Title:

Patient experience and physiological response to two commercially available daily disposable myopia control contact lenses

Author list:

Neema Ghorbani-Mojarrad[1,2]

Catherine Cargill[3]

Sophie Collard[3]

Louise Terry[3] (corresponding author)

1. School of Optometry and Vision Science, University of Bradford, Bradford, UK.
2. Wolfson Centre for applied health research, Bradford Teaching Hospitals, Bradford, UK.
3. School of Optometry and Vision Sciences, Cardiff University, Cardiff, UK.

Corresponding author contact details:

Address: School of Optometry and Vision Sciences, Cardiff University, Maindy Road, Cardiff, CF24 4HQ.

Telephone: 029 2087 0247

Email: terryl1@cardiff.ac.uk

Author declarations and disclosures:

The authors declare no competing or commercial interests. No financial disclosures

Ethical approval was obtained for the project from the School Research Ethics Committee, within the School of Optometry and Vision Sciences at Cardiff University.

Authors' contributions:

LT had full access to all the data in the study and acts as the guarantor for integrity of the data.

Concept and design: LT, NGM
Data collection and supervision: all authors
Statistical analysis: LT, CC, SC
Drafting of the manuscript: NGM, LT
Critical revision of the manuscript: all authors

Funding:

This project was supported by the British Contact Lens Association Summer Studentship Award (recipient Catherine Cargill under the supervision of Louise Terry and Neema Ghorbani Mojarrad).

Acknowledgements:

The authors would like to thank the participants who took part in this project, and the BCLA for their funding of this research. The authors would also like to thank Professor Jeremy Guggenheim for his guidance and feedback.

1

2

Patient experience and physiological response to two commercially available daily disposable myopia control contact lenses

ABSTRACT

Background: A range of myopia management (MM) contact lenses are becoming available to practitioners. These lenses are designed to slow myopia progression and axial elongation. This study explored the initial experience of participants wearing daily disposable MM contact lenses to investigate established factors previously associated with successful lens wear.

Methods: This was a prospective, double-masked, crossover study. Twenty participants aged 18-30 years old were assigned to wear two daily disposable MM lenses in a randomised order. Visual acuity, contrast sensitivity, and amplitude/lag of accommodation were assessed at baseline, post-insertion, and after 2 and 6 hours of lens wear. Self-reported lens comfort and vision quality were recorded at the same timepoints, and at 10 hours post-insertion. Pairwise comparisons were performed between the two lenses at each timepoint, as well as assessing changes throughout wear. The relationship of the measured parameters to overall lens satisfaction was also assessed.

Results: There were no significant differences between the two MM lenses at any timepoint for any of the participant-reported parameters, including overall satisfaction. A small difference in visual acuity was noted at 6 hours post-insertion, although this is unlikely to be clinically significant. Comfort decreased throughout the day, most notably at 10 hours post-insertion. A moderate positive correlation was observed between participant-reported visual quality and overall satisfaction. A similar pattern was seen for comfort and overall satisfaction. Self-reported vision quality and measured visual acuity were poorly correlated, highlighting the benefit of subjectively assessing the quality of vision with these lenses.

Conclusions: The participants demonstrated comparable measures across a range of measures between the two MM lenses. Notably, half of the participants demonstrated a clear lens preference, although the preferred lens varied between individuals. Candidates for MM may benefit from trialling more than one MM lens design, to maximise initial wearing satisfaction.

Keywords:

Myopia control, Myopia management, Dual focus, Extended depth of focus, Patient experience

Introduction

The prevalence of myopia has increased across the world in recent decades, and is predicted to rise further, with 50% of the global population predicted to be myopic by 2050.[1] Increased prevalence

in the population is cause for concern, as people with myopia require correction with spectacle lenses or contact lenses to view distance clearly, and also have a significantly increased risk of developing associated sight-threatening pathology. A lower level of myopia between -1.00D and -2.75D still introduces a 2-3 fold increased risk of myopic maculopathy, retinal detachment, and glaucoma compared to individuals who are emmetropic.[2] Because of this impending rise in the number of myopia-related eye conditions over the coming years and the expected economic burden on healthcare service providers, myopia has been categorised as a serious global public health concern, causing greater interest in prescribing interventions for myopia.[3, 4]

Due to the impact on future healthcare services and the increased risk of sight loss, many investigations into myopia interventions have been performed, particularly aimed at limiting myopia progression and axial elongation. This has led to the development of pharmacological and optical interventions, such as atropine and specialised contact lenses.[4] This includes soft contact lenses specifically designed to slow progression. These use either a dual-focus optical design or an extended-depth-of-focus design.[5-7] Peripheral myopic defocus has been shown to reduce the progression of axial elongation and refractive error in mammalian animal models,[8, 9] and human clinical trials.[10, 11] The primary outcome during MM clinical trials has been myopia control efficacy, with less emphasis on the report of initial lens comfort and patient satisfaction.[5, 7] Dropout is a significant problem in contact lens wear, with common reasons given by patients include poor vision at distance and near, handling difficulty, and discomfort [12, 13]. Such factors may impede the success of implementing myopia control through contact lens-based interventions. In this study, the initial patient experience and physiological response to two daily disposable myopia management contact lenses that are licenced for use in many parts of the world were explored.

Methods

Study Lenses

The two daily disposable contact lenses used in this study were MiSight® (MS; CooperVision Inc.) and NaturalVue® Multifocal 1 Day (NV; Visioneering Technologies Inc.). MS has an annular dual focus design, with four alternating distance and treatment zones (which include an addition power maximum of +2.00D),[14] whereas NV has an extended-depth-of-focus (EDOF) design, with distance correction in the centre, surrounded by a ring of steep progression into highly positive power at the edge of the optical zone equivalent to +20.00D plus power.[15] Additional characteristics of these lenses are shown in Table 1. These lenses were chosen for this experiment as both are commercially available and are licensed for use in myopia control in the UK.

Table 1. Characteristics of the study lenses. Information from The ACLM Contact Lens Year Book 2020.[16]

	MiSight®	**NaturalVue® multifocal 1 day**
Manufacturer	CooperVision Inc.	Visioneering Technologies Inc.
Material	Omafilcon A 2	Etafilcon A
Base curve (mm)	8.7	8.3
Total diameter (mm)	14.0	14.5
Water content (%)	60	58
Oxygen permeability (ISO units)	19	15
Back vertex power range (D)	-0.25 to -6.00	+4.00 to -12.25
UV inhibitor	None	Class 2

Study Design

This was a prospective, randomised, double-masked crossover study conducted at a single site. Participants were recruited between July 2019 and April 2020. The study was granted ethical approval from the University Research Ethics and Audit Committee prior to the study commencing. The study conformed to the tenets of the Declaration of Helsinki, and all participants provided written informed consent before taking part.

Inclusion criteria included: age between 18-30 years old, deemed suitable for contact lens wear following ophthalmic assessment, and current spectacle prescription available. The upper age limit was chosen to minimise the effect of accommodative reduction from presbyopia. Spherical equivalent refractive error range was limited to the available lens parameters (-0.25D to -6.00D). Those with a cylindrical refractive error of more than -1.00DC were excluded, as well as previous established rigid gas permeable lens wearers. As using contact lens neophytes may have introduced bias towards a preference for the second of the two test lenses worn, only individuals with previous soft contact lens wearing experience were included in this study. This also provided greater validity of participants' reports of lens handling preference between lenses. Participants who presented at either visit with contraindications to contact lens wear, such as hyperaemia (Efron grade ≥ 2), pain, corneal staining with sodium fluorescein (Efron grade ≥ 2), or a recent history of ocular infection or irritation, were also excluded.

Participants attended two visits in total, with a maximum gap of one week between appointments. They were also asked to avoid any contact lens wear for at least 24 hours before each study visit. At each visit, the participant was assigned one of the two lens types to wear for 10 hours, in a randomised

order (determined using an online coin toss). The lens packaging was over-labelled prior to the appointment by a different member of the research team, so that both the participant and the investigator conducting the data collection were masked to the lens type being worn. Lens fit was assessed using the simplified soft lens recording approach.[17]

Before lens insertion, participants underwent a series of visual function and physiological anterior eye measures to ensure that both eyes were healthy, and to monitor ocular response during contact lens wear. These procedures were repeated after lens insertion, and participants then underwent further measures at 2-hours and 6-hours post-insertion. A questionnaire was completed by participants at baseline, the 2-hour and 6-hour visits, and finally at 10 hours post-insertion, before lens removal. The questionnaire included visual analogue scales for rating each subjective parameter; these were then converted to a score out of 100. Participants were instructed to wear the lenses for 10 hours, but to monitor this, participants were asked to report their wearing time for each lens to the nearest half hour. A full list of assessments conducted at each timepoint can be found in Table 2.

Table 2. Study schedule for each of the two visits.

		Baseline	Insertion	2 hours post-insertion	6 hours post-insertion	10 hours post-insertion
Physiological measures	Visual acuity (ETDRS)	✓	✓	✓	✓	×
	Near visual acuity	✓	✓	✓	✓	×
	Contrast sensitivity (Pelli-Robson)	✓	✓	✓	✓	×
	Amplitude of accommodation (binocular; RAF rule)	✓	✓	✓	✓	×
	Accommodative lag/lead (Nott dynamic retinoscopy)	✓	✓	✓	✓	×
	Bulbar hyperaemia (Efron grading scale)	✓	✓	✓	✓	×
	Limbal hyperaemia (Efron grading scale)	✓	✓	✓	✓	×
Questionnaire items	Ocular comfort	✓	✓	✓	✓	✓
	Lens awareness	×	✓	✓	✓	✓
	Central vision	×	✓	✓	✓	✓
	Peripheral vision	×	✓	✓	✓	✓
	Ease of insertion	×	✓	×	×	×
	Ease of removal	×	×	×	×	✓
	Overall satisfaction	×	×	×	×	✓
	Wear time	×	×	×	×	✓

During wear, participants were asked to conduct their regular day-to-day activities. This broadly consisted of work-related office activities, lecture attendance, outside walking, and other actions they would usually perform on a typical day. This varied for each participant, but was to evaluate the lenses under habitual circumstances.

Data analysis

Data analysis was conducted using SPSS (version 25), on only the right eye of each participant. The data were found to be non-normally distributed (Kolmogorov-Smirnov test, $P<0.05$); non-parametric statistics were therefore used throughout the analysis.

Each questionnaire item or physiological measure at each timepoint was compared, pairwise, between the 2 lens types using a Wilcoxon Signed-Rank test. For between-timepoint comparisons, a Friedman test was performed, but baseline (pre-lens insertion) timepoint was excluded in order to enable evaluation of lens performance over the wearing time only. Spearman's rank correlation coefficients were calculated to examine the covariation between the various parameters investigated. Since the number of statistical tests performed was high, correction for multiple testing was considered. However, since this study was exploratory in nature, it was decided that multiple testing correction was not appropriate.[18] Therefore, unadjusted p-values are presented in the Results section.

Results

A total of 20 participants were enrolled. The mean ± standard deviation age was 23.8 ± 3.49 years (range 19 to 29) and the mean spherical contact lens correction power worn by participants was -2.65 ± 1.42D (range -0.50D to -5.75D). Seventeen (85%) of the participants were female. All lens fits were deemed acceptable during the initial assessment. All participants wore both sets of lenses and completed the trial successfully. No adverse events or contraindications were reported.

Lens type comparisons

The results of the pairwise comparisons of the physiological parameters and questionnaire responses are shown in Tables 3 and 4, respectively. Near visual acuity did not change at any timepoint with either lens; all values were recorded as N6 or better. Visual acuity was similar for both lenses, except at the 6-hour timepoint, when acuity was slightly poorer with NV than MS (-0.14 ± 0.12 and -0.20 ± 0.09 logMAR, respectively; $P=0.003$; Figure 1). Amplitude of accommodation was lower for the MS lens throughout the day, although this only attained statistical significance at the 2-hour timepoint (8.06 ± 2.06 and 9.15 ± 1.78 Dioptres, respectively; $P=0.007$). Contrast sensitivity and limbal hyperaemia were significantly different between trials at baseline, with the MS trial having a poorer

contrast sensitivity (P=0.035) and lower grade of limbal hyperaemia (P=0.046), prior to lens insertion. There were no statistically significant differences for any of the questionnaire responses assessed, including overall satisfaction, at any timepoint (P>0.05 in all cases).

Individuals commonly expressed a preference for one lens type over the other. Specifically, half the participants reported a difference in overall satisfaction of at least 25% between the lenses. However, there was no clear overall preference for a particular lens.

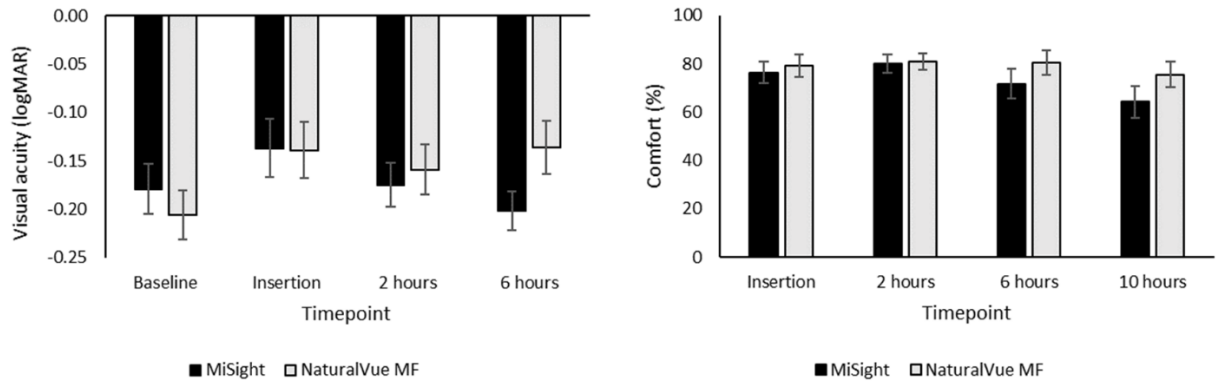


Figure 1. Comparison of visual acuity (left) and comfort (right) over time for the two lenses used in this study. Error bars represent standard error. Only parameters demonstrating a significant change throughout wear are shown (P>0.05; visual acuity and comfort).

Table 3. Comparison of the visual and physiological parameters assessed in the MiSight (MS) and NaturalVue multifocal (NV) contact lenses.

		Baseline			Insertion			2 hours post-insertion			6 hours post-insertion			Between timepoints
		Mean	**SD**	**P**	**Mean**	**SD**	**P**	**Mean**	**SD**	**P**	**Mean**	**SD**	**P**	**P**
Visual acuity (logMAR)	**MS**	-0.18	0.12	0.331	-0.14	0.13	1.000	-0.18	0.10	0.592	-0.20	0.09	**0.003***	**0.006***
	NV	-0.21	0.11		-0.14	0.13		-0.16	0.11		-0.14	0.12		0.265
Contrast sensitivity	**MS**	1.56	0.11	**0.035***	1.51	0.12	0.414	1.52	0.11	0.257	1.54	0.11	0.180	0.050
	NV	1.61	0.11		1.52	0.13		1.50	0.15		1.52	0.14		0.368
Amplitude of accommodation (D)	**MS**	9.28	1.63	0.148	8.30	2.00	0.287	8.06	2.06	**0.007***	8.50	1.29	0.105	0.726
	NV	9.63	1.60		8.93	1.65		9.15	1.78		8.84	2.16		0.232
Accommodative lag (D)	**MS**	0.33	0.55	0.889	0.49	0.75	0.637	0.43	0.79	0.799	0.37	0.68	0.859	0.250
	NV	0.30	0.35		0.26	0.44		0.22	0.46		0.26	0.45		0.459
Conjunctival hyperaemia (Efron grade)	**MS**	0.68	0.54	0.791	-			0.93	0.61	0.357	0.90	0.62	0.470	0.317
	NV	0.70	0.50		-			0.83	0.52		0.83	0.52		1.000
Limbal hyperaemia (Efron grade)	**MS**	0.55	0.46	**0.046***	-			0.68	0.41	0.206	0.75	0.50	0.527	0.180
	NV	0.75	0.47		-			0.78	0.47		0.80	0.55		0.655

Table 4. Comparison of the questionnaire responses for the MiSight (MS) and NaturalVue multifocal (NV) contact lenses.

		Baseline			Insertion			2 hours post-insertion			6 hours post-insertion			10 hours post-insertion			Between timepoints
		Mean	**SD**	**P**	**Mean**	**SD**	**P**	**Mean**	**SD**	**P**	**Mean**	**SD**	**P**	**Mean**	**SD**	**P**	**P**
Ocular comfort	**MS**	93.4	8.80	0.192	76.3	19.6	0.485	79.9	16.9	0.794	71.6	27.5	0.097	64.2	28.9	0.165	**0.007***
	NV	90.5	13.6		79.2	20.5		81.0	15.0		80.5	22.4		75.6	24.3		0.307
Lens awareness	**MS**				67.5	28.6	0.337	64.5	30.6	0.276	71.1	30.5	0.394	62.7	26.6	0.210	0.668
	NV				60.7	30.5		72.0	25.8		76.1	21.4		67.0	21.8		0.228
Central vision	**MS**				62.4	22.6	0.955	66.0	22.1	0.952	67.5	23.1	0.672	69.0	26.6	1.000	0.077
	NV				63.8	25.0		65.6	25.4		63.1	29.4		67.0	21.8		0.824
Peripheral vision	**MS**				66.1	27.2	0.571	70.9	20.5	0.144	70.0	22.1	0.107	67.4	22.4	0.587	0.277
	NV				64.2	28.3		63.3	29.2		61.2	27.4		64.4	23.0		0.742
Ease of insertion	**MS**				75.3	28.7	0.255										
	NV				82.2	23.1											
Ease of removal	**MS**													92.2	16.1	0.507	
	NV													93.4	15.5		
Overall satisfaction	**MS**													54.4	28.3	0.380	
	NV													59.3	27.2		
Wear time (hours)	**MS**													9.63	0.78	0.492	
	NV													9.85	0.67		

Comparisons over time

From lens insertion, an improvement in visual acuity for the MS lens was observed between lens insertion and 2 hours, which was maintained to the 6-hour timepoint (Friedman test; P=0.006; Figure 1). The NV lens displayed consistent visual acuity throughout this period (P=0.265). Visual acuity was the only physiological parameter demonstrating a statistically significant difference between insertion and later timepoints (Table 3). There were no clear trends observed in contrast sensitivity, amplitude of accommodation, or accommodative lag post-insertion.

Compared to baseline visual acuity (measured with habitual correction pre-lens insertion), the MS lens achieved comparable visual acuity, although visual acuity remained poorer than baseline for the NV lens throughout wear. An equivalent trend was noted for contrast sensitivity, with participants achieving a level of contrast sensitivity comparable to baseline when wearing the MS lens but a consistently reduced level when wearing the NV lens. However, the contrast sensitivities observed were not statically significantly different between lenses. Amplitude of accommodation was reduced compared to baseline at all timepoints for both lenses, however this demonstrated significance only for the NV lens (P=0.075 vs P=0.015 in the MS and NV lenses, respectively). Accommodative lag increased in the MS lens compared to baseline, whilst it reduced slightly for the NV lens. Both conjunctival and limbal hyperaemia were elevated from baseline after 2 and 6 hours of wear, although this was less marked for the NV lens where the baseline grades were higher. There were no significant changes in either parameter between the 2- and 6-hour timepoints for either lens (P>0.05 in all cases).

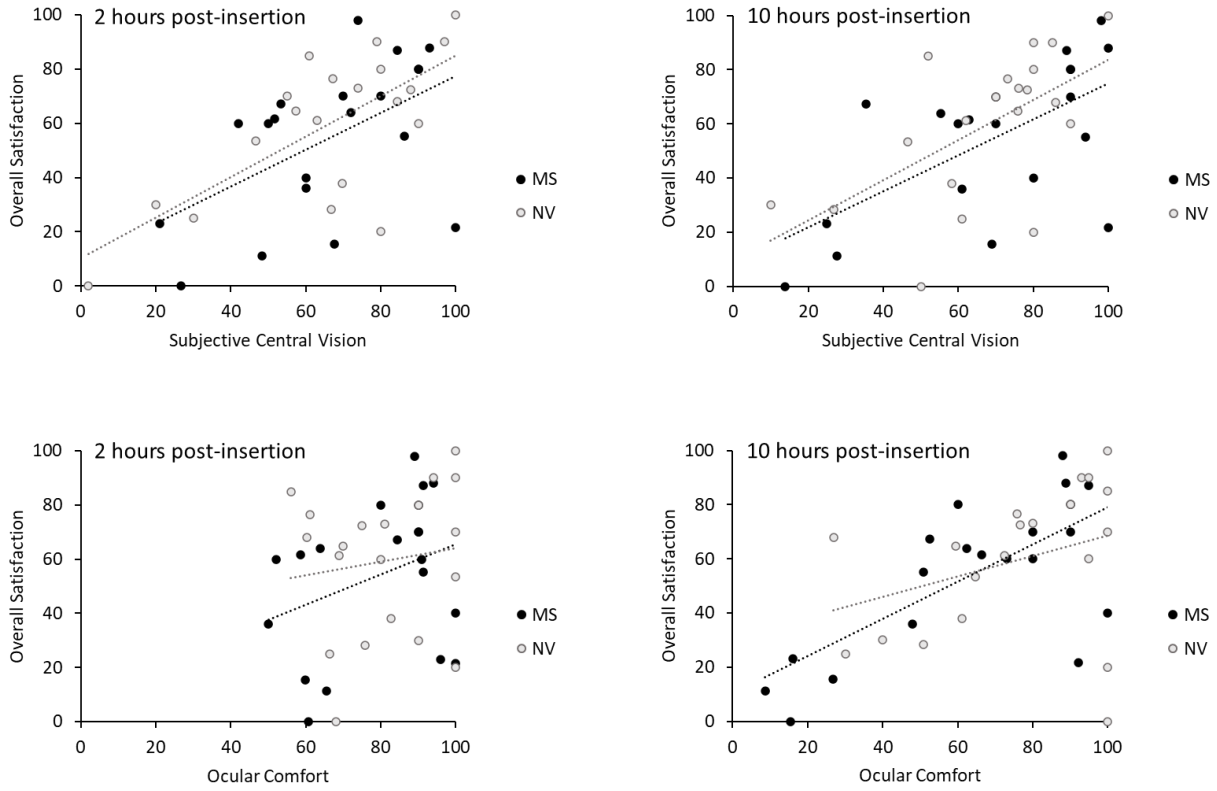
Questionnaire-based assessment of lens performance over time (Table 4) demonstrated no remarkable changes to central or peripheral vision throughout wear. Ocular comfort was significantly reduced at 6 and particularly 10 hours for the MS lens (P=0.007; Figure 1). Comfort was maintained in the NV lens at the 6-hour timepoint but reduced slightly – albeit non-significantly (P=0.307) – at 10 hours. Lens awareness peaked for both lenses after 6 hours of wear and reduced again at 10 hours. Participants found lens removal easier than insertion for both lenses.

Correlations

A moderate positive correlation (Figure 2; Table 5) was found between participant-reported central vision quality and overall satisfaction at all timepoints and for both lenses (e.g. at 10 hours post-insertion, Spearman's ρ=0.55 (P=0.012) and ρ=0.55 (P=0.013) for MS and NV respectively). A similar pattern was seen for the correlation between participant-reported peripheral vision quality and overall satisfaction. An analogous trend was seen for the correlation between ocular comfort and overall satisfaction. However, at 2 hours, this correlation was weak and not significant (Spearman's

186 ρ<0.2 for both lenses). The correlation between contrast sensitivity (as well as visual acuity) and
187 overall satisfaction was weak and did not reach significance (Table 5). The correlation between
188 participant-reported central vision quality and visual acuity was not significantly different from zero
189 at any timepoint, for either lens type lenses (Spearman's ρ<0.2 in all cases).

190



191 Figure 2. Correlation between participant-reported vision quality or ocular comfort versus overall
192 satisfaction for each lens type, at 2 hours and 10-hours post-insertion (MS=MiSight; NV=NaturalVue
193 multifocal).

194

Table 5. Summary of correlations assessed using Spearman's rank (correlation coefficient ρ and P value stated; MS=MiSight; NV=NaturalVue multifocal).

		Insertion		2 hours		6 hours		10 hours	
		ρ	P	ρ	P	ρ	P	ρ	P
Visual acuity vs overall satisfaction	MS	-0.326	0.161	-0.298	0.202	-0.330	0.155		
	NV	0.035	0.884	-0.044	0.855	-0.333	0.151		
Contrast sensitivity vs overall satisfaction	MS	0.389	0.090	0.365	0.113	0.400	0.081		
	NV	0.060	0.803	0.149	0.531	0.223	0.345		
Comfort vs overall satisfaction	MS	0.287	0.219	0.168	0.480	0.551	**0.012***	0.570	**0.009***
	NV	0.304	0.193	0.149	0.532	0.499	**0.025***	0.336	0.147
Central vision vs overall satisfaction	MS	0.302	0.196	0.552	**0.012***	0.428	0.060	0.551	**0.012***
	NV	0.513	**0.021***	0.546	**0.013***	0.519	**0.019***	0.546	**0.013***
Peripheral vision vs overall satisfaction	MS	0.139	0.558	0.417	0.067	0.465	**0.039***	0.453	**0.045***
	NV	0.314	0.177	0.464	**0.040***	0.824	**<0.001***	0.634	**0.003***
Visual acuity vs central vision	MS	-0.028	0.907	-0.132	0.580	-0.117	0.625		
	NV	-0.108	0.650	0.007	0.977	-0.058	0.809		

Discussion

This exploratory study investigated subjective impressions of contact lens satisfaction for two daily disposable myopia control contact lenses during initial wear. To the authors' knowledge, this is the first study evaluating short-term objective and subjective acceptability of these two MM contact lenses. Both lenses performed similarly and provided comparable outcomes across a wide range of parameters relevant to future dropout.

Physiological Measures

Visual acuity and contrast sensitivity did not differ during wear, with the only suggestive change being a slight improvement of visual acuity throughout the day with the MS lens, which was reflected by the significant difference in visual acuity between the lenses at the 6-hour timepoint. This observation may be due to changes in lens hydration or settling during wear, attributable to the design (NV has a greater sagittal height) and the respective lens materials. The data indicate that both lenses fitted well after initial insertion, with all lens fits demonstrating good centration and adequate movement on blink, however fit assessment was not repeated later in the day meaning lens settling cannot be determined. While the difference in visual acuity between lens types was statistically significant, it is unlikely to be clinically significant; the difference in the mean visual acuity at 6 hours was only 3 letters, which is unlikely to be noticeable to patients, particularly children. This is reflected by the subjective assessment of central vision, which showed minimal difference between the two lenses at any timepoint (see below).

Accommodative measures (amplitude and lag) demonstrated minor differences relating to lens type. Accommodative lag was greater at all timepoints after insertion for the MS lenses; however, this was not statistically significant, likely reflecting the variability in assessing this parameter. The amplitude of accommodation decreased slightly from baseline after lens insertion, although not to a clinically significant extent. This reduction in amplitude of accommodation was consistent with the results of other studies investigating accommodative responses in multifocal contact lenses (including the MS and NV lenses) in children and young adults.[14, 19, 20] There was a significant difference in accommodative amplitude with the two lens types at 2 hours post-insertion, however this was transient, with no significant differences seen at later timepoints.

Physiological changes such as conjunctival hyperaemia were observed with both lenses. These increased after two hours of lens wear. The level of limbal hyperaemia was similar with both lenses, and there was no discernible increase in conjunctival or limbal hyperaemia between 2 and 6 hours of wear. Increases in hyperaemia during contact lens wear have been noted previously, and have been

proposed as a response to the limited Dk/t of conventional hydrogel lenses to provide adequate oxygen to the peripheral cornea.[21] Whilst there were small hyperaemic changes noted in the present study, the increases from baseline did not exceed 0.3 Efron grade, which is close to the level of inter-observer agreement for this parameter.[22] As these measurements were not taken beyond 6 hours of wear, it was not possible to extrapolate physiological response to longer wearing times, or to relate this to the reduction in subjective comfort reported by participants after 10 hours of wear. The physiological response of current myopia control contact lenses after 10 hours of wear may warrant further investigation. Overall, all physiological measures demonstrated minimal fluctuation during lens wear. Where differences were observed, their magnitude was unlikely to be of clinical significance. The two MM lens types performed comparably for the first 6 hours of wear.

Questionnaire Responses

Both lenses demonstrated reduced levels of comfort towards the end of the day, with MS lenses demonstrating a significant reduction at the 10-hours post insertion compared to lens insertion. There were no significant differences in reported comfort between the two lenses at any timepoint, however, which may have been attributable to the variability of subjective reporting. A trend of gradually reducing contact lens comfort over the day concurs with previous reports, with various reasons being proposed, including lens design, material, and biochemistry.[23, 24] This reduction in comfort led to some participants being unable to wear their lenses for the full 10-hour period. This affected both lens types equally, despite the reported difference in lens comfort.

End of day discomfort and reduced wearing times have been commonly reported as key reasons for contact lens dropout.[24, 25] Although certain myopia interventions have been developed that do not require the use of contact lenses (e.g. specialised spectacles and atropine), these are not currently available to practitioners in some countries, and therefore success in managing myopia currently hinges on successful contact lens wear and avoiding dropout. In the present study, although 5 participants did not wear the lenses for the full 10 hours, all participants were able to complete at least 7 hours of wear successfully for both lenses. This is estimated to give sufficient time for the treatment effect in soft contact lenses that use myopic defocus,[26] however this was investigated in soft myopia control lenses of a different optical design and should therefore be applied to the lenses used in the present study with caution. To the authors' knowledge, a dedicated contact lens dropout study has not been currently conducted on children, which may now be of greater interest due to the newly emerging myopia management market and the increasing acceptance of fitting children with contact lenses.[27, 28] Fitting contact lenses at an older age has been associated with an increased risk of contact lens dropout in a large cohort that included individuals fitted when they were

children.[25] Therefore, it is likely that clinicians will experience a reduced dropout rate for these lenses compared to average values from reports in adults, particularly if there is a strong motivation from participants and their parents to continue myopia management.

There were no significant differences between the two lens types in any of the other participant-reported parameters assessed, including clarity of central and peripheral vision, ease of insertion and removal, and overall satisfaction. Satisfaction values at end-of-day for single vision soft contact lenses has been reported to average 80%,[29] much higher than the values reported with these lenses, however this was using a different optical design and lens material. With regard to which study lens participants assigned a higher overall satisfaction score, there was no clear preference for one lens over the other. However, more than 50% of participants had a relatively strong preference (defined as a difference in satisfaction of ≥ 25% between the lenses). The lenses were worn in a random order with both the participant and investigator masked to the lens identity, i.e. the randomisation and masking of lenses in the study methodology was implemented to control for bias. Due to the small sample size, the study had limited statistical power to identify demographic factors that influenced the likelihood of which lens participants preferred. Moreover, data on habitual pupil size was not recorded, which may have been a factor in participants' determination of their favoured lens. Nevertheless, there was a suggestive link with age (P=0.051), whereby younger participants more often preferred the MS lens and older participants the NV lens. Thus, the results suggest that patients interested in myopia control may benefit from trying both lenses (where possible and where the fit is deemed acceptable), and selecting their preferred option, to maximise wearing experience. This may lead to greater patient satisfaction and retention, resulting in more patients persevering with their myopia management intervention. An investigation into patient retention after being offered a choice of MM lenses rather than one option would provide further evidence of this.

Relationships between variables

Visual acuity had minimal correlation with overall lens satisfaction at any time point. This suggests that patient satisfaction cannot be predicted based on initial visual acuity when an MM lens is fitted. However, the range of visual acuities observed in the study population was -0.30 to 0.22 logMAR, hence participants with corrected visual acuity worse than 0.22 logMAR may not conform to this trend. Contrast sensitivity, which varied across a range of 1.20 to 1.65 logCS, had a weak correlation with overall satisfaction. This limited degree of correlation may have been due to the initially poor threshold of some participants, [30] or may reflect the limited accuracy and precision of the Pelli-Robson chart for fully gauging the real-world impact of a CS deficit. Participant-reported clarity of central vision was moderately associated with overall satisfaction. The exception to this was when the

MS lens was first inserted, where a weaker, non-significant correlation was found (ρ=0.30; P=0.196). Since this time-point is when patient-reported vision will typically be assessed during an initial lens fit, the weak correlation highlights the importance of allowing time for adaptation to MM lenses. The findings suggest that, where possible, patient-reported visual quality should be assessed after 2 or more hours of lens wear. Participant-reported clarity of peripheral vision provided a similar trend to the clarity of central vision, therefore practitioners may gain little from assessing this parameter separately.

The very weak correlation between visual acuity and participant-reported clarity of central vision is consistent with previous studies assessing soft multifocal contact lenses.[31-33] These studies suggested that this discrepancy is likely due to the use of an unrealistic high-contrast target in usual clinical practice for vision assessment, and the differences in visual distance ranges.[29-31] Typically, visual acuity does not accurately reflect real-life visual experience, because there is a wide range of visual environments hosting different contrast gradients and lighting levels outside clinical settings. It should also be noted that the participants in the present study (and previous referenced studies) were adults, and therefore the results may not fully reflect the visual demands and experiences of children. Despite this, practitioners may benefit from placing particular emphasis on their patients' subjective reports of vision to further appreciate the likelihood of overall lens satisfaction.

Comfort was positively correlated with overall satisfaction throughout wear, but this relationship only reached significance after 6 hours of wear. As both of the test lenses studied are made from hydrogel materials, this may have been due to lens dehydration or other material-related factors.[24] Silicone hydrogel materials are available (e.g. MYLO by Mark 'ennovy), which may be an option for MM patients unable to tolerate standard hydrogel lenses. This could include patients with marked dry eye or those who require longer-than-average wearing times.[6] However, the MYLO lens is a monthly disposable, which may deter some practitioners or patients/parents due to the additional care steps and subsequent increased risk of adverse events.[34] Practitioners may consider lubricating eye drops or shortening wear times as alternative approaches.

The strengths of this study were the double-masked study design, and the collection of data throughout each day of wear. The study had a number of limitations. Firstly, the small sample size limited the ability to perform a comprehensive analysis of factors affecting lens satisfaction. Secondly, the assessment of lens performance was carried out for a single day of wear. Ideally, a longer duration of follow-up would have allowed assessment of patient experience in greater detail. Thirdly, the participants were adults who were current or previous lens wearers, and therefore their experiences may not be representative of children who would typically be neophytes fitted with multifocal lens

designs for myopia management. Fourthly, despite implementing a 24-hour washout period during which participants were asked not to wear contact lenses prior to each visit, participants may nevertheless have benchmarked their self-reported lens satisfaction against their habitual lenses, which could have introduced bias. Finally, participants with dry eye were not excluded, which may have also resulted in lower reported levels of lens satisfaction than would otherwise have been the case. It should be noted that because this was an exploratory analysis designed to generate hypotheses rather than to test one specific hypothesis, the number of pairwise comparisons made was high, leading to an increased likelihood of type 1 error. Accordingly, the results should be interpreted with caution, inferring only general trends and future avenues for investigation.

Conclusion

In summary, participant-reported clarity of central vision and comfort during MM contact lens wear were strongly associated with overall satisfaction. Other factors relating to lens experience were much less informative. Both of the MM contact lenses tested performed similarly with regard to physiological responses and participant satisfaction. Notably, many participants had a strong individual preference for one lens type over the other, despite there being no clear preference for one lens type in the cohort as a whole. Therefore, the key recommendations from this work are firstly, that practitioners should recognise the disconnect between self-reported visual quality and measured visual acuity when fitting MM contact lenses, and secondly, where possible practitioners should fit patients with more than one lens type for patients to determine a preference (if any). In theory, such a strategy may minimize future dropout rates and promote sustainable myopia management. Future studies with a longer wearing duration (7-10 days) should test the hypothesis that providing patients with a choice of MM lens types will increase wearing time and reduce dropouts.

References

[1] Holden BA, Fricke TR, Wilson DA, Jong M, Naidoo KS, Sankaridurg P, et al. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. Ophthalmology 2016. https://doi.org/http://dx.doi.org/10.1016/j.ophtha.2016.01.006.

[2] Flitcroft DI. The complex interactions of retinal, optical and environmental factors in myopia aetiology. Progress in Retinal and Eye Research 2012;31(6):622-60. https://doi.org/10.1016/j.preteyeres.2012.06.004.

[3] BHVI, WHO. The report of the joint World Health Organisation - Brien Holden Vision Institure Global Scientific Meeting on Myopia In: Organisation WH, ed. 2016 ed.; 2016.

[4] Wildsoet CF, Chia A, Cho P, Guggenheim JA, Polling JR, Read S, et al. IMI – Interventions for Controlling Myopia Onset and Progression Report. Investigative Ophthalmology & Visual Science 2019;60(3):M106-M31. https://doi.org/10.1167/iovs.18-25958

[5] Chamberlain P, Peixoto-de-Matos SC, Logan NS, Ngo C, Jones D, Young G. A 3-year Randomized Clinical Trial of MiSight Lenses for Myopia Control. Optom Vis Sci 2019;96(8):556-67. https://doi.org/10.1097/opx.0000000000001410.

[6] Sankaridurg P, Bakaraju RC, Naduvilath T, Chen X, Weng R, Tilia D, et al. Myopia control with novel central and peripheral plus contact lenses and extended depth of focus contact lenses: 2 year results from a randomised clinical trial. Ophthalmic and Physiological Optics 2019;39(4):294-307. https://doi.org/10.1111/opo.12621.

[7] Aller T, Achenbach P, Cooper J, Dillehay S, Jamal N, Jeruss J, et al. Myopia management with naturalvue (etafilcon a) multifocal 1 day contact lenses: continuing evidence from clinical practice. Contact Lens and Anterior Eye 2019;42(6, Supplement 1):e24. https://doi.org/https://doi.org/10.1016/j.clae.2019.10.079.

[8] Arumugam B, Hung L-F, To C-H, Holden B, Smith EL. The effects of simultaneous dual focus lenses on refractive development in infant monkeys. Investigative Ophthalmology and Visual Science 2014;55:7423-32, https://doi.org/10.1167/iovs.14-14250.

[9] Smith EL, 3rd. Charles F. Prentice Award Lecture 2010: A case for peripheral optical treatment strategies for myopia. Optometry and Vision Science 2011.

[10] Anstice NS, Phillips JR. Effect of dual-focus soft contact lens wear on axial myopia progression in children. Ophthalmology 2011;118(6):1152-61, doi: 10.1016/j.ophtha.2010.10.035

[11] Aller TA, Liu M, Wildsoet CF. Myopia Control with Bifocal Contact Lenses: A Randomized Clinical Trial. Optometry and Vision Science 2016, doi: 10.1097/OPX.0000000000000808

[12] Sulley A, Young G, Hunt C. Factors in the success of new contact lens wearers. Contact Lens and Anterior Eye 2017;40(1):15-24. https://doi.org/10.1016/j.clae.2016.10.002.

[13] Dumbleton K, Woods CA, Jones LW, Fonn D. The impact of contemporary contact lenses on contact lens discontinuation. Eye Contact Lens 2013;39(1):93-9. https://doi.org/10.1097/ICL.0b013e318271caf4.

[14] Ruiz-Pomeda A, Perez-Sanchez B, Valls I, Prieto-Garrido FL, Gutierrez-Ortega R, Villa-Collar C. MiSight Assessment Study Spain (MASS). A 2-year randomized clinical trial. Graefe's archive for clinical and experimental ophthalmology = Albrecht von Graefes Archiv fur klinische und experimentelle Ophthalmologie 2018;256(5):1011-21. https://doi.org/10.1007/s00417-018-3906-z.

[15] Cooper J, O'Connor B, Watanabe R, Fuerst R, Berger S, Eisenberg N, et al. Case Series Analysis of Myopic Progression Control With a Unique Extended Depth of Focus Multifocal Contact Lens. Eye & Contact Lens 2018;44(5), https://journals.lww.com/claojournal/Fulltext/2018/09000/Case_Series_Analysis_of_Myopic_Progression_Control.14.aspx.

[16] Manufacturers TAoCL. The ACLM Contact lens Year Book 2020;1(1):86.

[17] Wolffsohn JS, Hunt OA, Basra AK. Simplified recording of soft contact lens fit. Contact lens & anterior eye : the journal of the British Contact Lens Association 2009;32(1):37-42. https://doi.org/10.1016/j.clae.2008.12.004.

[18] Armstrong RA. When to use the Bonferroni correction. Ophthalmic and Physiological Optics 2014;34(5):502-8. https://doi.org/https://doi.org/10.1111/opo.12131.

[19] Gong CR, Troilo D, Richdale K. Accommodation and Phoria in Children Wearing Multifocal Contact Lenses. Optom Vis Sci 2017;94(3):353-60. https://doi.org/10.1097/opx.0000000000001044.

[20] Gifford K, Schmid KL, Collins J, Maher C, Makan R, Nguyen TKP, et al. Accommodative responses of young adult myopes wearing multifocal contact lenses. Investigative Ophthalmology & Visual Science 2019;60(9):6376-.

[21] Holden BA, Sweeney DF, Swarbrick HA, Vannas A, Nilsson KT, Efron N. The vascular response to long-term extended contact lens wear. Clin Exp Optom 1986;69(3):112-9. https://doi.org/10.1111/j.1444-0938.1986.tb06800.x.

[22] Vianya-Estopa M, Nagra M, Cochrane A, Retallic N, Dunning D, Terry L, et al. Optimising subjective anterior eye grading precision. Contact Lens and Anterior Eye 2020;43(5):489-92. https://doi.org/10.1016/j.clae.2020.03.006.

[23] Chalmers RL, Begley CG. Dryness symptoms among an unselected clinical population with and without contact lens wear. Contact lens & anterior eye : the journal of the British Contact Lens Association 2006;29(1):25-30. https://doi.org/10.1016/j.clae.2005.12.004.
[24] Riley C, Young G, Chalmers R. Prevalence of Ocular Surface Symptoms, Signs, and Uncomfortable Hours of Wear in Contact Lens Wearers: The Effect of Refitting with Daily-Wear Silicone Hydrogel Lenses (Senofilcon A). Eye & Contact Lens 2006;32(6), https://journals.lww.com/claojournal/Fulltext/2006/12000/Prevalence_of_Ocular_Surface_Symptoms,_Signs,_and.7.aspx.
[25] Pritchard N, Fonn D, Brazeau D. Discontinuation of contact lens wear: a survey. Int Contact Lens Clin 1999;26(6):157-62. https://doi.org/10.1016/s0892-8967(01)00040-2.
[26] Lam CS, Tang WC, Tse DY, Tang YY, To CH. Defocus Incorporated Soft Contact (DISC) lens slows myopia progression in Hong Kong Chinese schoolchildren: a 2-year randomised clinical trial. British Journal of Ophthalmology 2014;98:40-5. https://doi.org/10.1136/bjophthalmol-2013-303914.
[27] Bullimore MA. The Safety of Soft Contact Lenses in Children. Optom Vis Sci 2017;94(6):638-46. https://doi.org/10.1097/opx.0000000000001078.
[28] Sindt CW, Riley CM. Practitioner attitudes on children and contact lenses. Optometry 2011;82(1):44-5. https://doi.org/10.1016/j.optm.2010.11.001.
[29] Diec J, Naduvilath T, Tilia D. Subjective Ratings and Satisfaction in Contact Lens Wear. 2018;95(3):256-63. https://doi.org/10.1097/opx.0000000000001187.
[30] Rumney NJ. Using visual thresholds to establish low vision performance. Ophthalmic and Physiological Optics 1995;15(s1):S18-S24. https://doi.org/https://doi.org/10.1046/j.1475-1313.1995.0150s1S18.x.
[31] Jong M, Tilia D, Sha J, Diec J, Thomas V, Bakaraju RC. The Relationship between Visual Acuity, Subjective Vision, and Willingness to Purchase Simultaneous-image Contact Lenses. Optom Vis Sci 2019;96(4):283-90. https://doi.org/10.1097/opx.0000000000001359.
[32] Woods J, Woods C, Fonn D. Visual Performance of a Multifocal Contact Lens versus Monovision in Established Presbyopes. Optom Vis Sci 2015;92(2):175-82. https://doi.org/10.1097/opx.0000000000000476.
[33] Papas EB, Decenzo-Verbeten T, Fonn D, Holden BA, Kollbaum PS, Situ P, et al. Utility of short-term evaluation of presbyopic contact lens performance. Eye Contact Lens 2009;35(3):144-8. https://doi.org/10.1097/ICL.0b013e3181a20361.
[34] Stapleton F, Naduvilath T, Keay L, Radford C, Dart J, Edwards K, et al. Risk factors and causative organisms in microbial keratitis in daily disposable contact lens wear. PloS one 2017;12(8):e0181343. https://doi.org/10.1371/journal.pone.0181343.