BMJ Open Ophthalmology

Astigmatism and maternal myopia as important factors affecting success rate of DIMS lens treatment

Patricia Domsa,^{1,2} Éva M Bankó ¹, Judit Körtvélyes,^{1,4} Christof Meigen, Rita Széchey,^{1,6} Krisztina Lantos, Zoltán Zsolt Nagy, Adrienne Csutak

To cite: Domsa P, Bankó ÉM, Körtvélyes J, et al. Astigmatism and maternal myopia as important factors affecting success rate of DIMS lens treatment. BMJ Open Ophthalmology 2024;9:e001499. doi:10.1136/ bmjophth-2023-001499

➤ Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjophth-2023-001499).

PD and ÉMB are joint first

ZZN and AC are joint senior authors.

Received 17 September 2023 Accepted 28 January 2024



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For numbered affiliations see end of article.

Correspondence to

Dr Éva M Bankó; banko.eva@ ttk.hu

ABSTRACT

Objective To assess the efficacy of myopia control spectacle lenses (defocus incorporated multiple segments/ DIMS) in slowing myopia progression among a diverse Central European paediatric population and investigate the contribution of baseline parameters on treatment outcomes.

Methods and analysis This retrospective observational study included 62 individuals aged 4–17 years (mean \pm SD: 10.21 \pm 2.70) with progressing myopia but without ocular pathology with a range of -0.88 to -8.25 D spherical equivalent refraction (SER) (-3.73 ± 1.56), coupled with astigmatism up to -3.25 D cylindrical. All participants were prescribed DIMS (Hoya MiyoSmart) spectacles. Key outcome variables were cycloplegic SER, measured for all participants and axial length (AL), assessed in a subset of patients, recorded at baseline, 6 months and 12 months. Quality of life assessments were conducted at baseline, at 2 weeks, and 3, 6, 9 and 12 months. Additionally, parental myopic dioptre was recorded when applicable.

Results At the 12-month mark, myopia progression in patients (mean±SE: -0.40±0.05) mirrored findings from prior European DIMS studies, but with 50% of patients showing no progression. A multivariate analysis of covariance model revealed that baseline astigmatism and younger age adversely affected therapy outcomes in both SER and AL, while severe maternal myopia led to greater SER progression. In contrast, only young age but not astigmatism was associated with AL increase in a comparable group of children with myopia, part of the LIFE Child Study, wearing single-vision spectacles, Patients reported consistent satisfaction with treatment, with minimal side effects, which diminished over the year. **Conclusion** In the European population, astigmatism, young age and severe maternal myopia are risk factors for suboptimal outcomes following DIMS therapy. Further research is necessary to elucidate the impact of

INTRODUCTION

astigmatism on myopic defocus therapy.

Myopia has witnessed a rapid increase in prevalence in recent years becoming a global public health concern. Over 30% of Europeans are affected by myopia, with numbers surpassing 40% among school-age children contributing to a significant vision concern within the region. Current estimated prevalence is

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Spectacle lenses with 'defocus incorporated multiple segments' (DIMS) technology reduce myopia progression in European population, and this effect is dependent on patients' age.

WHAT THIS STUDY ADDS

- ⇒ Efficacy of DIMS lenses is negatively affected by the presence of astigmatism and high maternal myopia.
- DIMS technology, a minimally invasive therapy to slow down myopia progression, has barely negative consequences in quality of life throughout the entire treatment even at a young age.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Further research into DIMS therapy should consider the degree and angle of astigmatism of patients when evaluating treatment outcome.
- ⇒ For patients with astigmatism and/or severe maternal myopia, combination therapy should be considered, such as DIMS technology and low-dose atropine, especially at a young age.
- ⇒ As the technology is well tolerated and effective over a wide dioptric range, it can be used in patients with high myopia.

slightly higher in Western Europe (36.7%), compared with Eastern Europe (32.2%).³ Nevertheless, based on the representative nationwide screening programme conducted on adults in the past 10 years, myopia prevalence is 43.45% in Hungary, and it is three times more frequent in younger people (58.7%; 18-35 years) compared with older age groups (19.4%; 56–70 years). This is in stark contrast with data from the first half of the 20th century, when myopia prevalence was well under 10% among schoolchildren in Budapest.⁴ Globally, myopia's prevalence is surging, with projections suggesting that by 2050, nearly half of the world's population could be impacted by this refractive error, with estimates of 65%, 56%, 54% and 50% in Asia, Western, Central and Eastern Europe, respectively, if serious countermeasures are



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not taken.³ Myopia's development is influenced by a complex interplay of genetic and environmental factors. Prolonged near work, limited outdoor time, education level, family history of myopia and certain ethnic backgrounds are key risk factors associated with its onset and progression.^{5 6} High myopia, characterised by a spherical equivalent of –6.0 D or worse, carries substantial ocular risks. These include myopic maculopathy, retinal detachment and glaucoma, leading to severe visual impairment and potential blindness.^{7 8}

Researchers and practitioners have been exploring innovative ways to control myopia progression. Several widely tried therapeutic approaches, including undercorrection, 9-13 pinhole glasses, blue light blocking glasses, bifocal glasses, 14 15 progressive addition spectacle lenses, 16-21 daytime single-vision soft contact lenses/ rigid gas permeable contact lenses^{22–27} and others, have demonstrated limited effectiveness in significantly retarding the progression of myopia. Research suggests that these interventions often fail to address the underlying mechanisms driving myopia's development and may provide only minimal benefits in controlling its advancement. Promisingly, effective myopia control strategies encompass a range of interventions, including increased outdoor time, 28-34 reduced engagement with smartphones and near tasks, 35-38 as well as the utilisation of advanced technologies like DIMS (defocus incorporated multiple segments) lenses, 39-44 highly aspheric lenslet lenses, ^{45–47} soft multifocal contact lenses, ⁴⁴ ^{48–54} orthokeratology ^{55–59} and low-dose atropine eye drops. ^{60–67} These approaches have demonstrated the potential to counter myopia progression by addressing various contributing factors and are paving the way for a more proactive approach to visual health management.⁶⁸

One such ground-breaking approach is the use of spectacle lenses with DIMS technology; DIMS technology operates by integrating a central optical zone for correcting distance vision and an annulus of tiny circular segments with a relative positive power of 3.50 D distributed across the mid-peripheral area, each ~1 mm in diameter, in a honeycomb pattern. ³⁹ ⁴⁴ ⁶⁹ ⁷⁰ This arrangement induces peripheral myopic defocus while maintaining clear vision, harnessing the principles of peripheral defocus and simultaneous vision to curtail axial elongation and mitigate myopia progression. Notably, these lenses offer a minimally invasive solution, making them a promising avenue for managing myopia while prioritising patients' well-being. ⁴³ ⁷¹

Although most of the available data concern Asian populations, a recent study has reported a significant efficacy rate of approximately 50–60% in reducing myopia progression among European populations using DIMS lenses. The Moreover, Truckenbrod et ali presented data indicating a parallel pattern of axial length (AL) growth between the Asian and European populations, and research on the adaptation and acceptance of DIMS among Chinese children contributed valuable insights, that apart from slightly affected mid-peripheral vision,

DIMS lenses received good tolerance and acceptance by Chinese children. 43

Even though there is a growing body of evidence of the effectiveness of DIMS lenses, the existing studies, except one,⁷⁴ have limited inclusion to moderate myopia with also a limit on the maximum allowed astigmatism. Our study, therefore, was aimed to assess the effectiveness of DIMS lenses in attenuating myopia progression within a European paediatric cohort, encompassing a diverse dioptre range from -0.88 spherical equivalent refraction (SER) to -8.25 SER with special focus on investigating the impact of baseline optic parameters as well as parental myopia on the efficacy of DIMS lenses. Additionally, we endeavoured to demonstrate the broad age range tolerance of DIMS lenses, spanning from 4 to 17 years. Our results highlight the significance of tailored strategies for children with familial predisposition and astigmatism as risk factors for therapeutic failure and underline adaptability of DIMS therapy across diverse paediatric age groups and a wide range of dioptres.

MATERIALS AND METHODS Study design

The study was a retrospective observational study with data collection carried out in a paediatric ophthalmology private practice setting in Budapest that has a reputation of offering state-of-the-art treatment including DIMS therapy. Due to the existing robust evidence supporting the technology's effectiveness, DIMS lenses (Hoya MiyoSmart, Tokyo, Japan) were offered to children with evolutive 75 myopia who had exhibited myopia progression in the preceding year (≥0.5 DSPH (spherical dioptre)/year). Thus, a comparable control group of evolutive myopes treated with single-vision spectacles was not available, and seems ethically unfeasible in light of previous results. Nevertheless, we included the analysis of AL data from a myopic subset of a larger cohort of German children participating in the LIFE Child Study.⁷³ Patients who had completed the first year of their DIMS therapy since 2021 with no data gaps were included in the study with cycloplegic autorefraction SER and AL as key outcome measures, which were assessed at baseline, 6 months (SER only) and culminating at the 12-month mark. The median time between baseline and 6-month and baseline and 12-month visits was 210 and 386 days, respectively. In addition to clinical assessments, participants completed a quality of life (QoL) questionnaire at baseline and after 2 weeks, 3, 6, 9 and 12 months, the baseline measurements relating to the previous singlevision spectacles of the patients. For reporting, the Strengthening the Reporting of Observational Studies in Epidemiology guidelines were used.⁷⁶

Participants

The study encompassed a cohort of 62 participants, comprising of ethnic Caucasians of Hungarian descent, ranging in age from 4 to 17 years (mean±SD: 10.21±2.70 years; 37 females [table 1]). Myopia was

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Age at enrolment (years)	10.21±2.70 (4-17)		
Gender			
Male, % (n)	40 (25)		
Female, % (n)	60 (37)		
Cycloplegic autorefraction	SER (D)	SPH (D)	CYL (D)
Right eye	-3.76±1.59 (-7.75 to -0.88)	-3.46±1.55 (-0.75 to -7.25)	-0.62±0.45 (-2.75 to 0)
Left eye	-3.70±1.63 (-8.75 to -0.63)	-3.38±1.58 (-0.5 to -8.0)	-0.64±0.61 (-3.75 to 0)
Average	-3.73±1.56 (-8.25 to -0.88)	-3.42±1.51 (-7.63 to -0.75)	-0.63±0.49 (-3.25 to -0.13)
Axial length (mm) (n=33)			
Right eye	24.53±0.95 (22.66-26.47)		
Left eye	24.49±0.97 (22.65-26.41)		
Average	24.51±0.96 (22.66-26.39)		
Myopic parents' D			
Maternal	-2.90±3.19 (0 to -13)		
Paternal	-1.09±1.92 (0 to -10.5)		

defined as SE ≤-0.5 D and participants exhibited myopia within the range of -0.875 to -8.75 D SER $(-3.73\pm1.56$ SER), coupled with astigmatism up to -3.25DCYL (cylindrical dioptre). Inclusion criterion was -0.5 DSPH or more progression in the year before DIMS therapy, while exclusion criteria included any significant ophthalmic pathology other than myopia and refractive errors exceeding -10.0 SPH or +4.0 CYL due to the limitations of the DIMS technology, which is not available for use beyond these dioptres.

Intervention

DIMS spectacles (Hoya MiyoSmart, Tokyo, Japan) were prescribed for all participants and they were instructed to wear them to waking hours replacing their single-vision spectacles. Participants were informed of the potential side effects and were asked to periodically fill out a QoL questionnaire related to DIMS.

Procedures

Clinical measurements included best-corrected visual acuity, autorefraction (Topcon KR-800, Tokyo, Japan) conducted in cycloplegia (achieved through two drops of 10 mg/mL (1%) cyclopentolate (Laboratório Edol Produtos Farmacéuticos, Portugal), with the second administered at 15 min and refractometry conducted 25 min after the second drop), as well as AL measurements (Topcon Myah, Visia Imaging, Italy) on a subgroup of patients (N=33). Furthermore, a dilated funduscopy was performed for every patient (SM-70N, Takagi Seico Co, Tokyo, Japan) with a Volk digital wide-field lens (Volk Optical, Mentor, Ohio, USA). To investigate the influence of parental myopia, anamnestic data on familial myopic history were collected with exact dioptre values gathered

from information on prescription glasses. For parents without myopia, zeros were entered instead. The QoL questionnaire was obtained from Hoya and included 14 questions with answers on a five-level Likert scale: the first half relating to symptoms experienced during wear, the second half relating to patient satisfaction.

Single-vision control group

For comparison, we used data from a myopic subset (N=187) of a larger cohort of German children participating in the LIFE Children Study,⁷³ where AL was measured and followed longitudinally. Since that dataset only had non-cycloplegic refractive data, only the AL outcome measure is analysed here. Age range and exclusion criteria were identical to our DIMS group for better comparison. However, no information was present on their myopic progression before enrolling in the study. For procedures, please refer to the original article. Their baseline optical parameters are detailed in table 2.

Statistical analysis

To describe overall progression, mean and SE were used for both SER (N=62) and AL (N=33). No progression was defined as both eyes having less than -0.5 SER D change at the end of the 1-year follow-up. 77 As no difference was found between eyes either in baseline characteristics or progression (paired t-test: all ts≤0.34, p≥0.23), we averaged all measured and calculated values across eyes to increase the signal-to-noise ratio. Normality assumptions were tested with one-sample Kolmogorov-Smirnov tests. A general linear mixed model (GLMM) was used for modelling treatment outcome to estimate the effect of baseline parameters. To do so, post-intervention results were calculated as change from baseline (CFB)-calculated

Values indicate mean±SD.

SPH, spherical.

Table 2 Baseline characteristics of a myopic subset of the LIFE Child Study dataset, N=187

LIFE Offild Study dataset, N=107				
Age at enrolment (years)	13.26±3.13			
Gender				
Male, % (n)	51 (96)			
Female, % (n)	49 (91)			
Non-cycloplegic autorefraction	SPH (D)	CYL (D)		
Right eye	-1.76±1.39	-0.56±0.48		
Left eye	-1.71±1.36	-0.57±0.47		
Average	-1.74±1.32	-0.57±0.47		
Axial length (mm)				
Right eye	23.91±1.04			
Left eye	23.98±1.02			
Average	23.90±1.02			
Maternal				
Myopic, % (n)	64 (120)			
Non-myopic, % (n)	36 (67)			

CYL, cylindrical; D, dioptre; SER, spherical equivalent refraction;

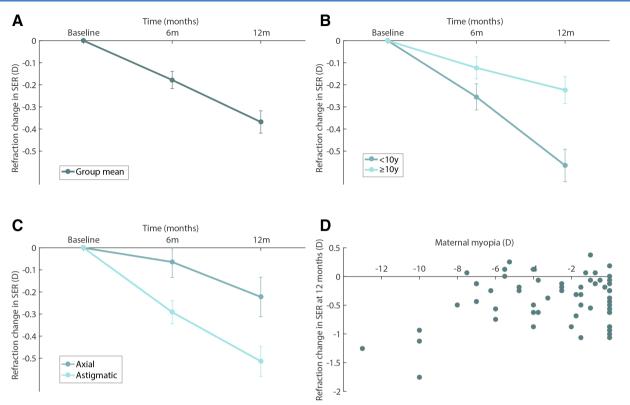
as post/pre-values—for both the 6-month (CFB $_{\!6\mathrm{m}}\!)$ and the 12-month (CFB_{12m}) visits and were used as dependent variables, with 'time' as a within-subject factor. Additional predictors included 'age', 'baseline SER' (in the case of SER analysis) and 'baseline AL' (in the case of AL analysis), 'maternal myopic dioptre' and 'paternal myopic dioptre' as covariates, and 'presence of astigmatism' as a between-subject factor. The model included an interaction term between 'time' and each predictor/covariate. For data obtained from the German LIFE Child Study dataset, data were available for AL measurements and only the myopic status of the mother was noted. Therefore, the GLMM used here had CFB_{12m} as dependent variable, with 'age' and 'baseline AL' as covariates, and 'maternal myopic status' and 'presence of astigmatism' as between-subject factors. Patients were categorised as astigmatic if either eye had a larger than -0.5 DCYL at baseline (N=38 out of 62). For understanding agerelated effects, patients were assigned into two separate age groups (<10 years and ≥10 years, N=26 and N=36, respectively) and a similar GLMM was conducted, and Tukey HSD tests were used for post-hoc comparison. Significant effects concerning covariates were tested with Pearson correlation or partial correlation analysis, while the relationship between the presence of astigmatism and progression was tested with Pearson X² test. Possible differences between the distributions of maternal and paternal myopic dioptres were evaluated by a two-sample Kolmogorov-Smirnov test. Statistical analyses were run using Statistica V.14 (TIBCO Software, Palo Alto, California, USA) and R code using R Studio (Posit Software, PBC, Boston, Massachusetts, USA).

RESULTS

Changes in spherical equivalent

Baseline characteristics of the study population can be found in table 1. The mean (±SE) unadjusted myopia progression (SER) over the 1-year period for the whole study group (N=62) was -0.40±0.05 D, with 31 (50%) patients showing no progression at the end of the 1-year period (figure 1A). To investigate the possible contribution of clinical factors to the individual variation in myopia progression, an analysis of covariance approach was adopted, where both CFB_{6m} and CFB_{12m} were included as dependent variables. We examined age, baseline and familial optical parameters, namely baseline SER, the presence or lack of clinically significant astigmatism (ie, type of myopia) at baseline, and parental myopia (maternal and paternal myopic dioptre) and their interaction with time to determine their effect on therapy outcome, that is, the SER change from baseline. As expected, time had the most pronounced effect on progression $(F_{(1.56)}=24.92, p<0.0001)$, as patients showing progression despite DIMS treatment progressed even further from the 6-month to 12-month visit. Patients' age did not have a significant main effect on progression (F_(1.56)=3.24, p=0.077) but significantly interacted with time ($F_{(1.56)}$ =12.44, p=0.0008). Thus, patients of different ages had different patterns in their progression dynamics. Pearson correlations revealed that while there was no agespecific progression at 6 months (CFB_{6m} vs age: $r_{(60)}$ =0.18, p=0.17), correlations between further progression and age $(CFB_{12m} - CFB_{6m})$ vs age: $r_{(60)} = 0.42 \, p = 0.001$, and 12-month progression and age (CFB_{12m}) vs age: $r_{(60)} = 0.37$, p=0.003) were significant. This was due to the fact that while older (≥10 years) patients' progression slowed down after 6 months, younger patients progressed further at a similar rate achieving significantly larger progression at 12 months (figure 1B, age group×time: $F_{(1.56)}$ =14.53, p=0.0003, post-hoc p=0.0004 for CFB $_{12m,YOUNG}$ vs CFB $_{12m}$ OLDER). There was also no effect of baseline SER D (main effect: F_(1,56)=0.001, p=0.97; interaction with time $F_{(1.56)}$ =0.04, p=0.85), indicating a similar efficacy profile of DIMS lenses for high as for moderate myopia.

Importantly, progression was also significantly affected by the presence of astigmatism $(F_{(1.56)}=5.20, p=0.026)$ with the astigmatic group displaying significantly greater overall progression compared with the purely axial myopic group (figure 1C, -0.49±0.07 SER vs -0.26±0.07 SER for patients with astigmatic and purely axial-type myopia at 12 months, respectively). This pattern was present throughout the study (time×astigmatism $F_{(1.56)}=1.54$, p=0.22). When assessing the presence of astigmatism in the non-progressing group of patients, there was a significant relationship between the presence of astigmatism and progression in SER (χ^2 =9.79, p=0.0018; 81% vs 41% of patients were astigmatic in the progressing vs non-progressing groups, respectively). The same pattern was found when analysing ${\rm CFB}_{\rm 12m}$ refractive data transformed into Long's matrix of (f11 f12 f22) $^{78-80}$ using an analogous model (online supplemental table 1; main



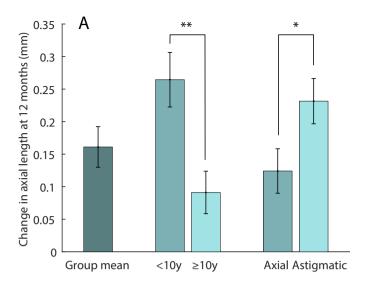
Model-adjusted mean progression in SER from baseline to 12 months. (A) Group progression (N=62). (B) Different progression dynamics of patients <10 years and ≥10 years old. Younger patients show faster progression, which does not taper off after 6 months. (C) Different progression rates between patients with astigmatism and those with axial myopia, the former showing significantly greater progression. (D) 12-month change as a function of maternal myopia. Only patients with mothers with severe (≥9 D) myopia show markedly larger progression. The values are least-squares estimates with continuous predictors as age, baseline dioptre, maternal and paternal dioptres fixed at their mean. Error bars indicate ±SE. SER, spherical equivalent refraction.

effect of astigmatism: F $_{(1,54)}$ =4.45, p=0.039; mean change $-0.37/-0.22\times79$ vs $-0.23/-0.04\times142$ for patients with and without astigmatism, respectively). Interestingly, the change in the f12 component, which is computed from the DCYL and its respective axis, showed virtually no difference between these patient groups (online supplemental figure 1). Therefore, it seems that the significant difference in SER change in patients with astigmatic and axial-type myopia comes from the different degree of change in spherical power, which could reflect the different rates of axial elongation between these groups.

Lastly, parental myopia also had a notable contribution to progression: maternal ($F_{(1,56)}$ =3.90, p=0.053), but not paternal myopic dioptre ($F_{(1,55)}$ =0.14, p=0.71), had a strong tendency to affect progression, with no significant interaction with time (all F \leq 1.01, p \geq 0.32). This pattern was driven by patients having a mother with severe myopia showing the most progression (figure 1D). The distinguished role of the mother—at least in our sample—is also supported by the finding that our pool of mothers displayed significantly higher myopia compared with that of the fathers (two-sample Kolmogorov-Smirnov test: $D_{(62,62)} = -0.30$, p<0.01; -2.90±0.41 D vs -1.09±0.24 D for mothers and fathers, respectively).

Changes in AL

The mean unadjusted 12-month increase in AL in a subset of our study group (N=33), where AL was measured, was 0.16±0.03 mm (figure 2A). The extent of axial elongation was significantly dependent on patients' age (F_(1.97)=10.42, p=0.003), with younger patients showing more pronounced elongation, while the effect of parental myopia only showed a non-significant trend $(F_{(1,27)}=3.32,$ p=0.079 and $F_{(1.27)}=2.77$, p=0.11 for maternal and paternal myopic dioptres, respectively). Baseline AL had no effect $(F_{(1.97)}=0.021, p=0.65)$. Notably, the presence of astigmatism had a significant effect on axial elongation as well $(F_{(1.27)}=4.73, p=0.039; 0.20\pm0.05 \,\text{mm} \,\text{vs} \,0.12\pm0.04 \,\text{mm}$ for patients with and without astigmatism, respectively). Importantly, the analysis of a larger cohort of German children wearing single-vision spectacles yielded contrasting results. While the axial elongation was also dependent on patients' age $(F_{(1.182)} = 46.94, p < 0.0001)$, with younger patients progressing at a larger rate, the presence of astigmatism had absolutely no effect on myopia progression $(F_{(1.182)} = 0.003, p = 0.96; 0.12 \pm 0.02 \text{ mm vs } 0.11 \pm 0.01 \text{ mm for}$ patients with and without astigmatism, respectively). In addition, maternal myopia had also no effect on progression $(F_{(1.182)}=0.54, p=0.46)$, as opposed to baseline AL,



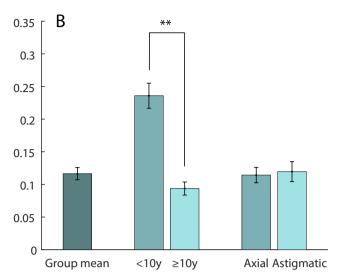


Figure 2 Group average and model-adjusted mean progression in axial length at 12 months split by age group and presence of astigmatism. (A) Data for children wearing DIMS lenses. The values are least-squares estimates with continuous predictors as age, baseline dioptre, maternal and paternal dioptres fixed at their mean (N=33). (B) Data for children wearing single-vision spectacles (N=187). Error bars indicate ±SE. *P<0.05, **p<0.01. DIMS, defocus incorporated multiple segments.

which influenced AL elongation ($F_{(1,182)}$ =9.17, p=0.003). These results obtained with single-vision children corroborate our findings that the efficacy of DIMS lenses in slowing down the myopia progression of patients with astigmatism seems to be less, compared with patients with axial-type myopia.

QoL questionnaire

The results of the QoL questionnaire demonstrated an excellent long-term overall acceptance of the DIMS spectacles for both the entire group (figure 3A) and for the youngest patients aged 4–7 years (figure 3B). In addition, there was very low incidence of side effects (figure 3C), which were almost completely resolved after 12 months except for a few cases of occasional eye strain, which seemed to persist throughout the study. Importantly, the young age group showed a very similar pattern (figure 3D) demonstrating the usability of DIMS glasses even at a young age. Interestingly, DIMS spectacles scored somewhat higher in user satisfaction and lower in the incidence of side effects compared with patients' previous single-vision glasses, which also emphasises its clinical relevance.

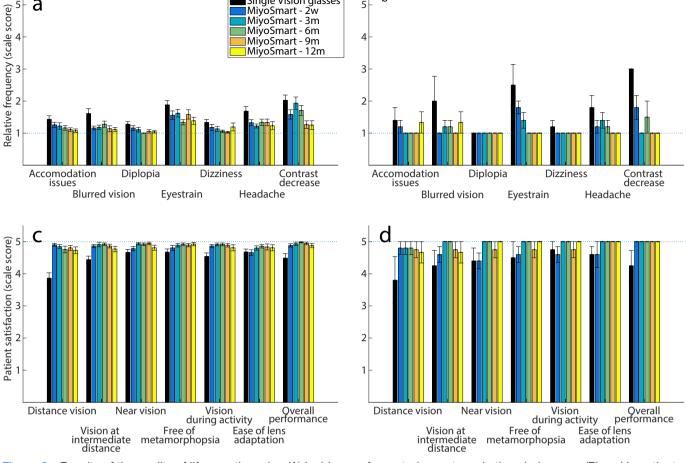
DISCUSSION

Our objective was to investigate the effectiveness of DIMS technology lenses within a more diverse paediatric population, building upon the established and promising literature. This endeavour aimed to deepen our understanding of the variables that might impact the success of this therapeutic approach. We have found that the presence of astigmatism in our group of patients with myopia resulted in larger progression compared with patients with purely axial myopia, potentially diminishing the effects of DIMS lenses in slowing myopia progression. In

addition, patients with severe maternal myopia also experienced a significantly more pronounced progression. Finally, younger age was associated with faster progression, which, unlike that of older children, did not slow down after 6 months, achieving larger progression at 12 months. These findings underline the importance of astigmatism, severe maternal myopia and young age as risk factors for myopia progression, even when using DIMS spectacles.

When comparing the mean progression of our patients with other published results, we found our results to be largely consistent with the 1-year results of Nucci et al⁷² in a European population but higher than the -0.17 D SER progression found by Lam et al⁶⁹ in an Asian population. While the impact of ethnic differences on myopia progression is somewhat controversial, 73 81 the difference may be attributed to the fact that both the current and the Nucci et al study predominantly included evolutive myopes who have shown myopia progression in the previous year, and larger astigmatism was allowed. Nevertheless, among our patients, 31 (50%) did not progress by the end of the 1-year period, defined by no dioptric deterioration exceeding -0.5 D SER in any eye. ⁷⁷ Taken together, the mean progression and per cent of nonprogressing myopes also show close resemblance to the only available large-scale retrospective study conducted in real-world clinical settings.⁷⁴ It has been shown that both children and adults tolerate DIMS lenses well, 43 69 82 with minimal mid-peripheral visual acuity and contrast sensitivity reduction in nasal and temporal gaze. We assessed acceptance throughout the 1-year treatment and obtained similar results, with minimal habituation complaints in children wearing DIMS lenses, primarily in the initial period of wear. Young children exhibited a

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ingle Vision glasses

MiyoSmart - 2w MiyoSmart - 3m MivoSmart - 6m MivoSmart - 9m

Figure 3 Results of the quality of life questionnaire. (A) Incidence of reported symptoms in the whole group (B) and in patients under 8 years old (N=8). (C) Patient satisfaction in the whole group (D) and in patients under 8 years old. Scales for rating ranged from 1 to 5 (never to always and poor to excellent, respectively). Error bars indicate ±SE.

similar profile highlighting the clinical relevance of DIMS spectacles. Interestingly, DIMS lenses scored somewhat higher in user satisfaction and lower in the incidence of side effects compared with patients' previous singlevision glasses, indicating comparable usability with the standard of care.

Previous larger DIMS studies^{69 70 72} tended to include participants with mild and moderate myopia not exceeding -5.0 D (SER). Consequently, there are limited data on the efficacy of DIMS lenses on patients with high myopia. Verkicharla et al⁸³ found that 1-year myopia progression was dependent on initial dioptres in children with myopia wearing single-vision lenses, with the largest progression seen in severe myopes (>9 D SER), followed by high, moderate and mild myopes, which is in line with findings of other studies.^{84 85} However, studies evaluating the efficacy of DIMS lenses did not find a similar relationship between initial dioptres and progression rate, as including baseline SER as a covariate did not affect therapy outcomes.⁶⁹ ⁷² Our results also support the idea that the initial dioptre value is not related to the degree of progression when using DIMS spectacles for myopia control, in line with the above findings. Therefore,

patients with high myopia can also benefit from this therapy.

It is well-known that curvatural myopes with a small AL form a well-defined group of patients with a low risk of progression, 77 and the effect of astigmatic defocus on the progression of myopia is an area of intense research.^{86–89} Nevertheless, in myopes showing progression, the presence of astigmatism is somewhat overlooked, as the commonly used practice of calculating the spherical equivalent merges the contribution of spherical and cylinder dioptres. Our results suggest that the efficacy of DIMS lenses is higher in pure axial myopes without astigmatism (\leq -0.5 DCYL), as mean progression (SER) was significantly lower in axial myopes, and there was a significant relationship between astigmatism and myopia progression: progressing myopes were twice more likely to have had astigmatism compared with non-progressing myopes. This group difference was reflected in spherical dioptre (f11 and f22 Long's matrix components of refractive power) and AL alterations, while no difference in the change in f12 component, reflecting only DCYL was observed between the two groups. Importantly, there was no difference in AL elongation between children with



axial and astigmatic myopia wearing single-vision spectacles. Indeed, the presence of astigmatism was also related to the lack of improvement in children with amblyopia as a result of augmented reality dichoptic training. 90 Moreover, imposing both spherical and cylindrical hyperopic defocus early in life was found to lead to differential changes in eye anatomy compared with purely spherical hyperopic defocus in chicks.⁸⁶ Myopic astigmatic defocus also had a significantly different impact on changes in choroidal thickness after short-term exposure compared with spherical myopic defocus in humans.⁸⁹ Our findings suggest that astigmatism is not an overall risk factor for progression. However, it may disrupt the uniformity of peripheral myopic defocus, potentially challenging the effectiveness of DIMS technology. Another possibility is that axial elongation and changes in corneal curvature are influenced by separate, interdependent biological processes^{87 88} and DIMS technology may primarily influence the former. Both hypotheses warrant further investigation in dedicated patient groups.

Our findings also indicate that age significantly influences myopia progression, with younger patients exhibiting greater progression. This is in line with results obtained with DIMS lens use and the normal progression of myopia. 69 81 83-85 Additionally, we demonstrated that the rate of progression is similar in the first 6 and second 6 months in younger patients, in contrast to children aged 10 years and older, where it slows down after the first 6 months. Moreover, in our patient group, maternal myopia also emerged as an important factor for progression, especially in the case of severe maternal myopia. Interestingly, our pool of mothers demonstrated much higher incidence and severity of myopia compared with the fathers. It is possible that children with mothers with severe myopia having high dioptres are indeed more susceptible to myopia, but it is also plausible that mothers with myopia, being more aware and concerned, 91 may seek out new therapeutic options sooner. The significance of parental myopia is equivocal in the literature as it emerges as a predisposing factor in some studies, ²⁸ ⁹² ⁻⁹⁴ whereas others do not find that it significantly affects progression^{69 81} and was also shown to affect progression using single-vision and progressiveaddition lenses differently. 95 Thus, this question merits further scrutiny.

Our study has some limitations, however. The limited availability of relevant literature on the effect of astigmatism on myopia progression makes it challenging to interpret the impact of astigmatism on DIMS therapy. One potential approach to address this issue is to reanalyse existing datasets on myopia progression using DIMS spectacles while considering astigmatism to evaluate its effect on progression. Another possible direction would be to explore newer lens designs in this context in a prospective study, comparing them with DIMS technology within a dedicated group of patients specifically selected for this purpose with careful consideration of astigmatism, age and parental myopia. In addition,

keratometric measurements alongside standard measurements would be valuable to better characterise the change in astigmatism.

Taken together, our results underline the importance of paying special attention to young children with myopic astigmatism, especially those with a family history of severe maternal myopia as our results suggest that in the European population, astigmatism, young age and severe maternal myopia are risk factors for suboptimal outcomes following DIMS therapy. Further research is necessary to elucidate the impact of astigmatism on myopic defocus therapy.

Author affiliations

¹Non Plus Ultra Vision Centre, Budapest, Hungary

²Department of Ophthalmology, University of Pécs Medical School, Pecs, Hungary

³HUN-REN Research Centre for Natural Sciences, Budapest, Hungary

⁴Heim Pál National Pediatric Institute, Budapest, Hungary

⁵LIFE Leipzig Research Center for Civilization Diseases, Leipzig University, Leipzig, Germany

⁶Semmelweis University of Medicine, Budapest, Hungary

⁷Department of Ophthalmology, Semmelweis University of Medicine, Budapest, Hungary

Acknowledgements The authors thank Anett Bihari and Boglárka Nagy for patient contact and communication and for aiding in data collection.

Contributors PD, JK, ZZN and AC conceived the study. PD, JK and RS collected ophthalmological data. KL curated data. ÉMB and CM analysed data. ÉMB, PD and JK wrote the manuscript. AC and ZZN reviewed and ÉMB revised the manuscript. PD acted as guarantor. All authors read and approved the final manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research. However, patients gave structured feedback on the new therapy. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Medical Research Council of Hungary under the file number BM/27036-3/2023. Participants gave informed consent to participate in the study before taking part. The study conformed to the Declaration of Helsinki.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Deidentified participant data are available on reasonable request from PD (domsa. patricia@npumail.hu). Data reuse is only permitted with permission from PD.

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ORCID iD

Éva M Bankó http://orcid.org/0009-0001-5354-5077



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SUPPLEMENTAL MATERIAL

Astigmatism and maternal myopia as important factors affecting success rate of DIMS lens treatment

Patricia Domsa^{1,2*}, Éva M. Bankó^{3*}, Judit Körtvélyes¹, Christof Meigen⁴, Rita Széchey^{1,5}, Krisztina Lantos², Zoltán Zs. Nagy⁵†, Adrienne Csutak²†

¹Non Plus Ultra Vision Centre, Budapest, Hungary, ²Department of Ophthalmology, University of Pécs Medical School, Pécs, Hungary, ³Brain Imaging Centre, HUN-REN Research Centre for Natural Sciences, Budapest, Hungary, ⁴LIFE Child, LIFE Leipzig Research Center for Civilization Diseases, Leipzig University, Leipzig, Germany, ⁵Department of Ophthalmology, Semmelweis University, Budapest, Hungary,

In addition to computing and analysing the spherical equivalent, we also transformed S/C_A refractive data into Long's matrix formalism based on the equations below[1]:

$$P = \begin{bmatrix} f11 & f12 \\ f21 & f22 \end{bmatrix}$$
$$f11 = S + C \sin^2 A$$
$$f22 = S + C \cos^2 A$$
$$f12 = f21 = -C \sin A \cos A$$

where P is the total refractive power, S is spherical power, C is cylindrical power with axis A. After computing descriptive and ANCOVA statistics the components were back transformed to determine the spherocylindrical parameters following Keating's method [2]:

$$C = \pm \sqrt{t^2 - 4d}$$

$$S = \frac{t - C}{2}$$

$$A = tan^{-1} \left(\frac{S - f11}{f12}\right)$$

where t is the trace, and d is the determinant of the matrix P:

$$t = f11 + f22$$

 $d = f11f22 - f12f21$

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Effect	Degr. of freedom	F	p	
Intercept	1	12,53640	0,000831	
Age	1	5,44532	0,023374	
Mother D	1	0,69864	0,406925	
Father D	1	0,07577	0,784165	
Baseline f11 eye ave	1	0,19729	0,658689	
Baseline f12 eye ave	1	3,57979	0,063853	
Baseline f22 eye ave	1	0,13105	0,718762	
Astigmatism	1	4,45179	0,039514	
Error	54			
Component	2	5,24723	0,006686	
Comp.*Age	2	3,49656	0,033775	
Comp.*Mother D	2	4,20396	0,017451	
Comp.*Father D	2	0,83757	0,435554	
Comp.*BL. f11 eye ave	2	15,56982	0,000001	
Comp.*BL. f12 eye ave	2	2,86704	0,061206	
Comp.*BL. f22 eye ave	2	16,19851	0,000001	
Comp.*Astigmatism	2	2,35092	0,100140	
Error	108			

Table S1. Statistical values for Long's matrix refractive components f11, f12, and f22 analysis. Significant results are indicated in red.

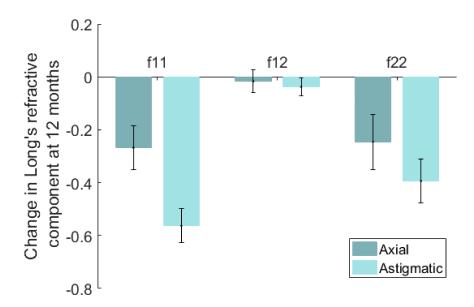


Figure S1. Change in refractive power (Long's components) over 12 months as a result of DIMS therapy. N=62, errorbars represent SE.