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Title:

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

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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

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1

2

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

5 **ABSTRACT**

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

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

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

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

29 **Keywords:**

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

31 **Introduction**

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

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

42 Due to the impact on future healthcare services and the increased risk of sight loss, many
43 investigations into myopia interventions have been performed, particularly aimed at limiting myopia
44 progression and axial elongation. This has led to the development of pharmacological and optical
45 interventions, such as atropine and specialised contact lenses.[4] This includes soft contact lenses
46 specifically designed to slow progression. These use either a dual-focus optical design or an extended-
47 depth-of-focus design.[5-7] Peripheral myopic defocus has been shown to reduce the progression of
48 axial elongation and refractive error in mammalian animal models,[8, 9] and human clinical trials.[10,
49 11] The primary outcome during MM clinical trials has been myopia control efficacy, with less
50 emphasis on the report of initial lens comfort and patient satisfaction.[5, 7] Dropout is a significant
51 problem in contact lens wear, with common reasons given by patients include poor vision at distance
52 and near, handling difficulty, and discomfort [12, 13]. Such factors may impede the success of
53 implementing myopia control through contact lens-based interventions. In this study, the initial
54 patient experience and physiological response to two daily disposable myopia management contact
55 lenses that are licenced for use in many parts of the world were explored.

56 **Methods**

57 ***Study Lenses***

58 The two daily disposable contact lenses used in this study were MiSight® (MS; CooperVision Inc.) and
59 NaturalVue® Multifocal 1 Day (NV; Visioneering Technologies Inc.). MS has an annular dual focus
60 design, with four alternating distance and treatment zones (which include an addition power
61 maximum of +2.00D),[14] whereas NV has an extended-depth-of-focus (EDOF) design, with distance
62 correction in the centre, surrounded by a ring of steep progression into highly positive power at the
63 edge of the optical zone equivalent to +20.00D plus power.[15] Additional characteristics of these
64 lenses are shown in Table 1. These lenses were chosen for this experiment as both are commercially
65 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

66

67 ***Study Design***

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

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

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

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

92 Before lens insertion, participants underwent a series of visual function and physiological anterior eye
 93 measures to ensure that both eyes were healthy, and to monitor ocular response during contact lens
 94 wear. These procedures were repeated after lens insertion, and participants then underwent further
 95 measures at 2-hours and 6-hours post-insertion. A questionnaire was completed by participants at
 96 baseline, the 2-hour and 6-hour visits, and finally at 10 hours post-insertion, before lens removal. The
 97 questionnaire included visual analogue scales for rating each subjective parameter; these were then
 98 converted to a score out of 100. Participants were instructed to wear the lenses for 10 hours, but to
 99 monitor this, participants were asked to report their wearing time for each lens to the nearest half
 100 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
<i>Physiological measures</i>	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)	✓	✓	✓	✓	✗
<i>Questionnaire items</i>	Ocular comfort	✓	✓	✓	✓	✓
	Lens awareness	✗	✓	✓	✓	✓
	Central vision	✗	✓	✓	✓	✓
	Peripheral vision	✗	✓	✓	✓	✓
	Ease of insertion	✗	✓	✗	✗	✗
	Ease of removal	✗	✗	✗	✗	✓
	Overall satisfaction	✗	✗	✗	✗	✓
	Wear time	✗	✗	✗	✗	✓

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

106 ***Data analysis***

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

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

119 **Results**

120 A total of 20 participants were enrolled. The mean \pm standard deviation age was 23.8 ± 3.49 years
121 (range 19 to 29) and the mean spherical contact lens correction power worn by participants was -2.65
122 $\pm 1.42D$ (range $-0.50D$ to $-5.75D$). Seventeen (85%) of the participants were female. All lens fits were
123 deemed acceptable during the initial assessment. All participants wore both sets of lenses and
124 completed the trial successfully. No adverse events or contraindications were reported.

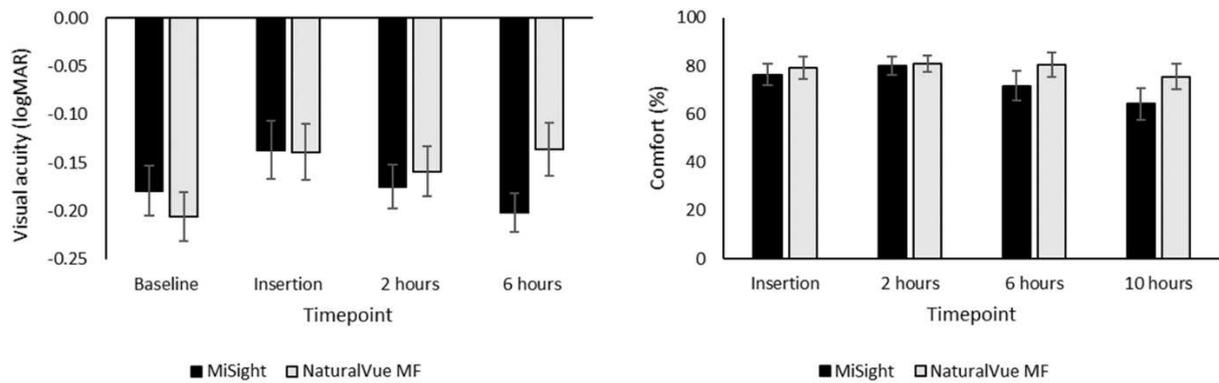
125 ***Lens type comparisons***

126 The results of the pairwise comparisons of the physiological parameters and questionnaire responses
127 are shown in Tables 3 and 4, respectively. Near visual acuity did not change at any timepoint with
128 either lens; all values were recorded as N6 or better. Visual acuity was similar for both lenses, except
129 at the 6-hour timepoint, when acuity was slightly poorer with NV than MS (-0.14 ± 0.12 and $-0.20 \pm$
130 0.09 logMAR, respectively; $P = 0.003$; Figure 1). Amplitude of accommodation was lower for the MS
131 lens throughout the day, although this only attained statistical significance at the 2-hour timepoint
132 (8.06 ± 2.06 and 9.15 ± 1.78 Dioptres, respectively; $P = 0.007$). Contrast sensitivity and limbal
133 hyperaemia were significantly different between trials at baseline, with the MS trial having a poorer

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

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

140



141

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

145

146 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

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151 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
Overall satisfaction	MS													54.4	28.3	0.380	
	NV																59.3
Wear time (hours)	MS													9.63	0.78	0.492	
	NV																9.85

152

153

154 **Comparisons over time**

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

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

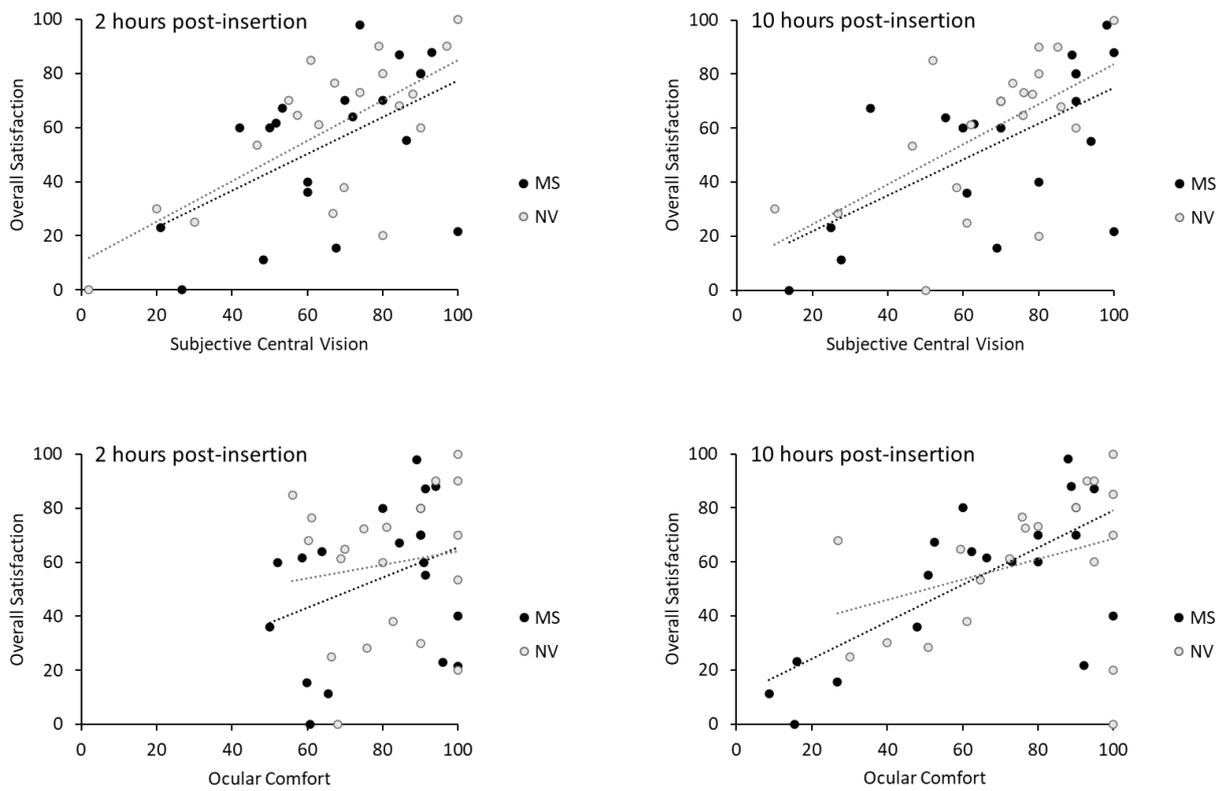
173 Questionnaire-based assessment of lens performance over time (Table 4) demonstrated no
174 remarkable changes to central or peripheral vision throughout wear. Ocular comfort was significantly
175 reduced at 6 and particularly 10 hours for the MS lens ($P=0.007$; Figure 1). Comfort was maintained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

179 **Correlations**

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

186 $p < 0.2$ 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 $\rho < 0.2$ 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

195

196 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		

197

198

199 **Discussion**

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

205 ***Physiological Measures***

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

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

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

231 proposed as a response to the limited Dk/t of conventional hydrogel lenses to provide adequate
232 oxygen to the peripheral cornea.[21] Whilst there were small hyperaemic changes noted in the
233 present study, the increases from baseline did not exceed 0.3 Efron grade, which is close to the level
234 of inter-observer agreement for this parameter.[22] As these measurements were not taken beyond
235 6 hours of wear, it was not possible to extrapolate physiological response to longer wearing times, or
236 to relate this to the reduction in subjective comfort reported by participants after 10 hours of wear.
237 The physiological response of current myopia control contact lenses after 10 hours of wear may
238 warrant further investigation. Overall, all physiological measures demonstrated minimal fluctuation
239 during lens wear. Where differences were observed, their magnitude was unlikely to be of clinical
240 significance. The two MM lens types performed comparably for the first 6 hours of wear.

241 ***Questionnaire Responses***

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

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

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

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

287 ***Relationships between variables***

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

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

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

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

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

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

339 **Conclusion**

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

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