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Visual performance in myopic adolescents fitted with pupil-optimised multifocal soft contact lens

Ceren Durmaz Engin[a,*], Dilhan Karaca[b]

[a] *Buca Seyfi Demirsoy Education and Research Hospital, Department of Ophthalmology, Izmir, Türkiye*
[b] *Karadeniz Eregli State Hospital, Department of Ophthalmology, Zonguldak, Türkiye*

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Abstract

Aim: This study aims to assess the influence of a newly developed pupil-optimized multifocal soft contact lens (MFSCL) in comparison to single-vision contact lenses (SVCL) on visual performance among adolescent myopes.

Materials and Methods: Myopic adolescents, aged 14 to 18 years, who were habitual SVCL users, were subjected to a trial involving MFSCL with a mid-addition power. Various visual parameters including distance and near visual acuity (VA), maximum reading speed (MRS), reading acuity, contrast sensitivity, and stereoacuity under photopic conditions were measured for MFSCL and compared to SVCL.

Results: No statistically significant differences were observed between SVCL and MFSCL in terms of near VA, MRS, contrast sensitivity, and stereoacuity ($p>0.05$ for all). However, a decrease in distance VA was noted with MFSCL ($p = 0.021$). Moreover, reading acuity, which denotes the smallest print size comprehensible without significant errors, was found to be smaller when using MFSCL ($p<0.001$).

Conclusion: In adolescent myopic patients, mid-add power in MFSCL did not significantly impact near VA and contrast sensitivity when compared to SVCL, while a decrease in distance VA was observed. Moreover, MFSCL did not affect reading speed but did enable the reading of smaller font sizes.

Introduction

Myopia is the leading cause of distance refractive error. In recent years, the global prevalence of myopia has witnessed a remarkable surge, with a significant increase noted in regions such as East and Southeast Asia [1]. According to the World Health Organization (WHO), approximately 30% of the world's population received a diagnosis of myopia in 2020. Projections suggest that if current trends persist, by the year 2050, nearly 5 billion people, or roughly 50% of the global population, will be affected by myopia [2]. The presence of myopia, especially when it progresses rapidly, is associated with an increased risk of various ocular complications, including cataracts, glaucoma, retinal detachment, and myopic maculopathy [3]. These situations not only pose a significant problem for individuals, but they also impose a substantial economic burden on society. One particularly concerning trend is the onset of myopia at younger ages, even during the pre-school years. Therefore, myopia control beginning at a young age is a significant public health concern in the present day.

Contemporary strategies for myopia control encompass various approaches, including single-vision or bifocal spectacle lenses [4], orthokeratology [5], low-dose atropine therapy [6] and multifocal soft contact lenses (MFSCL) [7]. Multifocal contact lenses employ an optical design featuring concentric zones with different refractive powers. This optical design is influenced by the "peripheral defocus" theory and by regulating peripheral blur, those lenses hold promise in mitigating the stimulus for axial elongation and myopia progression [8]. They enable individuals to perceive objects at different distances with a specified degree of clarity by controlling depth of focus [9]. Enhanced depth of focus, especially during activities involving near tasks like using electronic devices and reading, improves visual comfort and reduces ocular fatigue. Additionally, these lenses have the potential to reduce the accommodative effort associated with near work, a factor often linked to myopia progression. Multifocal lenses have been successfully employed in presbyopia treatment globally [10,11]. The development of MFSCL with different designs considering

*Corresponding author:
Email address: cerendurmaz@gmail.com (Ceren Durmaz Engin)

variations in people's distance refraction values, pupil diameters, and accommodative capacities has led to its use in different age groups, including myopic pre-presbyopes. While most of those MFSCL are employed off-label for myopia control in many countries, the only MFSCL approved in Europe and America for controlling myopia progression in children has not yet become accessible in our country [12].

Over the past decade, numerous studies have demonstrated the positive impact of MFSCLs on myopia control and improved visual acuity (VA) [8,9,13,14]. These studies were primarily conducted on elementary school-aged children, who typically have a higher capacity for accommodation, making it easier to achieve visual adaptation to the lens. However, it's important to note that the use of contact lenses can have side effects, including corneal abrasions, ocular allergies, and, more seriously, keratitis [15]. Therefore, their use in this age group should be approached with caution and under the supervision of parents. Adolescents, on the other hand, are common users of contact lenses. Considering that they still face the risk of myopia progression, we sought to assess the tolerability of MFSCL in adolescents. We also wanted to evaluate the impact of MFSCL on near tasks especially reading. Therefore, the objective of this study is to evaluate the impact of a new pupil-optimized MFSCL on visual performance in adolescent myopes in comparison to single-vision lenses.

Materials and Methods

Study population

In this retrospective study, the myopic adolescents, aged 14 to 18 years, who applied for contact lens examinations at Karadeniz Ereğli State Hospital between December 2021 and August 2022, were examined. This study was performed in accordance with the principles of the Declaration of Helsinki and was approved by the institutional Ethics Committee (Bulent Ecevit University, Date: 09/2023, Number:2023/16) . Informed consent was waived due to the retrospective nature of the study. However, before the MFSCL trial, all possible risks associated with the contact lens are explained in detail to the patients and their parents, and only those with patient and parental consent are provided the MFSCL trial in our clinic.

Participants were included if they were current wearers of spherical single vision (monofocal) contact lenses (SVCL) manufactured in Senofilcon A material (Acuvue OASYS, Johnson & Johnson, Jacksonville, FL, USA), had myopia with a spherical equivalent ranging from -2.00 D to -6.00 D, had astigmatism not exceeding 0.50 D, had a best corrected distance VA of 20/20 in both eyes, were involved in a MFSCLs trial, attended all scheduled follow-up examinations, and had worn the MFSCL at least 8 hours/day. Exclusion criteria included non-attendance at follow-up examinations, not wearing the contact lens regularly, incomplete data for any study parameters, trial with a MFSCLs manufactured from materials other than Senofilcon A, history of ocular allergies, infections, or dry eye conditions due to MFSCL usage, amblyopia, tropia or phoria in one eye, or a difference of 2 diopters or greater in spherical equivalent between two eyes.

MFSCL trial

A routine baseline ophthalmic examination included visual functions, intraocular pressure, phoria at near and distance, biomicroscopy, and dilated fundoscopy for all participants. Pupil size was measured with a pupil gauge in photopic conditions. Visual functions included distance VA using the Snellen chart, near VA, maximum reading speed (MRS; reading speed irrespective of print size), and reading acuity (RA; the smallest print size that can be read without making a significant mistake) using a noval iPad application of the MN-Read chart, which had a validation in Turkish language [16,17], contrast sensitivity using the Pelli Robson chart, and stereopsis with the TNO stereopsis test, all of which are evaluated under photopic conditions. Distance VA was performed monocularly and binocularly, and near acuity measures were performed binocularly. After examining those parameters with the patient's current monofocal spherical contact lens, a mid-add MFSCL was fitted without changing the spherical equivalent of the contact lens. Overrefraction was performed if a decrease in distance VA was observed. Subsequently, participants were given a two-week adaptation period with MFSCLs, followed by a comprehensive follow-up examination to evaluate their visual performance. Participants experiencing issues with visual quality, allergies, or infection-related complications were offered alternative MFSCL designs or advised to continue with their existing spherical contact lenses. Participants who had a successful trial and were satisfied with MFSCLs were prescribed the lenses for continued use.

Trial lenses

The MFSCLs included in this study are Acuvue OASYS Multifocal Contact Lens with mid add (+1.50D to +1.75D) (Johnson & Johnson, Jacksonville, FL, USA), which have a pupil-optimised design and are worn with daily replacement for 2 weeks. These lenses are made of Senofilcon A material, and their base curve is 8.4 mm, water content is 38%, lens diameter is 14.30 mm and DK value is 147 x 10-9 (cm^2/s). This center-near contact lens have different optic zone diameters according to age and spherical refraction.

The use of MFSCLs for refractive correction was conducted in compliance with the Turkish Ministry of Health's regulations and possessed the necessary regulatory clearances, including the Product Tracking System (PTS) system registration and EC certification.

Statistical analysis

The sample size required for each group was determined using G-Power software with an alpha value of 0.05, resulting in a minimum of 28 participants. The primary hypothesis of this study is to investigate whether there is a difference in visual performance between single vision contact lenses (SVCL) and multifocal soft contact lenses (MFSCL). In present study, only data from the right eye was included in the analysis for monocular tests, including distance VA and contrast sensitivity, while results for near VA, MRS, RA, and stereopsis tests were presented on a binocular basis. Snellen chart's VA values were converted

Table 1. Visual performance parameters with SVCL and MFSCL of the study patients.

	SVCL (n=30)	MFSCL (n=30)	p
Distance VA (logMAR)	-0.05 ± 0.05 (-0.16 – 0)	-0.04 ± 0.05 (-0.16 – 0)	**0.021**
Near VA (logMAR)	0.09 ± 0.04 (0 – 0.2)	0.08 ± 0.05 (0 – 0.2)	0.083
MRS	148.23 ± 15.17 (122 – 175)	149.20 ± 14.74 (120 – 176)	0.208
RA (logMAR)	-0.09 ± 0.02 (-0.12 – 0.06)	-0.11 ± 0.03 (-0.18 – 0.06)	**<0.001**
Contrast sensitivity	1.61 ± 0.10 (1.50 – 1.80)	1.60 ± 0.09 (1.50 – 1.80)	0.083

MFSCL, multifocal soft contact lens; MRS, maximum reading speed; RA, reading acuity; SVCL, single vision contact lens; VA, visual acuity.
Paired samples t-test was conducted (p values <0.05 were considered to be statistically significant).

Table 2. Correlation analysis between spherical equivalent of MFSCL, pupil diameter and visual function parameters.

Correlation coefficient	SE of MFSCL	Pupil size	Distance VA	Near VA	MRS	RA	CS	SA
SE of MFSCL	**1**							
Pupil size	-0.173	**1**						
Distance VA	-0.677**	0.217	**1**					
Near VA	-0.572**	0.238	0.514**	**1**				
MRS	-0.213	0.179	0.252	0.379*	**1**			
RA	0.223	0.170	-0.08	0.073	-0.305	**1**		
CS	0.156	0.088	0.135	-0.106	-0.161	-0.078	**1**	
SA	-0.005	0.137	0.023	0.032	0.214	-0.020	-0.212	**1**

*: Correlation is significant at the 0.05 level (2-tailed). **: Correlation is significant at the 0.01 level (2-tailed).
CS, contrast sensitivity; MFSCL, multifocal soft contact lens; MRS, maximum reading speed; RA, reading acuity; SA, stereoacuity; SE, spherical equivalent; SVCL, single vision contact lens; VA, visual acuity.

to logMAR. Tabulated results are presented as mean ± standard deviation. The normality of the data was assessed using the Shapiro-Wilk test. The comparison of the visual outcomes of two contact lens groups in the same eye were conducted using the paired samples t-test. Pearson correlation analysis was conducted for spherical equivalent and pupil size of the patient with visual function parameters. Data analysis was conducted using SPSS Vers. 25 software and p values <0.05 were considered to be statistically significant.

Results

There were 14 female and 16 male participants with a mean age of 15.80 ± 1.37 years and ranged between 14 and 18 years old. The mean spherical equivalent of the baseline monofocal soft contact lens of the enrolled sample was -3.84 ± 1.03 D (range: -5.75 to – 2.00 D). After overrefraction the mean spherical equivalent of the MFSCL for best distance vision was changed to -3.90 ± 0.96 D (range: -5.75 to – 2.25 D). The mean time period for active use of SVCL before switching to MFSCL was 26.3 ± 6.0 months (range: 8 – 36 months), while it was 7.1 ± 3.2 months (range: 4 – 12 months) for MFSCL use.

While there was no significant difference between SVCL and MFSCL in terms of near VA, MRS, contrast sensitivity, and stereoacuity (p>0.05 for all), distance VA was observed to decrease with the use of MFSCL (p=0.021). The reading acuity, which refers to the print size that can be comprehended without a substantial error, was shown to be smaller when using MFSCL (<0.001). Visual performance parameters with SVCL and MFSCL of the study patients were given in Table 1.

There was a moderate negative correlation between the spherical equivalent of MFSCL and distance VA (CC=-0.677, p=0.01), and near VA (CC=-0.572, p=0.01) while no other significant correlations were observed with the SE of MFSCL. The pupil size was not found to be correlated with any of the study parameters. MRS had a weak positive correlation with near VA (CC=0.379, p=0.05). Correlation analysis between spherical equivalent of MFSCL and visual function parameters were shown in Table 2.

Discussion

This study investigated the impact of a new pupil-optimized MFSCL on visual function in adolescent myopes, comparing it to SVCL. While MFSCL use resulted in a decrease in distance VA, the VA still remained over 20/20. The existing literature on MFSCL use in myopic pre-presbyopia patients provides conflicting findings. For instance, Huang et al. [18] reported no statistically significant difference in high and low contrast distance VA between MFSCL and SVCL after a 1-month evaluation period in juvenile myopic patients. The BLINK study, which examined myopia progression in the 7-11 age group using MFSCL, revealed no significant disparities in high-contrast distance VA and near VA among high-add and mid-add MFSCL and SVCL wearers at the final visit. However, the SVCL group exhibited superior performance in low-contrast distance VA [19]. Bickle et al. [20] conducted a comparative analysis of visual performance in 11 children using SVCL and +2.00, +3.00, and +4.00 add MFSCL. Their findings indicated a decline in distance VA with +3.00 and +4.00 add MFSCL, while no significant differences were observed with +2.00 add MFSCL. The researchers concluded that add powers of +3.00 D and higher were associated with more pronounced objective and subjective vision-related issues in comparison to single-vision lenses, whereas the +2.00 D add multifocal lenses were well tolerated.

Sanchez et al. [21] conducted a comparative study involving spectacles with PureVision (B&L) MFSCLs featuring low and high add powers, as well as Biofinity lenses with +1.5 D and +2.5 D add powers. Similar to our results, their findings revealed a decrease in distance VA for subjects using all types of MFSCLs. Likewise, Vedhakrishnan et al. [22] reported a reduction in distance VA with MFSCL relative to SVCL in young adults, accompanied by an improvement in NVA. In our study, however, we did not identify any significant difference in near VA between the two lens types. In line with our findings, Przekoracka et al. [23] examined the effects of +2.00 and +4.00 add MFSCL in young adults and did not find any statistically significant difference in near VA when compared to SVCL. The different outcomes of those studies may stem from disparities in the optical design and spherical equivalent values of the study lenses, diverse demographic features of the study participants, and different post-MFSCL follow-up durations.

No additional negative power was required to be added to the spherical equivalent of the MFSCL for better distance VA in approximately 77% of cases included in our study. Similar to previous cases, seven patients required myopic overrefraction [24].

Visual acuity testing under photopic conditions is a widely used measure to assess the quality of vision. However, it becomes more informative when complemented by contrast sensitivity testing [25]. Therefore, an additional assessment of contrast sensitivity was conducted in the current study. In our study, we did not observe any significant differences in contrast sensitivity between SVCL and MFSCL. Conversely, Bickle et al. [20] observed a decrease in contrast sensitivity with MFSCL, regardless of the add power, in their study comparing SVCL and MFSCL in myopic children. Similarly, Gong et al. [26] noted a reduction in contrast sensitivity in children wearing Biofinity MFSCL with +2.5 D add. Nti et al. [27], in a study involving 25 non-presbyopic adult patients, observed a decrease in photopic and mesopic distance (4 meters) contrast sensitivity with a +2.50 D add MFSCL compared to SVCL, but they did not find a significant difference in contrast sensitivity when measured at near distances (40 cm). In our study, we assessed contrast sensitivity using the Pelli Robson chart at a 1-meter distance. Apart from the examination method, differences in contact lens design may also explain the varying findings across studies. Anstice et al. [28] suggested that +2.0 D add bifocal contact lenses, known as Dual focus lenses, did not significantly affect contrast sensitivity function in children, indicating that the impact of MFCLs on visual function may depend on CL design. Another possible explanation is that MFSCL might weaken visual performance at distance, which engages more concentration. This additional cognitive demand could potentially enhance fixation stability and subsequently improve contrast sensitivity [29]. Additionally, considering the known influence of pupil size on contrast sensitivity, the pupil-optimized design of the lens used in our study may account for the absence of a decrease in contrast sensitivity [30].

Pupil diameter is not only important for contrast sensitivity; it can also influence visual acuity in MFSCL users. Notably, pupil diameter tends to decrease with increasing age, implying that children typically possess larger pupils in comparison to the elderly population. It is worth noting that MFSCLs may potentially lead to adverse effects on visual quality, giving rise to disruptive visual symptoms such as halos and glare. These effects are particularly noticeable at night when the pupils dilate to larger sizes [31]. Moreover, several studies have underscored the importance of aligning the optical zone of MFSCLs with the pupil size, as this alignment has been shown to enhance visual performance both at a distance and in near vision [22,32,33]. The absence of a correlation between pupil diameter and the study parameters in our study may be attributed to the use of a pupil-optimized lens. We may hypothesize that, given that the optic zone diameter is relatively well-suited for the pupil, changes in the study parameters are likely independent of pupil diameter.

In our study, although we did not observe any differences in MRS with MFSCL, the smallest print size that could be read without a significant error was smaller when using MFSCL. While there is a lack of studies on this topic in children, there are conflicting results in studies involving adults. Gregory et al. [34] found that reading performance, measured in words per minute, was inferior with two different types of MFSCL compared to SVCL, regardless of letter size, in adult subjects. This outcome was attributed to the optical design of the lenses used in the study, which had center-distance and extended depth of focus (EDOF) designs. Conversely, Plainis et al. [35] reported an improvement in the average silent reading speed in a presbyopic population when using multifocal correction compared to SVCL. The fact that the lens we fitted in our study had a center-near design may offer an explanation for our findings.

The limitations of our study include the inability to measure high-order aberrations, accommodation amplitude, and low-contrast VA due to the lack of equipment. However, we believe that these measurements, typically used in academic research, do not play a significant role in clinicians' decision-making processes, given that they are not routinely included in contact lens examinations. Furthermore, it should be noted that the objective measurement of visual performance achieved with MFSCL does not always align perfectly with subjective satisfaction scales. Therefore, evaluating patient satisfaction with valid scales is also a limitation of our study. Lastly, our study did not investigate the impact of MFSCL on myopia progression, as this was beyond the scope of our research. However, to our knowledge, it is worth highlighting that our study's primary strength lies in the evaluation of the visual outcomes of a new MFSCL with a pupil-optimized design for the first time. Considering that neither dual-focus nor center-distance MFSCLs, which have been shown to potentially slow myopia progression, are available as trial lenses in our country, we believe that demonstrating the visual performance of this accessible lens in myopic individuals could pave the way for future prospective studies with larger patient cohorts.

Conclusion

To conclude, our present study has demonstrated that basic visual functions, including near VA and contrast sensitivity, remained largely unaffected by MFSCL with mid-add power in adolescent myopes when compared to SVCL. Yet, we observed a decrease in distance VA. Furthermore, while MFSCLs did not impact reading speed, they did show potential for improving the legibility of smaller fonts. To validate and expand upon our findings, prospective, large-scale studies employing more comprehensive diagnostic tools are warranted.

Financial interest statement

None of the authors have any financial interests or personal relationships to any of the products or services mentioned in this study.

Ethical approval

This study was was approved by the Bulent Ecevit University Non-invasive Clinical Research Ethics Committee (Date: 09/2023, Number:2023/16).

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