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Effect of myopia management contact lens design on accommodative microfluctuations and eye movements during reading

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ABSTRACT

Background: Soft contact lenses have been developed and licensed for reducing myopia progression. These lenses have different designs, such as extended depth of focus (EDOF) and dual focus (DF). In this prospective, double-masked, cross-over study, different lens designs were investigated to see whether these had impact on accommodative microfluctuations and eye movements during reading.

Methods: Participants were fitted with three lenses in a randomised order; a single vision (SV) design (Omafilcon A2; Proclear), a DF design (Omafilcon A2; MiSight), and an EDOF lens design (Etafilcon A; NaturalVue),. Accommodative microfluctuations were measured at 25 cm for at least 60s in each lens, using a Shin-Nippon SRW-5000 autorefractor adapted to continuously record accommodation at 22Hz. Eye movement data was collected with the Thomson Clinical Eye Tracker incorporating a Tobii Eye bar. Eye movements include fixations per row, fixations per minute, mean regressions per row, total number of regressions, and total rightward saccades. Accommodation data was analysed using power spectrum analysis. Differences between the lenses were compared using a related sample two-way Friedman test.

Results: Twenty-three participants (18–29 years) were recruited to take part. The average mean spherical error was −2.65D ± 1.42DS, with an average age of 23.4 ± 3.5 years. No significant difference for accommodative microfluctuations was found. Significant differences were found for fixations per row ($P = 0.03$), fixations per minute ($P = 0.008$), mean regressions per row ($P = 0.002$), and total number of regressions ($P = 0.002$), but not total rightward saccades ($P = 0.10$). Post-hoc analysis indicated the EDOF lens results were significantly different from the other lenses, with more regressive eye movements observed.

Conclusions: Regressive saccades appear to increase when wearing EDOF lens designs, which may impact visual comfort. Further studies in children, over a longer period of adaptation are necessary to assess the potential impact of this finding on daily reading activities in children.

1. Introduction

Myopia prevalence has been increasing across the globe, with rates estimated to continue to rise over the next few decades [1]. Within the UK, the prevalence has doubled over the last 50 years, with more children becoming myopic [2]. This is of concern, as not only does myopia cause the ongoing need for refractive correction, which has an impact on the children's quality of life [3], but it can also have implications for the child's future ocular health and life choices. Presence of myopia, particularly that of higher degrees of myopia can have implications for eligibility to join certain occupations (such as the armed forces or becoming a pilot), along with a future increased risk of sight threatening pathology, such as retinal detachments or myopic macular degeneration [4,5]. For these reasons, myopia management interventions have become increasingly popular [6]. This includes behavioural strategies such as increased time outdoors [7], pharmacological interventions such as atropine [8], along with optical methods, such as spectacle interventions and contact lens options [9,10].

Regarding contact lens interventions, initially orthokeratology and 'off-label' multifocal contact lens designs were used for myopia management. More recently, several lenses have been designed that are licensed specifically for myopia control. Two daily disposable contact

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lenses have been licenced in the UK for use in myopia management: the MiSight 1 Day (Omafilcon A2; CooperVision) and the NaturalVue Multifocal (Etafilcon A; Visioneering Technologies Inc.). Both these options are made from hydrogel materials (see Table 1), but employ different designs to create a peripheral myopic defocus for myopia control [11,12]. MiSight 1 Day uses a dual-focus design (alternating rings of distance prescription and + 2.00 DS addition), with distance prescription at the centre [13,14]. NaturalVue Multifocal uses an extended depth of focus design, in which the positive relative defocus increases progressively into the periphery of the lens [15]. Both lenses employ radial symmetry in these designs, with their power profiles displayed in Fig. 1 [16].

The use of multifocal designs will result in partial image blur, which may have an impact on the visual performance of these lenses [17]. Previous assessments for visual performance have included binocular vision impact, and ocular accommodation [16,18–20]. Measures related to ocular accommodation have shown varied results. A previous study measuring accommodation between the two daily myopia management lenses found no difference between them using Nott retinoscopy [19], whereas other studies such as Schmid et al., and Gifford et al., found differences between lenses when testing accommodation with an autorefractor [16,18].

It is also possible that these designs may have an effect on reading speed and related eye movement in reading tasks. Reading requires visual prehension in order to allow for forward saccades when progressing across a line of text [21]. Given the designs of these lenses potentially influence the clarity of vision in the periphery and parafoveal area, it is possible that reading eye movements in these tasks could be affected. Given reading is a very common daily task and that children – the primary target demographic for myopia management intervention – would be developing their reading skills within school, understanding whether these lens designs can impact ocular accommodation or reading eye movements is important. Therefore, the objective of this study was to investigate if these myopia management contact lenses induced any differences in accommodative microfluctuations or reading eye movements during the first hour of wear.

2. Methods

This study was performed over June – August 2021 at a single site. The study received ethical approval from the University of Bradford Research Ethics Committee and was carried out in accordance with the Declaration of Helsinki.

2.1. Study lenses

The three contact lenses used for this study were the Proclear 1 Day (Omafilcon A2; CooperVision), MiSight 1 Day (Omafilcon A2; CooperVision), and the NaturalVue Multifocal (Etafilcon A; NaturalVue). The details of these lenses are listed in Table 1. Proclear 1 Day was used as the single vision (SV) control as this lens is made of a similar material to the other two lenses, and has been used as a control lens in previous myopia management studies [11].

Table 1
Parameters of the lenses used in the study, taken from the Association of Contact Lens Manufacturers (ACLM). Note that lens and parameter availability listed here were correct at the time of the study, although these may have changed subsequent to the time of the study.

	Proclear® 1 Day	MiSight® 1 Day	NaturalVue® multifocal 1 day
Manufacturer	CooperVision Inc.	CooperVision Inc.	Visioneering Technologies Inc.
Material	Omafilcon A 2	Omafilcon A 2	Etafilcon A
Base curve (mm)	8.7	8.7	8.3
Total diameter (mm)	14.2	14.2	14.5
Water content (%)	60	60	58
Oxygen permeability (ISO units)	19	19	15
Back vertex power range (D)	+8.00 to − 12.00	−0.25 to − 6.00	+4.00 to − 12.25
UV inhibitor	None	None	Class 2

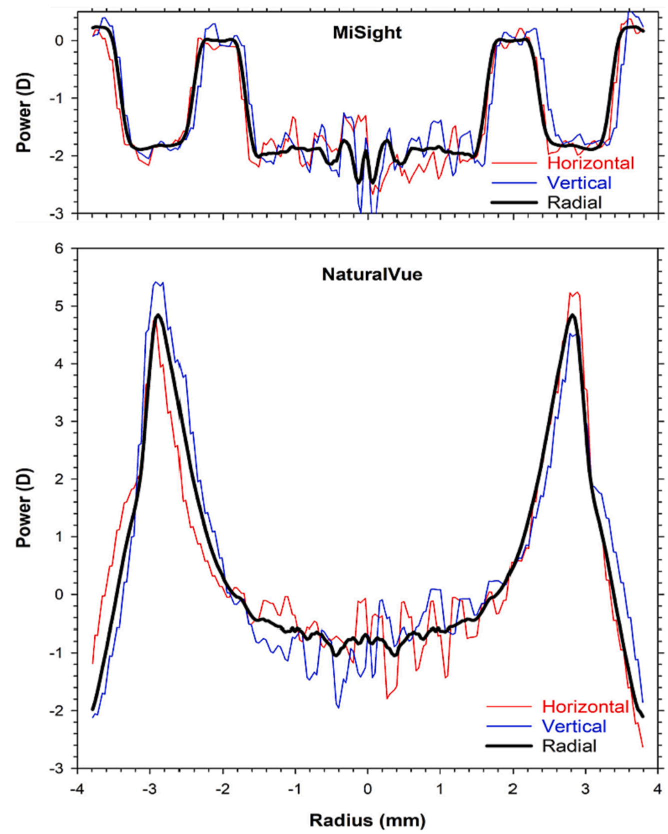

Fig. 1. Power profiles showing horizontal, vertical and radial average values for the Misight 1 Day and NaturalVue lens designs. Figure adapted from Gifford et al. 2021 [16].

2.2. Study design

This was a prospective, double-masked, cross-over study. Young adults were invited to take part through email notifications, social media, and word of mouth.

Inclusion and exclusion criteria for the participants is listed in Table 2. Participants were asked to wear the three study lenses over a single visit on one day. A participant information sheet was issued, and informed consent was given after participants had a chance to ask

Table 2
List of inclusion and exclusion criteria for participation in the study.

Inclusion	Exclusion
Participant provided written informed consent prior to participation	Previous or current ocular disease that could affect contact lens wear or prior refractive/corneal surgery
Age between 18 and 30 years of age (inclusive)	Symptomatic dry eye
Refractive error within the available parameters for all lenses, and astigmatism < 1.25DC	Currently pregnant or breast-feeding
Patient willing and able to wear contact lenses and comply with study procedures throughout visit	Has a known allergy or hypersensitivity to saline, contact lenses or their material constituents, or fluorescein
A sight test within the last 24 months	Unacceptable contact lens fit seen with any of the study contact lenses

questions about the study. Once enrolled, participants had their pupil sizes measured in a room with light conditions averaging 21 cd.m^2 (Chroma CS 100 photometer, Minolta, Germany), using a pupillary diameter rule and were asked for their spectacle prescription to prepare their contact lenses, in accordance to the manufacturers fitting guides, with adjustments if necessary. The different lenses were fitted in a random order, with one member of the study team, who was not the data collector, organising the lenses for the participant. Once each lens had been applied to the participant's eye, they were given 10 min for the lenses to settle [22]. After this, visual acuity (VA) was measured monocularly and binocularly with an ETDRS chart (Chart R), to ensure that their vision with the lenses was within 1 line of their best corrected VA. The participants then underwent a contact lens fitting assessment using the Simplified Fitting Scale [23]. The fit was deemed acceptable if the Simplified Fitting Scale had a score of $\pm$ 1 or less, for any of the lens fitting features. This procedure was repeated for each study lens. All activities performed with the lenses, including the study measures, were performed under the same luminance listed above.

2.3. Accommodative microfluctuations

Once the initial lens fitting and VA assessment was complete, accommodative microfluctuations were measured using a Shin-Nippon SRW-5000 Autorefractor (Rexxam Co. Ltd, Osaka, Japan), adapted to allow for continuous measurement of accommodation at a rate of 22 Hz (Fig. 2) [24]. Accommodative microfluctuations were recorded while viewing a Maltese cross (size 2 $\times$ 2 mm) at a fixation distance of 25 cm for a minimum of 60 s, with the participant asked to blink normally and maintain focus on the target. Five segments of data, each 128 data points long, were extracted from the accommodative trace. Blinks were filtered from this signal and the power spectral density was computed for each of these 5 segments using the Welch's Periodogram function in the SciPy Python library. The average power for the low (0–0.6 Hz) and high (1–2.3 Hz) frequency bands were calculated and averaged for the five segments [25]. Variability of the accommodation response was also determined by calculating the mean standard deviation of the accommodative data from the 5 segments.

2.4. Reading eye movements

The reading task followed after the measure of accommodative microfluctuations, participants were then directed to a reading task. The reading task was performed with measured eye movements, using the Thomson Clinical Eye Tracker (Thomson Vision Solutions, UK) which incorporates a Tobii Eye Bar (Tobii, Stockholm, Sweden), as seen in Fig. 2. The Thomson Clinical Eye Tracker makes use of the Wilkins Rate of Reading test in a digitally presented format. The Wilkins Rate of Reading test uses 15 words selected for their readability, repeated in a random order. The test measures reading speed and accuracy, and has shown good repeatability and reliability for testing reading speed and difficulties for a range of individuals [26,27]. For the Eye Tracker software, the text length default setting is 300 words, (i.e. 20 lines of text with 15 words per line), using the same words as the original non-digital test. The typical letter body size for the characters is 1.9x1.8 mm.

The Tobii Eye Bar was calibrated for each participant before starting, to take account of their sitting position and distance in relation to the

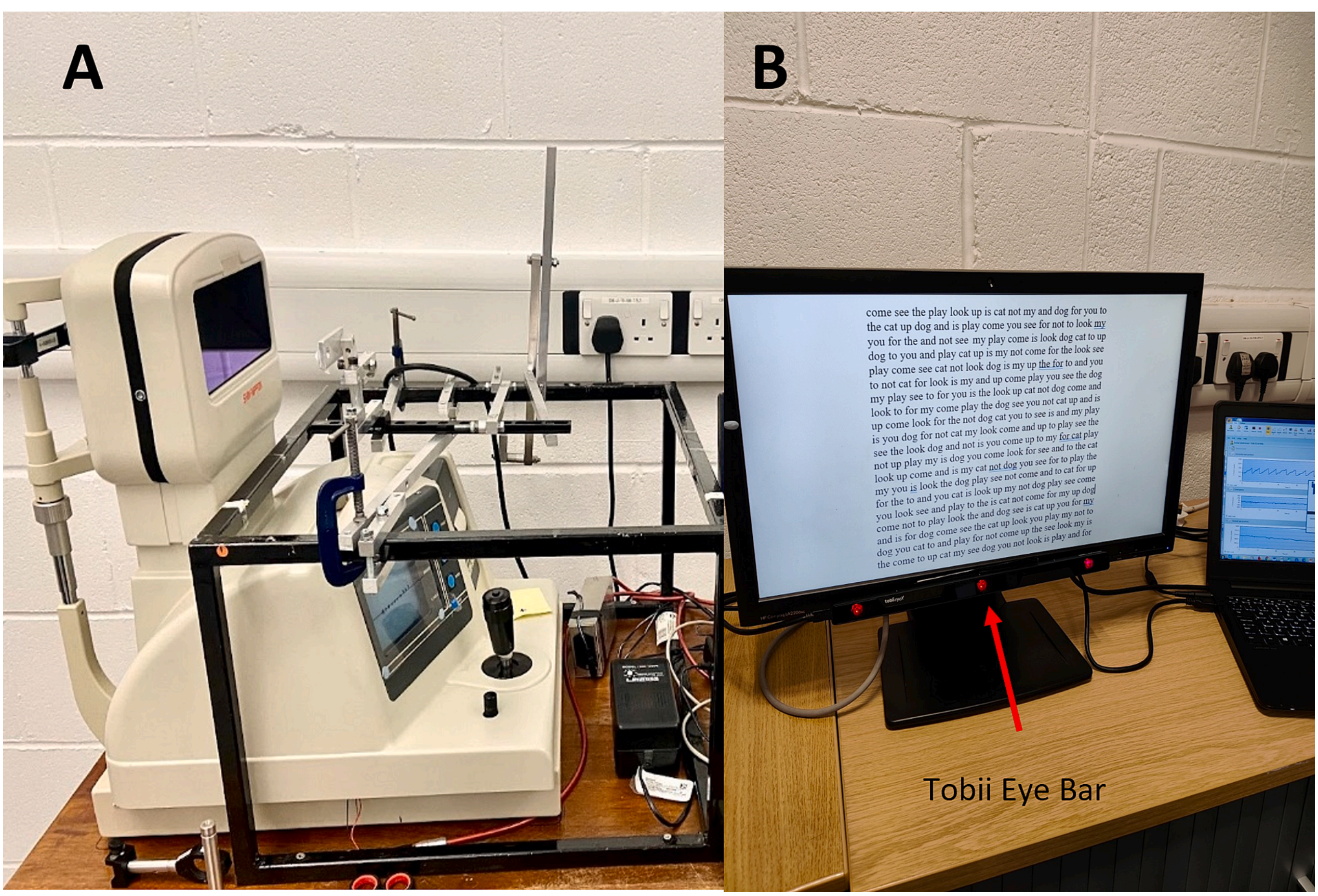

Fig. 2. Images of the instrumentation used for data collection. Panel A shows the Shin-Nippon 5000 SRW adapted for live recording of accommodative microfluctuations. Panel B shows the set up for the Clinical eye tracker, that incorporates a Tobii Eye Bar (below the screen, shown with the red arrow). The Wilkins Rate of Reading task used has been enlarged for demonstration purposes within the figure.

screen (21.5 in. LCD screen; HP Inc., Palo Alto, United States), set at 50 cm throughout. After successful calibration, participants were then asked to read through the text for 60 s during which they were recorded by the Eye Tracker. To allow for effects of learning and fatigue, participants were then asked to repeat the reading task for a second time, with measurements saved for both performances. The eye movements measured consisted of: mean fixations per row, fixations per minute, total rightward saccades, total number of regressions, and mean regressions per row. Values for these measures between the two attempts were averaged for analysis.

2.5. Statistical analysis

The accommodative microfluctuations and reading eye movement data obtained demonstrated a non-normal distribution (Kolmogorov-Smirnov $P < 0.04$ for all), and thus the non-parametric Friedman test was used for all comparative analyses. Statistical significance was defined as $P < 0.05$. For any statistically significant differences found, post-hoc pairwise comparisons were performed to investigate the results using Dunn's pairwise post hoc tests. Correlations were performed using Spearman's Rank. All statistical analyses were performed within SPSS (Version 27, IBM).

3. Results

3.1. Participant demographics and contact lens fitting

A total of 23 participants were recruited that met the inclusion criteria. All patients who fitted the eligibility criteria demonstrated good lens fitting, with all three study lenses. Details of the participants baseline measures and demography are in Table 3.

3.2. Accommodative microfluctuations

Of the 23 participants recruited, accommodative microfluctuation data from 20 participants provided undisrupted data to allow for power spectrum analysis. The three participants that were unable to contribute data was primarily due to small pupil size and frequent eye movement that failed to allow continuous data recording with the adapted Shin-Nippon SRW-5000 autorefractor. The exclusion of these participants did not alter the demographic differences significantly (Table 3).

Average microfluctuation values for low frequency components were 0.07 ± 0.09 D^2/Hz, 0.10 ± 0.07 D^2/Hz, and 0.09 ± 0.07 D^2/Hz for the SV, DF, and EDOF lenses, respectively with no statistically significant difference found between the lenses ($P = 0.142$). With high frequency components, the average values were 0.02 ± 0.01 D^2/Hz, 0.03 ± 0.02 D^2/Hz, and 0.02 ± 0.01 D^2/Hz, respectively, with no statistically significance observed ($P = 0.09$). The variability of the accommodative traces were 0.36 ± 0.14 D, 0.42 ± 0.12 and 0.39 ± 0.08D for the SV, DF, and EDOF lenses, respectively with no statistically significant difference found between the lenses ($P = 0.247$). Using pooled data, there was no correlation between participant pupil size and accommodative microfluctuations ($P = 0.65$), nor with age and accommodative microfluctuations ($P = 0.33$).

Table 3
Baseline measures and demography of the participant study samples, presented as average value ± standard deviation. Study samples were different sizes due to the poor data quality of 3 participants for measures on accommodative microfluctuations. Comparison of the differences in the group demographics are shown.

	Accommodative Microfluctuations (n = 20)	Reading Eye Movements; all participants (n = 23)	Average Difference (P value of difference)
Age (years)	23.1 ± 3.4	22.2 ± 2.9	0.9 (0.33)
Average Mean Spherical Equivalent (Dioptres)	−2.23 ± 1.99	−2.53 ± 2.00	0.3 (0.75)
Amplitude of accommodation (binocular; Dioptres)	11.00 ± 1.12	11.25 ± 0.99	0.25 (0.43)
Habitual pupil size (right eye; millimetres)	4.25 ± 1.32	3.80 ± 0.82	0.45 (0.10)
Baseline visual acuity (right eye; log MAR)	0.02 ± 0.10	0.00 ± 0.06	0.02 (0.88)

3.3. Reading eye movements

Reading eye movement data was collected on all 23 participants. The average values for different reading eye movements are visualised in Fig. 3. Significant differences were observed between the lenses for mean fixations per row ($P = 0.032$), fixations per minute ($P = 0.008$), total regressions ($P = 0.002$), and mean regressions per row ($P = 0.002$). No significant difference was found between total number of rightward saccades (0.099). Post-hoc pairwise comparisons indicated that the differences were due to Lens 3, the EDOF lens design, demonstrating significant differences compared to lens 1 and 2 for the different measures in all prior significant measures. Pairwise comparisons are shown in Table 4. Using Spearman's rank correlation between the central VA in the contact lenses and reading eye movements did not identify any significant correlations for each of the different lenses.

4. Discussion

In this study, accommodative microfluctuations and reading eye movements were investigated when wearing two licensed myopia management contact lenses with different optical designs. The lenses were tested in the same participants to see whether there were any observable differences between them.

Accommodative microfluctuations have been of interest due to the observed differences in their magnitude in different refractive groups [28]. There has been varied results looking at the influence of accommodation in myopia development, due to the reported link of myopia progression with near work, and the morphological differences between refractive groups and ciliary muscle anatomy [29,30]. Accommodative microfluctuations have been shown to be more unstable in myopes during prolonged near work [31], and thus it is hypothesised that an increased amount of accommodative microfluctuations may be an indication of, or risk factor for, myopia progression.

Accommodative microfluctuations have been shown to increase in variability under conditions where the depth of focus is enlarged, such as reducing target luminance [32]. Based on this, it was not unreasonable to hypothesise that the variability of the accommodative microfluctuations would increase when wearing the EDOF and/or DF lens. Indeed, other studies have observed a significant increase in accommodative microfluctuation variability in young adults wearing DF lenses compared to SV lenses [33]. However, no such difference in accommodative microfluctuations between these three lenses were observed in our study. However, when comparing that work against this study, there were some differences in the accommodative task employed [33]. The previous study used a target with a reduced accommodative demand (2D vs 4D) and a longer task duration (≈10 min vs 1 min). Furthermore, the task in that study was a detection task, whereas this study implemented passive observation, with no specific visual task employed.

It is unlikely that the sample size of this study would be insufficient to capture any increase in the variability of microfluctuations. Accommodative data was recorded for 20 participants, and would feasibly allow for a change in variability of 0.089D to be reliably detected ($\alpha = 0.05$, power = 80 %). This would be more than sufficient to detect the

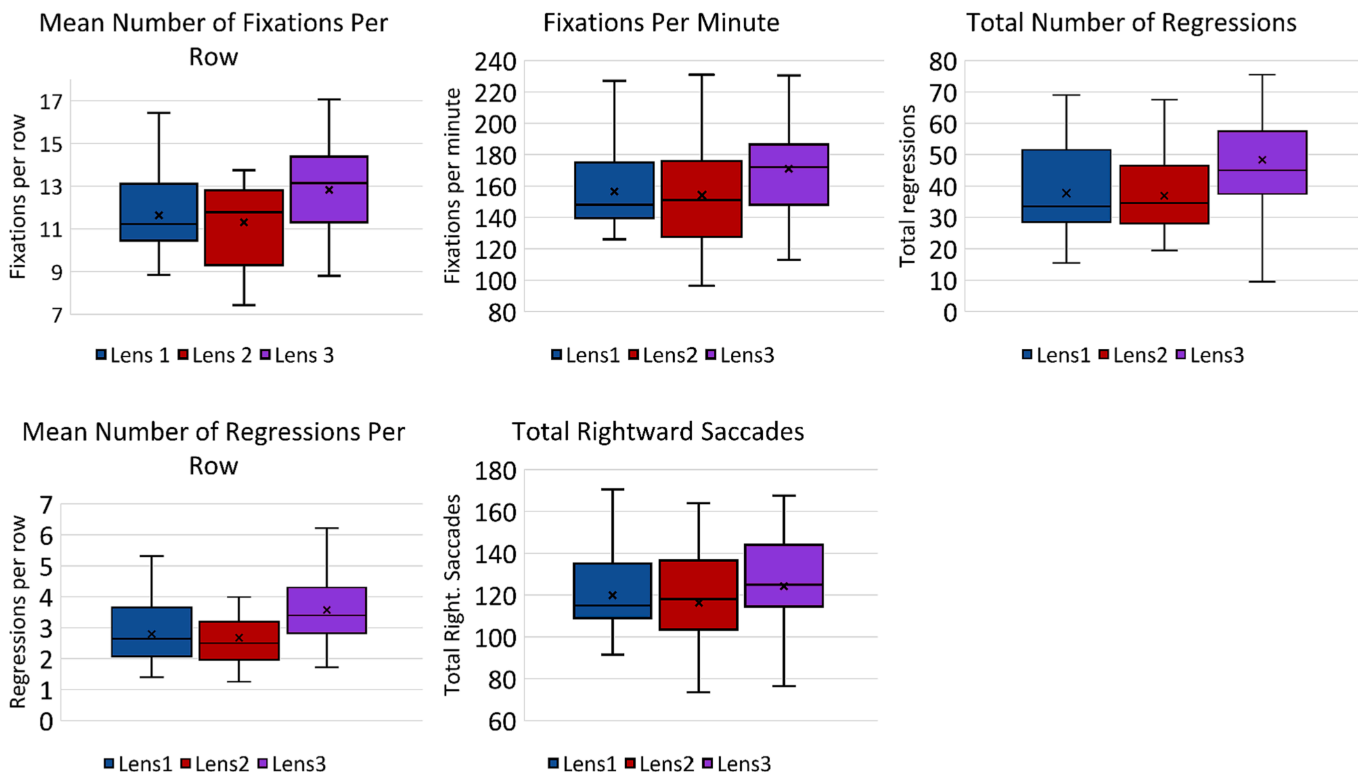

Fig. 3. Box and Whisker plots demonstrating the differences between reading eye movements between the three lenses used in the study. The line within the box indicates the median value, and the cross indicates the mean value. Single vision, dual focus, and extended depth of focus designs were all tested and are labelled as lens 1, lens 2 and lens 3, respectively.

Table 4
Post-hoc pairwise comparisons of reading eye movements between the three lens designs. Comparison was not possible for measures of total rightward saccades due to the result of the Friedman test showing similar distributions of results between lenses. Bold significance values with an asterisk indicate differences that are statistically significant ($P < 0.05$).

Eye movement measure	Pairwise comparison	Test statistic	Significance
Mean fixations per row	*Lens 1 – Lens 2*	0.174	0.555
	Lens 1 – Lens 3	−0.739	**0.037***
	Lens 2 – Lens 3	−0.565	**0.049***
Fixations per minute	*Lens 1 – Lens 2*	−0.130	1.00
	Lens 1 – Lens 3	−0.848	**0.012***
	Lens 2 – Lens 3	−0.717	**0.045***
Total number of regressions	*Lens 1 – Lens 2*	−0.043	1.00
	Lens 1 – Lens 3	−0.935	**0.005***
	Lens 2 – Lens 3	−0.891	**0.008***
Mean regressions per row	*Lens 1 – Lens 2*	0.00	1.00
	Lens 1 – Lens 3	−0.913	**0.006***
	Lens 2 – Lens 3	−0.913	**0.006***
Total rightward saccades	*Lens 1 – Lens 2*	Not applicable	
	Lens 1 – Lens 3	Not applicable	
	Lens 2 – Lens 3	Not applicable	

mean changes in variability of 0.32D previously observed [33].

The magnitude and variability of the microfluctations has been linked to the blur sensitivity of the eye, with an increase in fluctuations occurring under conditions that reduced blur sensitivity [32]. There is also longstanding evidence that blur detection thresholds themselves are reduced in the presence of myopic (and hyperopic) defocus [34,35]. If the myopic defocus present in a portion of the field when wearing the DF or EDOF lens had the same effect as defocus applied across the whole field[34], then the reduced blur sensitivity in these conditions may be an attenuating influence on the blur thresholds and magnitude of the accommodative microfluctuations.

Changes in the variability of the accommodative response may have also been masked by the instrumentation used to capture the fluctuating response of the accommodation system. The infra-red beam of the autorefractor that is projected onto the retina has an outer diameter of ≈2.9 mm at the cornea. This would mean that the beam could be passing through portions of the DF and EDOF lens where increased lens power is present (Fig. 1), and any small lens movements could interfere with the detection of the accommodative changes. This could be addressed using a different method for measuring microfluctuations, such as inserting the lenses monocularly and measuring the accommodative response in the fellow eye. This would overcome the problems from the multifocal optics, but would require the assumption of a harmonious synchronous accommodative response between the eyes.

Nonetheless, the lack of significance found corresponds to other studies looking at more macro-scale accommodative response differences between different lens designs. Prior reports suggested that there were no significant differences in accommodation between single vision contact lens designs and the dual focus concentric lens designs [36]. Gifford et al., found a reduced accommodative response with the NaturalVue lens, and a greater instability of accommodation for the DF lens design [16]. The results from this study did not capture any differences between the lenses, supporting the former data. Further studies looking at accommodative microfluctuations with multifocal lenses may benefit from applying different approaches, to see whether any differences are found.

Regarding the reading tasks, a difference in the number of total fixations during a reading task was observed, along with the number of corrective leftward eye movements – known as regressions – between the lenses. However, the number of rightward saccades were similar. Post-hoc analysis indicated that the observed difference was primarily seen for lens 3, the EDOF lens design, with no significant differences seen in pairwise comparisons between lens 1 and lens 2, the SV and DF lens, respectively, and that this was sustained after correction for multiple testing. This implies that fixation ability through the interpretation of peripheral visual information was impacted by the EDOF lens design, and this may have induced a measurable increase in compensatory eye movements between saccades.

Reading is a complex visual task that requires good foveal vision at the location of fixation. Visual acuity drops off rapidly in the parafoveal region [37], however it is still used to derive information and context from identified letters and words [21]. It is also used to help between saccades for fixation guiding, and provides a preview effect to skip words for a smooth reading experience and increased reading speed [21]. As the experiment used the Wilkins Rate of Reading test, which uses random words to ensure the ability to guess future words is limited, the influence of parafoveal defocus may have been exacerbated, as there can be no context derived from the passage of text. Therefore, the reading task may have been more difficult than typical tasks. In turn, the detail within the parafoveal view may have been relied on more greatly, causing the need to perform more fixation and regressions when reading through the passage of text. As seen in Fig. 1, the DF contact lens has a larger central zone for distance prescription than the EDOF lens, which has an increase in positive power within the central 1 mm of the lens. It may be that the EDOF lens with its gradual change in positive power closer to the central part of the lens, can cause differences in the focus and ability to use the parafoveal region in reading. Whether this effect continues after a period of adaptation would require further long term assessment, and is important to understand as these contact lens designs are aimed at use by children, who may be less confident in their reading abilities, and this may cause an inadvertent impact on reading-related educational activities [38].

An adjustment to the regular eye movements during a reading task may be hypothesised to influence reading speed and accuracy, as participants may need to perform a greater number of regressions to read a passage of text. Although neither reading speed or accuracy were directly assessed, the difference between the DF design and the EDOF design would suggest that there could be a difference in reading speed performance between the two lens designs. A recent study that investigated reading speeds in different multifocal contact lenses, using a different reading text and methodology, found that reading speed was reduced with the same EDOF lens design compared to SV lenses, however this result was also observed with other multifocal designs with larger central distance power zones, and they did not include the DF lens tested within this study [39]. Therefore, a study incorporating a larger sample with multiple different multifocal contact lens designs, would be beneficial to address whether these differences in reading eye movements directly translate to reading speed differences. Nevertheless, it may be worthwhile for clinicians to be aware that there are reports of differences in eye movement behaviour and reading speed in myopia management lenses, particularly before any adaptation period, when talking about these options and obtaining informed consent.

The strengths of this study were that the lenses were fitted in a randomised order, and that both the data collector and the participant were masked from the lens type during the process. This meant that the impact of repeatedly using lenses over a short period of time was shared between the lenses, along with any influence of lens order on any lens settling or ocular surface effects. The study also used licenced lenses for myopia control, meaning that the different lens designs used for myopia control for clinical practice could be directly compared.

A limitation of the study is the short period of time that the lenses were used, meaning that participants did not have a significant period of time to adapt to the different lens designs. Furthermore, measures of peripheral vision in the lenses were not collected. This would have been beneficial, as it may have provided context to compare any relative peripheral visual acuity loss with the reading eye movement data. Future studies may benefit to include this when analysing reading eye movements to understand how much of the changes in eye movements may be attributable to visual acuity loss. It is also important to note that the study was performed in young adults. Performing the study in children, over a longer period of time will allow assessment of whether these eye movement differences are retained in children with less matured accommodation systems and binocular coordination, and determine if there is any improvement over time with adaptation.

5. Conclusion

This study found no association between different myopia management lens designs and the presence of accommodative microfluctuations. Reading eye movements may be affected by different lens designs for myopia management, particularly on initial use, although studies in children wearing these lenses over a longer period of time are needed to confirm these results. This could have significant impact for clinicians, as it may either influence the lenses that they prescribe, or contribute to the advice that they give parents and children when discussing lens management options.

6. Author declarations and disclosures

The authors declare no competing or commercial interests with any of the materials used in this study. No financial disclosures.

Ethical approval was obtained for the project from the Research Ethics Committee at the University of Bradford.

7. Authors' contributions

NGM, MC, and AM had full access to the data in the study and act as the guarantors for the integrity of the data.

Concept and design: NGM, AM, MC.

Data collection and supervision: all authors.

Statistical analysis: NGM, AM, MC.

Drafting of the manuscript: NGM.

Critical revision of the manuscript: all authors.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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