differences between lenses for VA and binocular/accommodative function are presented in Table 2. MiSight was significantly better than both F2 and DT for monocular and binocular HCVA at 6 m ($P \leq 0.002$) and binocular HCVA at 50 cm ($P \leq 0.02$). There were no significant differences between lenses for any other VA measure ($P>0.07$).

There were no differences between lenses for phoria ($P=0.61$). F2 was better than MiSight for monocular-AF ($P=0.007$), whereas there was no difference between DT and MiSight ($P=0.76$).

There were no differences between lenses for either AR or AR_{SD} at 6 m ($P>0.5$) nor were there any difference between DT and MiSight at 70 cm and 40 cm ($P>0.06$). Accommodative response and AR_{SD} were significantly lower with F2 at 70 cm and 40 cm compared with MiSight ($P \leq 0.007$). For AR and AR_{SD}, repeatability was not significant ($P>0.09$) and there was an interaction between lens and repeatability ($P>0.4$).

Accommodative response with time for all lens designs is presented in Supplemental Digital Content 2, http://links.lww.com/ICL/A242. All lenses followed a similar trend in that the AR was initially higher than the accommodative demand at 6 m and initially lower than the accommodative demand at 70 cm and 40 cm. The AR stabilized for each lens design within 1 to 2 s at all accommodative demands.

Lens Fitting, Lens Surface, and Ocular Surface

F2 and DT showed less primary gaze movement and lag (mean difference [MD]<0.03 mm and <0.09 mm, respectively, $P<0.001$) and were tighter (MD<6%, $P<0.001$) than MiSight. There were no differences between lenses for centration ($P>0.3$), wettability ($P=0.98$), or deposition ($P=0.93$). Wettability and deposition were worse at the assessment visit ($P<0.001$), but the effect was independent of lens ($P>0.06$).

Eyes wearing MiSight showed less limbal hyperemia than either F2 or DT (MD<0.2 units, $P<0.02$). MiSight also showed less conjunctival staining than F2 (MD=0.4 units, $P=0.001$) but not DT ($P=0.21$). There were no differences between lenses for bulbar or palpebral hyperemia, corneal staining, or palpebral roughness ($P>0.28$).

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TABLE 2. *Differences in Visual Acuity and Binocular/Accommodative Function Between Control (MiSight) and Test (F2 and DT)*

	Distance		Lens Design × Distance	MiSight	F2		DT		Proclear 1 Day
Variable	Measured at:	*P*	*P*	Mean±SD (95% CI)	Mean±SD (95% CI)	*P* (Relative to MiSight)	Mean±SD (95% CI)	*P* (Relative to MiSight)	Mean±SD (95% CI)
Visual performance: visual acuity									
Monocular HCVA (logMAR)	6 m	—	—	−0.04±0.08 (−0.05 to −0.02)	0.00±0.09 (−0.01 to 0.02)	***<0.001***	−0.01±0.10 (−0.02 to 0.01)	***0.001***	−0.06±0.07 (−0.08 to −0.04)
Monocular LCVA (logMAR)	6 m	—	—	0.45±0.15 (0.42 to 0.48)	0.48±0.17 (0.45 to 0.52)	0.07	0.45±0.18 (0.42 to 0.48)	0.07	0.32±0.11 (0.30 to 0.35)
	6 m			−0.11±0.06 (−0.13 to −0.10)	−0.07±0.08 (−0.10 to −0.05)	***<0.001***	−0.08±0.07 (−0.10 to −0.06)	***0.002***	−0.12±0.06 (−0.14 to −0.10)
	70 cm			−0.07±0.08 (−0.09 to −0.04)	−0.07±0.08 (−0.09 to −0.05)	0.16	−0.05±0.09 (−0.08 to −0.03)	0.16	−0.09±0.07 (−0.11 to −0.06)
Binocular HCVA (logMAR)	50 cm	***<0.001***	***0.03***	−0.11±0.07 (−0.13 to −0.09)	−0.08±0.08 (−0.10 to −0.06)	***0.02***	−0.07±0.09 (−0.09 to −0.05)	***<0.001***	−0.09±0.08 (−0.12 to −0.07)
	40 cm			−0.08±0.03 (−0.09 to −0.07)	−0.08±0.04 (−0.09 to −0.07)	0.11	−0.07±0.05 (−0.08 to −0.05)	0.11	−0.09±0.03 (−0.10 to −0.08)
Binocular LCVA (logMAR)	6 m	***<0.001***	0.44	0.29±0.11 (0.26 to 0.32)	0.31±0.12 (0.28 to 0.35)	0.72	0.30±0.16 (0.26 to 0.34))	0.72	0.19±0.08 (0.16 to 0.22)
	70 cm			0.12±0.08 (0.10 to 0.14)	0.11±0.09 (0.09 to 0.14)		0.13±0.10 (0.10 to 0.15)		0.08±0.08 (0.05 to 0.10)
Binocular vision									
Phoria ($^{\Delta}$)	3 m	***<0.001***	0.85	−1.9±4.0 (−3.4 to −0.4)	−2.0±4.2 (−3.6 to −0.4)	0.61	−1.8±3.6 (−3.1 to −0.4)	0.61	−1.3±3.4 (−2.5 to −0.1)
	40 cm			−3.7±5.2 (−5.6 to −1.7)	−4.2±5.7 (−6.4 to −2.1)		−3.6±5.5 (−5.6 to −1.5)		−3.2±6.2 (−5.4 to −1.0)
Accommodation									
Monocular-AF (cycles/min)	40 cm	—	—	10.5±5.3 (8.5 to 12.5)	12.2±5.9 (10.0 to 14.4)	***0.007***	10.9±6.6 (8.5 to 13.4)	0.76	11.7±5.4 (9.8 to 13.6)
Dynamic monocular AR (D)	6 m	***<0.001***	**0.06**	0.2±0.1 (0.2 to 0.3)	0.2±0.1 (0.19 to 0.23)	0.54	0.2±0.1 (0.2 to 0.3)	0.54	0.2±0.3 (0.2 to 0.3)
	70 cm			1.0±0.4 (0.9 to 1.0)	0.8±0.4 (0.7 to 0.8)	***< 0.001***	0.9±0.3 (0.8 to 0.9)	0.15	1.0±0.4 (0.9 to 1.1)
	40 cm			1.7±0.5 (1.6 to 1.8)	1.6±0.5 (1.5 to 1.7)	***0.007***	1.7±0.5 (1.6 to 1.8)	0.43	1.9±0.6 (1.7 to 2.0)
Dynamic monocular AR_{SD} (D)	6 m	***<0.001***	***0.03***	0.13±0.06 (0.11 to 0.14)	0.13±0.08 (0.11 to 0.14)	0.79	0.12±0.07 (0.11 to 0.13)	0.79	0.13±0.09 (0.11 to 0.14)
	70 cm			0.22±0.08 (0.20 to 0.24)	0.17±0.07 (0.16 to 0.19)	***<0.001***	0.20±0.08 (0.18 to 0.25)	0.09	0.23±0.09 (0.21 to 0.25)
	40 cm			0.23±0.09 (0.22 to 0.25)	0.20±0.08 (0.19 to 0.22)	***<0.001***	0.23±0.10 (0.21 to 0.25)	0.06	0.25±0.12 (0.22 to 0.27)

P values significant at the 5% level are shown in bold, italic font. Interaction between lens design and distance significant at the 10% level are shown in bold font. Proclear 1 day data are presented for reference purposes only.

Phoria: positive=esophoria, negative=exophoria.

AF, accommodative facility; AR, accommodative response; CI, confidence interval; HCVA, high-contrast visual acuity; LCVA, low-contrast visual acuity.

DISCUSSION

This study reports on the visual performance and binocular/accommodative function of S.T.O.P. designs F2 and DT compared to MiSight. The two measures of visual performance (subjective ratings and VA) showed contrasting results. F2 was rated higher than MiSight for clarity of vision (intermediate and near) and lack of ghosting, while MiSight was rated higher than DT for clarity of vision at near (Table 1). The mean VA was generally better with MiSight, achieving statistical significance for monocular HCVA at 6 m and binocular HCVA at 6 m and 70 cm compared with both F2 and DT (Table 2).

Several studies have reported similar discrepancies between subjective visual performance and VA with MiSight,[19,31,32] and an explanation based on optical modeling has been provided by Sha et al.[19] In brief, MiSight results in relatively large blur patches in the line spread function indicating reduced contrast and lower subjective visual performance, but a relatively steep slope in the edge spread function offering better resolution ability and thus better VA.[19]

For multifocal CLs, subjective measures are a better indicator of visual performance than VA,[33,34] and considering the small differences in VA (MD≤2 letters), the visual performance of S.T.O.P. designs seem comparable with MiSight, while F2 is better for some aspects of subjective visual performance. Any variability in vision caused by the dynamic optical cue provided by S.T.O.P. designs seem to be no different to the static optical cue provided by MiSight, based on the significant differences in performance extreme for clarity of vision and vision when driving ($P<0.001$) being independent of lens ($P<0.6$). Furthermore, the results from this study are not influenced by comfort[19] because there were no difference between lenses ($P=0.70$), although all lenses showed the expected decrease in comfort at lens removal.[35]

There was also no difference between lenses for overall vision satisfaction, despite a clinically relevant difference of 10 units[36] being achieved between F2 and MiSight. However, this result was probably influenced by the higher than expected SD with MiSight (25 vs. 18 units), resulting in available statistical power reduced to less than 65% and suggesting that the nonsignificant difference may have been influenced by a type II error. There was no difference between lenses for willingness to purchase, suggesting that myopes are willing to sacrifice some visual performance for the perceived benefit of achieving reduced myopia progression, as has been previously reported.[19]

Binocular function was comparable between lenses, and monocular accommodative function was comparable between MiSight and DT (Table 2). The power maps for MiSight and F2 (Fig. 2) show that the plus power with MiSight is distributed away from the lens geometric center, while any plus power with F2 is distributed asymmetrically but close to the lens geometrical center. Thus, F2 is more likely to influence accommodation, as demonstrated by the reduced AR at 70 cm and 40 cm compared with MiSight. The higher AR_{SD} with MiSight compared with F2 at 70 cm and 40 cm suggests that AR was less stable while wearing MiSight. Both reduced and more stable AR at 70 cm and 40 cm while wearing F2 compared with MiSight are demonstrated in the dynamic AR plots as presented in Supplemental Digital Content 2, http://links.lww.com/ICL/A242. A recent study by Gifford et al.[37] reported similar findings in that static AR with MiSight approximated a single vision lens and was increased and more unstable compared with multifocal designs. Monocular-AF was also higher with F2 compared with MiSight, which agrees with Sha et al.[19] who reported MiSight caused greater disruption to monocular-AF compared with other multifocal designs. These differences in monocular accommodative results between MiSight and F2 may have influenced the higher ratings for clarity of vision (intermediate and near) with F2, despite the nonsignificant difference between lenses for near phoria (P=0.61) suggesting comparable binocular AR.[38]

Both S.T.O.P. designs were observed to be tighter fitting with less movement (P<0.001) compared with MiSight. Although these findings may not have affected the overall results of this study, they may have influenced differences in limbal hyperemia and conjunctival staining between S.T.O.P. and MiSight.

Irrespective of this study's findings, the utility of S.T.O.P. designs lie in the field of myopia management. The efficacy of S.T.O.P. designs for reducing myopia progression compared with MiSight will be assessed in a multisite, randomized clinical trial (NCT05243836).

There were some potential limitations in this study. Although MiSight is intended for single use, it was reused, which may have adversely affected the results at the assessment visit. However, there were no differences between lenses for wettability or deposition (P>0.9), and although both variables were worse at assessment visits (P<0.001), the effect was independent of lens (P>0.06). Subjective performance was assessed with a nonvalidated questionnaire, but the randomized, cross-over design would have kept any issues regarding bias or content validity constant through the repeated measures of the questionnaire.[19,25] Therefore, these potential limitations did not affect this study's overall findings.

CONCLUSIONS

The dynamic optical cue provided by S.T.O.P. designs F2 and DT shows comparable visual performance and binocular/accommodative function compared with the static optical cue provided by the MiSight design. F2 outperformed MiSight in some aspects of subjective visual performance and monocular accommodative function.

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