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ORIGINAL RESEARCH

Relationships Between Success Factors in Daily Disposable Multifocal Contact Lenses

Sarah E Guthrie[1], Doerte Luensmann[1], Jill Woods[1], Jose Vega[2], Gary Orsborn[2]

[1]Centre for Ocular Research & Education (CORE), School of Optometry and Vision Science, University of Waterloo, Waterloo, Ontario, Canada; [2]CooperVision Incorporated, San Ramon, CA, USA

Correspondence: Sarah E Guthrie, Email sarah.guthrie@uwaterloo.ca

Purpose: To explore links between subjective comfort and vision in habitual multifocal soft contact lens (MFCL) wearers when refit with daily disposable MFCLs, to determine which factors are relevant for success with MFCLs and evaluate consistency between MFCLs of different designs.

Patients and Methods: This work examined subjective measures in a randomised, participant masked, bilateral wear crossover study at five optometry practices. Fifty-eight habitual MFCL wearers wore stenfilcon A multifocal (stenA-MF; CooperVision Inc) and delefilcon A multifocal (delA-MF; Alcon) for two-weeks. Subjective ratings included satisfaction with comfort and vision and agreement questions.

Results: Agreement with "I would like to wear this MFCL in the future" was taken to indicate success with each MFCL; agreement was significantly higher with stenA-MF. There was strong correlation between agreement responses for "I would like to wear this MFCL in the future" and "MFCL met my needs for vision" with both lenses ($p<0.01$). However, it was only with stenA-MF, which had higher agreement responses to both statements ($p<0.05$), that responses to these two statements correlated with satisfaction with end-of-day (EOD) comfort ($p<0.01$). These differences in correlations between the two lenses are seemingly driven by greater satisfaction with stenA-MF for near and intermediate vision ($p<0.05$).

Conclusion: Subjective vision and comfort were only correlated when vision met the needs of most participants. Meeting participants' needs for vision correlated strongly with wanting to wear a MFCL. Results indicate that meeting vision needs is more important than meeting comfort needs when influencing whether presbyopic patients continue wearing MFCLs.

Keywords: comfort, vision, presbyopia, soft contact lens, correlation

Introduction

Presbyopia, a common age-related condition characterised by an inability to focus on near objects, is affecting an increasing proportion of the world's population. In 2020, the presbyopic segment of the population (those 42 years or older) was 48% in the United Kingdom and 45% in the United States, with those segments predicted to continue growing.[1,2] The average person in these countries can now expect to spend roughly half their lives as a presbyope.[3]

While many contact lens wearers are at risk of dropping out of lens wear due to factors such as lens handling, discomfort and poor vision,[4–6] presbyopic contact lens wearers face additional challenges with comfort and vision.[7] The frequency of signs and symptoms of dry eye tends to increase with age[8,9] and are more common for women compared to men.[8,10] Newly presbyopic contact lens wearers face the choice of choosing new lens correction options – multifocal contact lenses, monovision, reading spectacles, or even dropping out of contact lens wear altogether. Reported contact lens prescribing trends in 2021 reveal that globally approximately half of patients over the age of 45 were fit with multifocal contact lenses and a third used single vision with reading spectacles.[11] There are reports that some practitioners retain a reluctance to fit multifocal contact lenses[12] but evaluating patients' reports of success and performance with multifocal contact lenses will provide key understandings on how to increase the number of successful multifocal contact lens wearers.

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Rueff et al reported on a survey of 496 presbyopic patients, where 73 (15%) had recently discontinued contact lens wear.[7] They found similar and high proportions of participants reported poor vision (38%) and discomfort (35%) as their primary reason for discontinuation.

Recent works have explored the relationship between comfort and vision with equivocal results.[13,14] Diec et al conducted a retrospective analysis of comfort and vision ratings including non-presbyopic myopes in single vision contact lenses and presbyopic participants wearing a variety of multifocal contact lenses.[13] They found that for non-presbyopes, vision satisfaction influenced comfort, but that this effect was significantly reduced in the presbyopic group. Conversely, they also found that comfort influenced vision most strongly in the presbyopic group. Maldonado-Codina et al found a strong positive correlation between subjective ratings of comfort and vision quality in toric contact lens wearers,[14] concluding that a perceived decrease in vision quality may have a negative impact on subjective comfort.

Jong et al conducted a retrospective analysis of visual acuity and subjective ratings of vision quality in 141 presbyopes and found the latter to be a better predictor of success than measured visual acuity,[15] where success was equated with a participant's willingness to purchase.

This work aims to further examine the subjective ratings of multifocal contact lens wearers, explore any links between their satisfaction with comfort and vision for each lens type, and determine the relationship of comfort and vision with the success metric of "I would like to wear this multifocal contact lens in the future". To enable this investigation, relevant data from a recent clinical study has been analysed and is reported here; the full study data has already been reported elsewhere.[16–18]

Materials and Methods

The study conducted was a prospective, randomised, participant-masked, bilateral crossover study conducted at five optometric practice sites in the United States (ClinicalTrials.gov identifier: NCT04449263). Ethics clearance was obtained through Sterling Institutional Review Board (Atlanta, GA) for each site, prior to commencement of the study. All study investigators were trained on the International Council for Harmonisation (ICH) guidelines for Good Clinical Practice and the study was conducted in accordance with the tenets of the 1964 Helsinki Declaration and its later amendments. Informed consent was obtained from all participants prior to enrolment in the study and prior to any study procedures being conducted.

This manuscript examines the subjective measures of the study, where participants rated and compared the performance of two silicone hydrogel daily disposable multifocal contact lenses - stenfilcon A multifocal (stenA-MF) (MyDay® Multifocal, CooperVision) and delefilcon A multifocal (delA-MF) (DAILIES TOTAL1® Multifocal, Alcon). Table 1 describes the lens parameters of these study lenses. Participant eligibility was determined at a screening visit. The main inclusion criteria for the study required eligible participants to be:

- At least 42 years of age;
- Able to wear the study lenses for at least 8 hours a day, 5 days a week;
- A habitual wearer of multifocal soft contact lenses (daily disposable or reusable), for the previous 3 months minimum;
- Having refractive astigmatism no higher than −0.75DC in either eye;
- Presbyopic, requiring a spectacle prescription reading addition of at least +0.75D and no more than +2.50D;
- Correctable to binocular distance vision of at least 6/9 Snellen (or +0.20 logMAR) which participants also deem to be "acceptable".

Table 1 Study Lenses

	stenA-MF	delA-MF
Lens name	MyDay® multifocal	DAILIES TOTAL1® Multifocal
Manufacturer	CooperVision	Alcon
Material	stenfilcon A	delefilcon A
Design type	Binocular Progressive System™	Precision Profile® Design
Dk/t @-3.00 (barrier/cm)	100	156
Water content (%)	54	33

Participants were excluded from the study if they habitually wore one of the study contact lenses, presented with any active ocular disease or infection, or reported a systemic condition or unstable medication routine that was regarded as likely to cause variability in vision and/or lens comfort during the study period.

Participants wore each of the study lenses in random order in their indicated daily disposable modality. Randomisation followed a lens assignment table designed to maintain equality in first lens worn. Participants were masked to lens type by over-labelling the lens foils. Investigators were not masked as they needed to follow the specific lens fitting guides during lens optimisation. For each lens pair, powers were reviewed after three to seven days of wear, and optimised if needed, prior to a 2-week (14–16 days) wear period. There was no wash out period between lens types.

Lens fit was confirmed to be acceptable prior to lens dispense. High contrast visual acuity (Snellen) was measured under photopic conditions using ETDRS charts at near (40 cm) and at intermediate (75 cm), and using their standard distance vision equipment for distance acuity (≥4 m).

At the conclusion of each 2-week lens wear period, participants were asked to provide subjective ratings of the lenses by combining responses for right and left into one score and considering a typical day in the previous week. Ratings were completed on paper questionnaires. Questions related to

- Satisfaction: vision for near, intermediate and distance, and end-of-day (EOD) comfort (1-fell short of needs; 2-met needs; 3-exceeded needs)
- Agreement (4-strongly agree; 3-slightly agree; 2-slightly disagree; 1-strongly disagree)

At the same time, participants provided an estimate of their typical total wear time in a day (hours) and their typical comfortable wear time in a day (hours).

At the end of the study participants were asked for a lens preference between the two study lenses using a 5-point Likert scale (strong/slight preference for each lens or no preference) based on

- Overall comfort
- Vision for near, intermediate, distance, and digital device use.

Statistical Analysis

Statistical analysis was performed using Statistica 13 (TIBCO Software Inc., Palo Alto, California, USA), with the exception of the binomial tests used to analyse the results for the count data of subjective preference questions which were performed using IBM SPSS Statistics 27 (IBM, Armonk, NY, USA). Binomial testing allotted the "no preference" responses evenly between lens types.

Subjective data were collected as one measure for both eyes and all data were compared between lens types using Wilcoxon matched pairs testing. Means, medians, ranges and standard deviations are provided for each variable.

Data from subjective ratings for both lenses were also analysed by Spearman correlations.

A linear mixed model was used to assess the potential impact of order of wear, age and habitual lens type on the study variables.

Results

Demographics

Fifty-eight participants (8 male, 50 female) completed all study visits and were included in the data analysis. There were no discontinuations and no ocular or serious adverse events. Mean participant age was 54.4 ± 7.3 years [42 to 70 years]. Their mean right eye spherical equivalent refraction was −1.10 ± 2.7D [−6.50D to +3.75D], near addition +2.00 ± 0.4D [+1.00D to +2.50D]. The four most common habitual lens types were Air Optix® Aqua Multifocal (13), 1-DAY ACUVUE® MOIST Multifocal (12), Biofinity® Multifocal (11), DAILIES® AquaComfort Plus® Multifocal (10) and ULTRA® for Presbyopia (5); other brands were a count of 2 or less.

Subjective Ratings

Table 2 summarises participant responses to the subjective questions.

For the two agreement statements, which can be considered as indicators of multifocal contact lens (MFCL) success, participants had statistically significantly stronger agreement with the stenA-MF lens over the delA-MF lens:

- "This MFCL met my needs for vision"; 3.3 stenA-MF vs 2.9 delA-MF (p=0.02)
- "I would like to wear this MFCL in the future"; 3.0 stenA-MF vs 2.6 delA-MF (p=0.03)

Satisfaction with vision was statistically significantly greater with stenA-MF for intermediate (2.0 vs 1.8, p=0.01) and near (1.9 vs 1.5, p<0.01) distances. The other ratings of EOD comfort, EOD dryness, vision for distance during the day were rated similarly for the two lens types and the differences were not statistically significant (all p>0.05).

Wear time and comfortable wear time were not statistically different between lens types.

There was no effect of order of wear, participant age or habitual lens type on any variable (p>0.05).

A broader range of subjective questions were included in the full data set. These results have been reported previously and are not repeated here because correlations analysis showed that they are not relevant to the purpose of this manuscript.[16–18]

Participant Preferences

At the end of the study, participants responded to a number of preference questions comparing the study lenses, and those related to comfort and vision were: overall comfort, overall vision and vision for near, intermediate, distance, digital device use (Figure 1).

Participants favoured stenA-MF for overall comfort (26 vs 9, p=0.03), intermediate vision (25 vs 8, p=0.03), vision for digital device use (27 vs 10, p=0.03) and overall vision (34 vs 10, p=0.04). There were no statistically significant differences for near (29 vs 14, p=0.06) and distance vision (13 vs 19, p=0.51). Preferences were not affected by order of wear, participant age or habitual lens type (p>0.05).

Table 2 Participant Reported Outcomes Recorded After 2 Weeks of Lens Wear (Mean ± Standard Deviation (Median)[Range])(n=58)

	stenA-MF	delA-MF	p value
AGREEMENT **4-strongly agree; 3-slightly agree; 2-slightly disagree; 1-strongly disagree**			
Multifocal Contact Lens (MFCL) met my needs for vision	3.3 ± 0.8 (3)	2.9 ± 1.0 (3)	0.02
I would like to wear this MFCL in the future	3.0 ± 1.0 (3)	2.6 ± 1.2 (2.5)	0.03
SATISFACTION ***1-fell short of needs; 2-met needs; 3-exceeded needs***			
End-of-day (EOD) comfort	2.0 ± 0.6 (2)	2.0 ± 0.5 (2)	0.72
End-of-day (EOD) dryness	1.9 ± 0.7 (2)	1.9 ± 0.6 (2)	0.88
Vision for distance during the day	2.1 ± 0.5 (2)	2.0 ± 0.4 (2)	0.24
Vision for intermediate	2.0 ± 0.5 (2)	1.8 ± 0.6 (2)	0.01
Vision for near	1.9 ± 0.6 (2)	1.5 ± 0.6 (1)	<0.01
WEAR TIME (hours) **0.5-hour increments**			
Wear time	12.6 ± 2.6 (12) [6–19]	12.1 ± 3.2 (12) [5–16]	0.11
Comfortable wear time	11.6 ± 3.2 (12) [2–19]	11.0 ± 3.4 (11.8) [4–16]	0.08

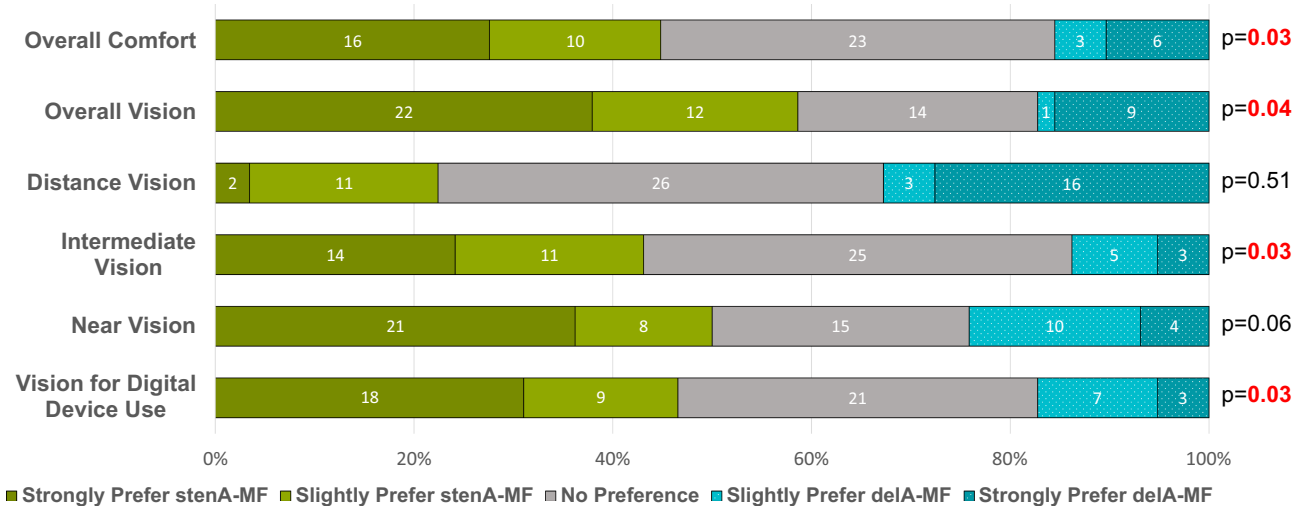

Figure 1 Lens preference as reported at the end of the study (n=58).

Visual Acuity

Visual acuity, recorded after the 2-week lens wear period, is provided in Table 3. Vision with stenA-MF was statistically significantly better at near (0.08 vs 0.14, p<0.01) and intermediate (0.08 vs 0.12, p<0.01) distances. Visual acuity at distance was similar for both lens types.

Correlations Between Variables

Correlation analysis was conducted on the results for each lens separately (n=58). For each lens type, satisfaction with EOD comfort was significantly correlated with satisfaction with EOD dryness (stenA-MF: r_s=0.71, p=<0.01; delA-MF: r_s=0.67, p<0.01) (Figure 2A), and comfortable wear time (CWT) (stenA-MF: r_s=0.30, p=0.02; delA-MF: r_s=0.37, p<0.01).

For stenA-MF, responses to "This MFCL met my needs for vision" were significantly correlated with ratings of satisfaction with EOD comfort (r_s=0.36, p=0.01), but this was not the case for delA-MF (r_s=−0.06, p=0.68) (Figure 2B). The same is true for the statement "I would like to wear this MFCL in the future". For stenA-MF the responses were significantly correlated with satisfaction with EOD comfort (r_s=0.46, p<0.01), but not for delA-MF (r_s=0.03, p=0.81) (Figure 2C).

There was a significant correlation between the two agreement questions "MFCL met my needs for vision" and "I would like to wear this MFCL in the future", for each lens type (stenA-MF: r_s=0.81, p<0.01; delA-MF: r_s=0.84; p<0.01) (Figure 2D).

Considering the lens preferences provided at the end of the study, preference based on overall comfort was significantly correlated with lens preference based on vision at near (r_s=0.61, p<0.01), intermediate (r_s=0.48, p<0.01),

Table 3 LogMAR Visual Acuity (OU) After 2 Weeks of Lens Wear at Near (40 cm), Intermediate (75 cm) and Distance (≥4 m) (Mean ± Standard Deviation (Median)[Range]) (n=58)

	stenA-MF	delA-MF	p value
Distance visual acuity OU (≥4m)	0.01 ± 0.07 (0.00) [−0.13–0.20]	0.01 ± 0.06 (0.00) [−0.13–0.18]	0.64
Intermediate visual acuity OU (75cm)	0.08 ± 0.10 (0.06) [−0.10–0.32]	0.12 ± 0.12 (0.10) [−0.10–0.42]	<0.01
Near visual acuity OU (40cm)	0.08 ± 0.10 (0.08) [−0.20–0.32]	0.14 ± 0.12 (0.14) -0.16–0.40]	<0.01

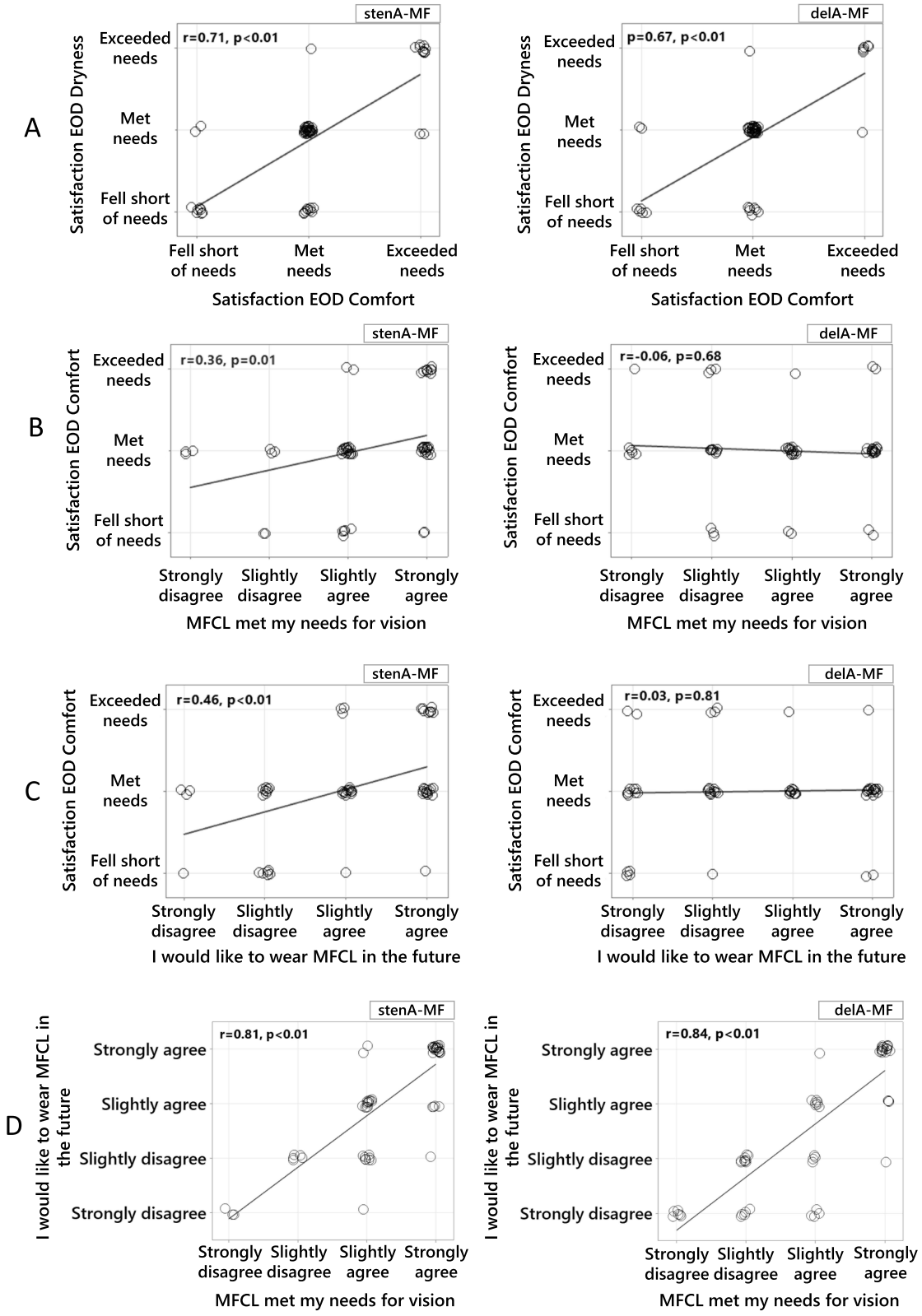

Figure 2 Spearman correlation and scatter plot, separated by lens, of participant subjective ratings of: (**A**) satisfaction with end-of-day (EOD) comfort against satisfaction with EOD dryness; (**B**) satisfaction with EOD comfort against agreement with "multifocal contact lens (MFCL) met my needs for vision"; (**C**) satisfaction with EOD comfort against "I would like to wear this MFCL in the future"; (**D**) "MFCL met my needs for vision" against "I would like to wear this MFCL in the future", all after two weeks of lens wear for the stenA-MF (left) and delA-MF (right) lenses. To avoid overlapping data, random jitter was applied to each data point in the x and y directions (n=58).

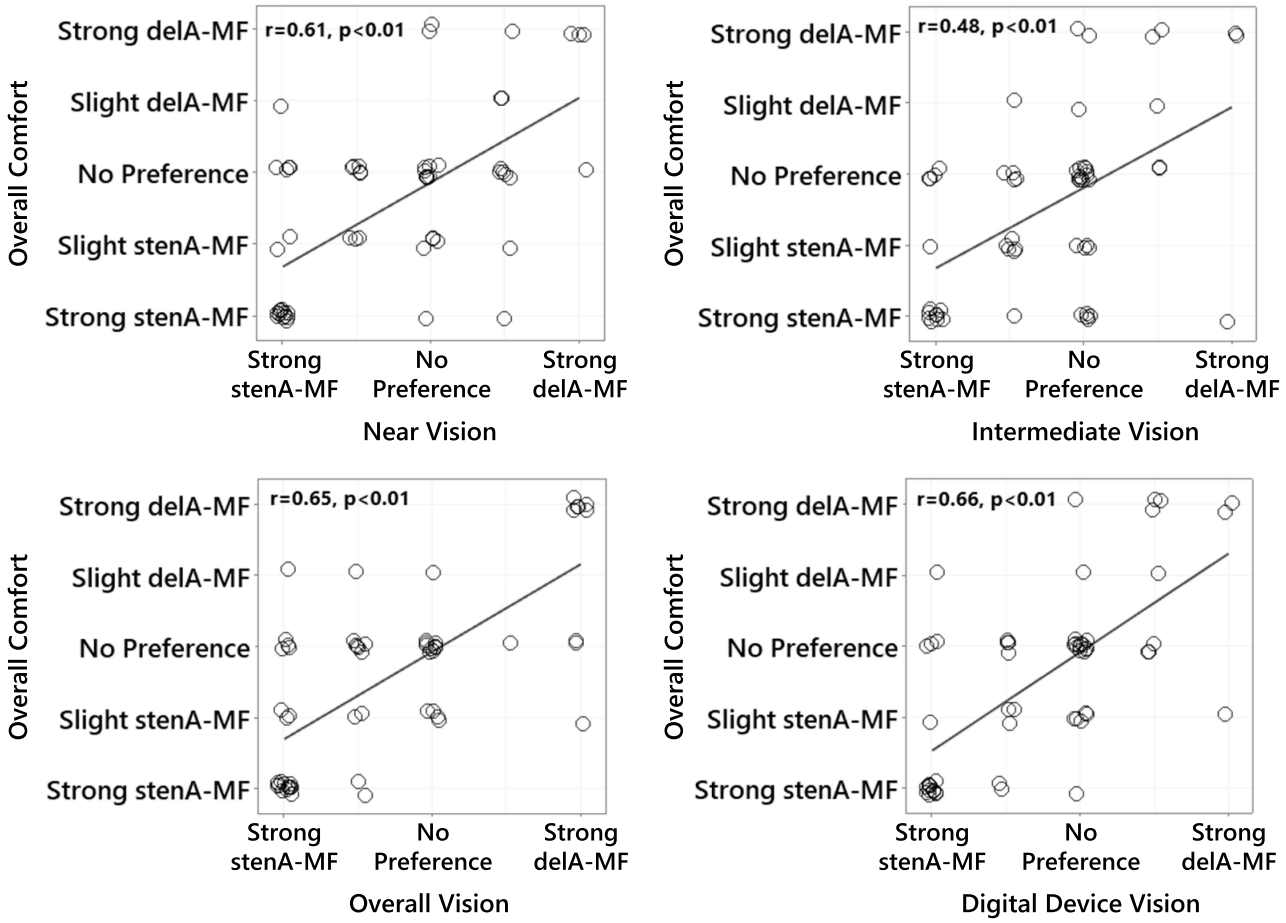

Figure 3 Spearman correlation and scatter plot of participant subjective preference based on overall comfort against preference based on near vision, intermediate vision, overall vision and vision for digital device use. To avoid overlapping data, random jitter was applied to each data point in the x and y directions (n=58).

for digital device use (r_s=0.66, p<0.01) and overall (r_s=0.65, p<0.01) (Figure 3). Distance vision was not significantly correlated (r_s=−0.02, p=0.89).

Lens preference based on overall vision was also correlated with lens preference based on vision at near (r_s=0.85, p<0.01), intermediate (r_s=0.71, p<0.01), and for digital device use (r_s=0.87, p<0.01) (Figure 4). Distance vision was not significantly correlated (r_s=0.15, p=0.27).

Discussion

This was a participant-masked dispensing study examining subjective ratings with two different daily disposable, silicone hydrogel, multifocal contact lenses worn for 2 weeks each. This lens wear period is in agreement with work by Fernandes et al which suggests that up to 15 days are sufficient for sensory adaptation to multifocal contact lenses.[19]

Data in Figure 2A explore variables which would normally be associated with ocular comfort symptoms and evaluates correlations between satisfaction with EOD comfort and satisfaction with EOD dryness and comfortable wear time. Correlations for these variables were consistent for both lens types. As one would expect, strong correlations were seen between satisfaction with EOD dryness and comfort for both lens types.

With stenA-MF, compared to delA-MF, participants were overall in greater agreement that the lens met their needs for vision, were in greater agreement that they would like to wear it in the future, were more satisfied with intermediate and near vision, and had better measured near and intermediate visual acuities. When considering if satisfaction with EOD comfort and EOD dryness had an impact on the subjective ratings of "MFCL met my needs for vision" (Figure 2B) and "I would like to wear this MFCL in the future" (Figure 2C), an interesting result can be seen. Moderate correlations were

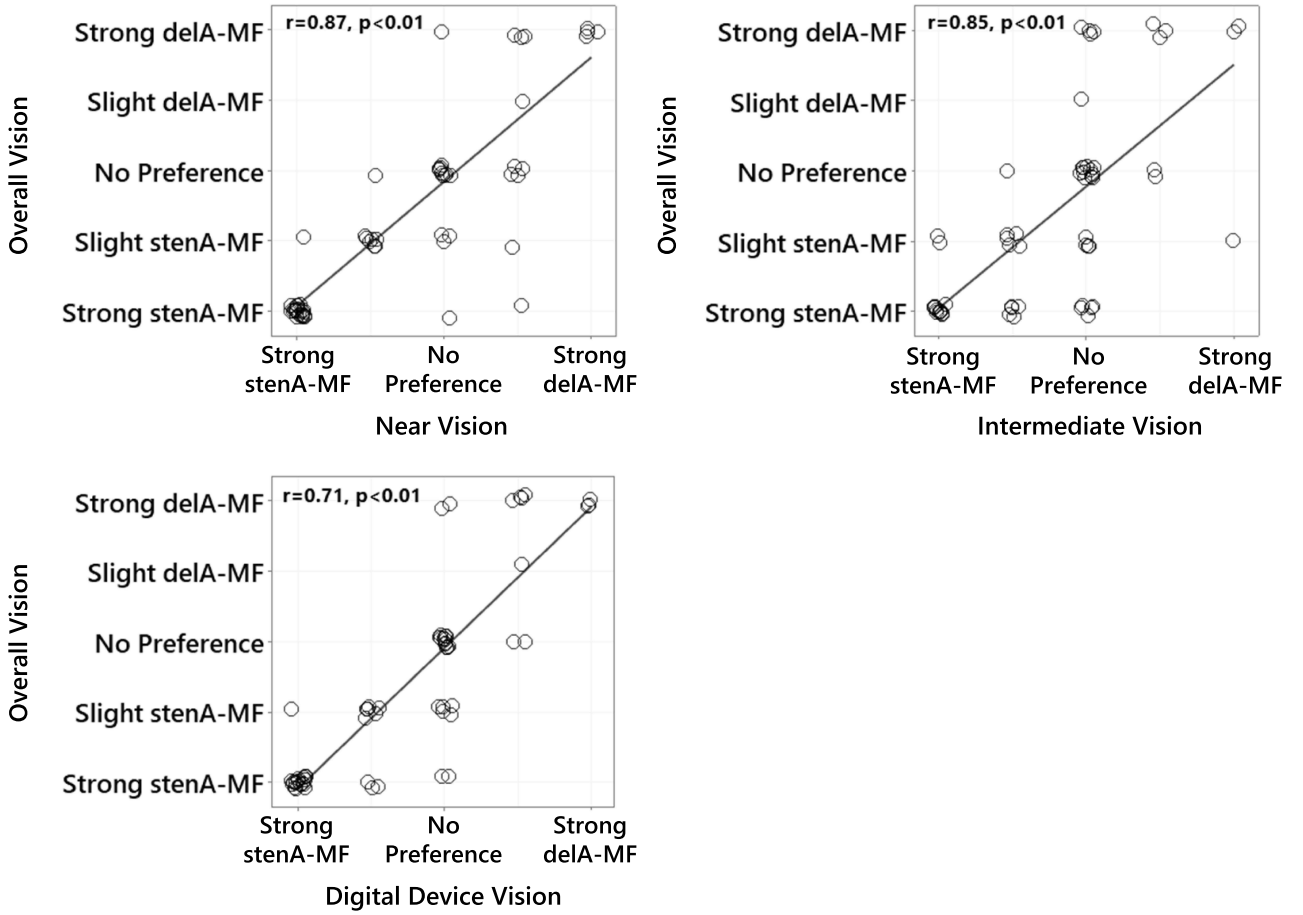

Figure 4 Spearman correlation and scatter plot of participant subjective preference based on overall vision against preference based on near vision, intermediate vision and vision for digital device use. To avoid overlapping data, random jitter was applied to each data point in the x and y directions (n=58).

found for stenA-MF, but the variables were uncorrelated for delA-MF. This indicates that EOD comfort and dryness did not have a significant impact on overall vision or the desire to continue wearing the lens. In these cases, any dissatisfaction with vision (ie, participants reporting that the MFCL did not meet their needs for vision) was not linked to discomfort and, similarly, comfort rating was not a predictor of whether a participant agreed they would like to continue wearing a MFCL.

It is possible that the weak/no correlations were because both study lenses resulted in high levels of satisfaction with comfort and long hours of comfortable wear time. Perhaps if discomfort had been an issue with either lens, the results may have shown higher correlations and supported comfort as more predictive of wanting to wear MFCL. Alternatively, perhaps presbyopes perceptions of visual success are less influenced by comfort, as reported by Diec et al[13] who concluded that a presbyope's perception of comfort and vision are not necessarily related, and that they are more able than non-presbyopes to differentiate between these two factors. It should also be noted that while we would expect an older eye to have more symptoms of dryness,[8,9] it has been shown that presbyopic participants rate contact lens comfort higher than younger wearers.[20] In this study, rather than using a numerical rating scale where the top score indicates perfection, the satisfaction scale asked how the performance was relative to the participant's expectations. As participants in this study were an older, more experienced group of contact lens wearers they may also have set realistic expectations of contact lens comfort. Combined with the use of the lower number of just three response choices of "exceeded…, met…, and fell short of my needs", rather than a 0–100 scale, these factors would create less scatter in the data, thus making it harder to find correlations. While the use of the "exceeded…, met…, and fell short of my needs" scale does make it harder to find correlations, it should be noted that it does create a more normalized interpretation of participant

success than a typical 0–100 scale, where a score of 60 for one participant might indicate a satisfactory performance but another might interpret 80 as the cut off for acceptability. Effectively, this "needs" scale removes interparticipant variability.

While comfort does not seem to play a part in predicting success, strong correlations are found between "MFCL met my needs for vision" and "I would like to wear this MFCL in the future" for both lens types (Figure 2D). This is perhaps intuitive – as long as a lens is not uncomfortable, a presbyope would want a multifocal contact lens to meet their needs for vision above all other factors. While it's possible that presbyopes have come to expect a visual compromise, especially if they are experienced with older multifocal designs, having their expectations met for vision is clearly a driving factor in wanting to continue wearing a multifocal contact lens.

While agreement and satisfaction were measured immediately after each lens type was worn, overall preferences were collected at the end of the study, after both lens types had been worn (Figure 1). A majority of responses to lens satisfaction questions for EOD comfort showed that both lenses met participant's needs; however, lens preference based on overall comfort showed a significant preference for stenA-MF. A majority of participants also preferred their vision with stenA-MF with only distance vision showing no clear preference between study lenses. When considering correlations of lens preference based on overall comfort with lens preference based on the 4 vision variables (near, intermediate, overall, digital device use) (Figure 3), moderate correlations were found. While this is something of a discrepancy with the results of the satisfaction with EOD comfort, it should be noted that in previous measures, participants only provided ratings of "exceeded…, met…, and fell short of my needs". Small differences in lens comfort would not be apparent on that scale. But, when asked for a preference, those differences would become apparent. It might also be the case that when considering overall comfort at the end of the study, the lens with better vision was remembered as having overall less lens awareness.

High correlations between the preferences based on the different vision distances (Figures 3 and 4) again underline the trend of participants to prefer their vision with stenA-MF and is an intuitive outcome based on the preference results.

This work highlights the large number of factors at play when considering participant success with MFCL. Previous work by Diec et al[13] combined subjective responses for many different MFCL to explore correlations between comfort and vision. While this does yield correlations, it is a simplification of the overall lens wear experience. As shown here and in previous work,[21] if the participant is unhappy in one aspect of the lens wear experience, then this may be reflected in all subjective ratings. With the current high comfort and vision standards of modern contact lens wear, future studies which examine correlations in situations where participant satisfaction is low in one or more area could yield more information to inform the connections between factors in the lens wear experience.

There are a few limitations of the study design. Participant masking of the study lenses was facilitated by attaching a strongly adhesive over-label to each blister pack dispensed. However, it should be recognised that some participants may try to remove the over label and they may also research the blister pack shape, although there were not any reports of this type of unapproved activity during the study. Any unmasking may create bias towards one lens or the other, and in this study, it cannot be certain that any possible participant-initiated unmasking would bias all participants in the same way.

There are a few limitations of the analysis. Firstly, a Spearman correlation is generally used for variables measured on an interval or ranked scale and does assume a linearity of the data. It has been applied to this categorical data with the assumption that the response scales would have been treated by the participants in a linear manner and so provide a meaningful and useful analysis.

Secondly, limiting the participant responses to Likert scales creates a blending of results and provides a firm context for the participant to determine their rating. However, it makes it difficult to determine correlations between variables. It would be more ideal to use an anchored 0–100 scale which would provide a greater range of data values, thus allowing better spread of data which would allow for a more robust correlation analysis. Similarly, the high rates of success with both study lenses in the test population lead to a clustering of data at the high end of scales. It should also be noted that due to the wide variation in lens designs and material properties of multifocal contact lenses, these results cannot be taken as necessarily representative of all types of multifocal contact lenses.

Conclusions

In this study with two daily disposable, silicone hydrogel, multifocal soft contact lenses with different optical designs, various comfort and vision metrics were intricately related. Comfort and vision preferences were moderately correlated, but satisfaction with end-of-day comfort and vision were only correlated when there was higher agreement that vision met participants' expectations. These results suggest that for this group of presbyopic participants, being satisfied that their visual needs had been met was linked more strongly than comfort ratings with their desire to continue wearing the multifocal lenses. While it is accepted that good end-of-day comfort is an important factor for contact lens success generally, these results suggest that attaining satisfaction with vision may be even more important than comfort for retaining presbyopes in multifocal soft contact lenses.

Data Sharing Statement

Individual participant data will not be shared.

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