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Age-matched analysis of axial length growth in myopic children wearing defocus incorporated multiple segments spectacle lenses

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ABSTRACT

Background/aims Defocus incorporated multiple segments (DIMS) spectacle lenses are known to be able to inhibit axial length (AL) growth in myopic children compared with single vision (SV) spectacle lenses. However, it is not known whether AL growth is sufficiently inhibited to achieve the treatment goal of physiological AL growth.

Methods Of the data already collected in 2014–2017 by Lam *et al*, the AL growth with DIMS and SV spectacle lenses was re-evaluated according to the age-matched myopia control system. The individual AL growth after the first year of treatment of each eye was plotted against the corresponding age of the same time point in a colour-coded scheme. The two treatment groups were further subdivided based on their age and their baseline AL.

Results Overall, 65% (61% of male, 70% of female) of eyes with DIMS spectacle lenses and 16% (16% of male, 16% of female) of eyes with SV spectacle lenses are within range of physiological AL growth rate. Median AL growth rate of eyes with DIMS spectacle lenses is also within the range of physiological growth. In the subgroups, eyes with DIMS spectacle lenses were also superior to the ones with SV spectacle lenses regarding this treatment goal. Of the children with SV spectacle lenses, older children and children with eyes with high baseline AL were least likely to achieve physiological AL growth rate.

Conclusions DIMS spectacle lenses can bring the AL growth rate of myopic children to the level of physiological AL growth rate, indicating 100% reduction of excessive myopic AL growth, independent of age and baseline AL. Older children and children with eyes with high AL have the risk to have increased AL growth without treatment.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Myopia poses a risk for severe eye diseases and irreversible vision loss in adulthood. Myopia management or control treatments, applied in children, aim to keep the final myopia as low as possible and thus minimise this risk. In studies, several different myopia treatments, including defocus incorporated multiple segments (DIMS) spectacle lenses, have shown that they can inhibit myopia progression and axial length (AL) growth by a certain percentage compared with control treatment. However, it is not known whether AL growth is sufficiently inhibited to achieve the treatment goal of physiological AL growth to maximally reduce the risk of ocular disease in adulthood.

WHAT THIS STUDY ADDS

⇒ In 65% DIMS spectacle lenses could bring the AL growth rate of myopic children to the normal level of physiological AL growth rate, while single vision (SV) spectacle lenses reached this treatment goal only in 16%. Of the children with SV spectacle lenses, older children and children with eyes with high baseline AL were least likely to achieve the treatment goal of physiological AL growth rate in the first year of treatment.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Not only younger myopic children, but also older myopic children and children with eyes with high baseline AL should receive myopia treatment. For future studies on myopia treatments, baseline AL should also be an inclusion criterion and evaluation of AL growth should be done in consideration of individual age. The age-matched myopia control system can be used to assess both the AL growth of a child as well as the AL growth of an entire study group.

INTRODUCTION

Myopia describes the imbalance between the axial length (AL) of the eye and the refractive power of the eye, which causes the sharp image of a distant object to appear in front of the retina, leaving a blurred image on the retina, more specifically the fovea. Most common is a so-called axial myopia,[1 2] which means that the eye is too long for the total refractive power of the eye. The blurred vision can be easily corrected with spectacle or contact lenses. However, axial myopia leads to structural changes in the eye tissues,[3] how Donders wrote down already in 1886 and concluded that a myopic eye was a 'diseased eye'.[4] He highlighted that any progressive myopia was a concern for the future, because if it remained progressive vision would soon deteriorate and not infrequently be irretrievably lost by the age of 50 or 60, if not much earlier, either by retinal detachment or haemorrhage, or finally by atrophy and degeneration of the macula lutea.[4] One hundred years later, it was confirmed that myopia-related retinal disorders, and particularly myopic

macular degeneration, are the most common cause for visual impairment until senior age.[5 6] Depending on the degree of myopia, the risk of myopic macular degeneration, retinal detachment, cataract and open angle glaucoma increases,[7] while age of myopia onset and duration of myopia progression are found to be strong predictors for high myopia.[8] Slowing of the progression of myopia, and thus a reduction in the final stage of myopia, in turn lowers the risk of myopic maculopathy.[9]

As myopia, or rather the underlying excessive AL growth, usually starts in childhood,[10 11] this is the time to intervene to keep myopia and thus the risk of serious eye problems as low as possible. Over the last years, several various treatment options have been developed with the goal to inhibit myopia progression ('myopia treament'). These include but are not limited to atropine eye-drops, orthokeratology contact lenses, rigid and soft contact lenses, bifocal, multisegmented and progressive spectacle lenses.[12]

As one of the non-invasive methods there are spectacle lenses with 'defocus incorporated multiple segments' (DIMS), which comprises multiple segments with a relative positive power of +3.5 D arranged around a central optical zone for correcting myopia and thus providing sharp distance vision. More details on the therapeutic mode of action, design and optical properties of DIMS spectacle lenses can be found in the literature.[13–16] The beneficial effects of DIMS spectacle lenses have been demonstrated in randomised controlled trials compared with single vision (SV) spectacle lenses in Asian eyes.[14 17 18] In the first publication on DIMS spectacle lenses, which contains the 2-year outcomes, Lam *et al*[14] found that, after 2 years, eyes with DIMS spectacles had significantly less myopia progression by 55% ($p<0.0001$) and significantly less axial elongation by 62% ($p<0.0001$). It was, therefore, concluded that DIMS spectacle lenses are capable of slowing myopia progression and axial elongation in myopic children, with good tolerability and acceptance of the special designed lenses.

As the portfolio of myopia-inhibiting treatment options has expanded greatly in recent years, the way in which these treatment options are evaluated is regularly reviewed.[19] For example, the need for an untreated control group is increasingly discussed as an ethical dilemma to be resolved. Furthermore, several issues make direct comparison study results of different treatment options in terms of their effectiveness difficult. Among these are:

1. It is known that AL growth depends on age, with growth rates decreasing with age.[20–22] Grouping all treated/untreated eyes regardless of the age and evaluating their AL growth after a certain period might lead to misleading conclusions.
2. Calculating the inhibitory effect (%) of the treated group vs the control group, depends largely on the behaviour of the used control group. Percentages in terms of effectiveness are therefore difficult to compare across different study groups.
3. Just as the treatment options to be investigated differ in their mode of action, the used control treatments also differ (ie, SV contact lenses, SV spectacle lenses)—again complicating the comparison of study results.
4. Although guidelines for definition have been proposed,[1] almost every study sets its own standards on what is considered to be myopia and how myopia progression and AL growth should be categorised in terms of severity. Ultimately, there is no consensus on the specific goal of myopia treatment and, therefore, no decision-making guide as to whether or not treatment is effective in an individual case.

For the evaluation of children's AL measurements in our own clinical practice in Germany, we have developed a system, in which the actual annual AL growth rate of a patient is classified against the average physiological AL growth rate of an age-matched cohort of children who become or remain emmetropic: the age-matched myopia control (AMMC) system. This approach of an eye growth as a function of age can also be found in the literature for assessing the growth velocity of the human body.[23–26] From the degree of approximation of the actual growth rate to the physiological growth rate, conclusions can be drawn about the effectiveness of the current treatment[27 28] in order to adjust it as appropriate. We consider reaching the range of physiological growth rate as a treatment success. Moreover, this approach of evaluating AL growth is ideally suited for assessing study results independent of possibly limiting factors. Especially since recent research has shown that there is no evidence of physiological AL growth rates to be higher in East Asian eyes versus non-East Asian eyes, so we expect to be able to apply these physiological growth curves to East Asian eyes as well.[29]

This paper aims to serve two purposes:

1. Since it is unknown whether AL growth is sufficiently inhibited by DIMS spectacle lenses to achieve the treatment goal of physiological AL growth, this paper reassessed first-year AL data from the above-mentioned study by Lam *et al*[14] using the AMMC system.
2. The method of AMMC is reviewed by means of already published data, which allows direct comparison between different methods to evaluate effectiveness of myopia treatments.

MATERIAL AND METHODS

Study design

Details on study design, randomisation, procedures and measurements etc can be found in Lam *et al*.[14]

Subjects

Inclusion criteria were the following (excerpt)[14]:

- 8–13 years old.
- Spherical equivalent refractive error (SER): −1.00 to −5.00 dioptres (D).
- Astigmatism of 1.50 D or less.
- Anisometropia of 1.50 D or less.
- Monocular best corrected visual acuity of 0.00 logMAR or better.

Regarding AL, there were no inclusion criteria. AL measures after 1 year are available for 79 (46 males, 33 females) eyes in the DIMS group and for 81 eyes in the SV group (44 males, 37 females). With the exception of one eye in the SV group, the baseline ALs of these eyes were above the 50th percentile of reference curves.[20]

Data analysis according to AMMC

To monitor the effectiveness of myopia treatment, we have developed a routine in which we compare a patient's annual AL growth rate to the average physiological AL growth rate of an age-matched cohort of children who become and remain emmetropic. Epidemiological data from Truckenbrod *et al*[20] and our own data collection from emmetropic school children in Germany[30] were used to calculate the physiological AL growth rate. From the degree of agreement of the AL growth rate with the physiological axis growth rate, a conclusion can be drawn about the effectiveness of the current treatment.[27 28]

Specifically, we plotted the AL growth rate against age in a simplified nomogram and divided the AL growth rates into three different categories (figure 1): The 'green zone' reflects an uncritical AL growth rate that corresponds (within a +25% boundary to cover measurements fluctuations) to the physiological AL

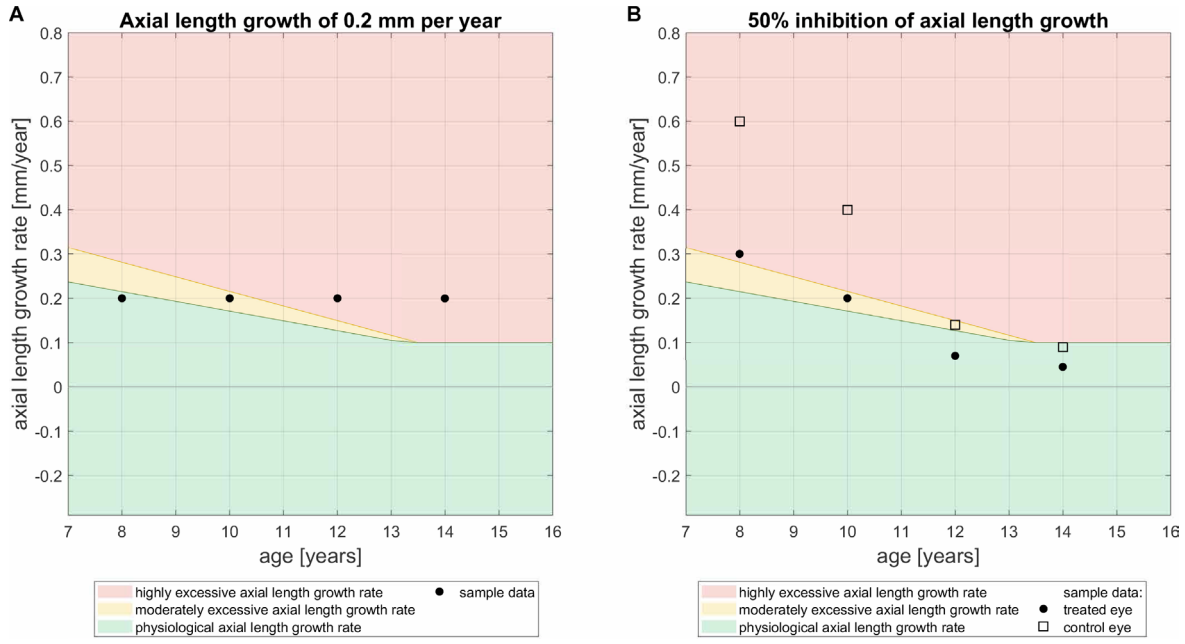

Figure 1 Age-matched myopia control (AMMC) system with fictitious sample data: Annual axial length (AL) growth is plotted individually versus the actual age. Within the color-coded zones, the 'green zone' corresponds (within a 25% boundary of agreement) to the physiological AL growth rate; the 'yellow zone' reflects a moderately excessive AL growth rate, corresponding to more than +25% but less than +50% the average physiological AL growth rate; the 'red zone' reflects a highly excessive AL growth rate, corresponding to more than 50% above the physiological AL growth rate. (A): same fixed AL growth rate (0.2 mm/year) for different ages. (B): same fixed inhibition of AL growth (50%) of at treated eye (solid circles) compared to a control eye (unfilled squares) with different absolute AL growth values and for different ages.

growth rate. The 'yellow zone' reflects a moderately excessive AL growth rate +25% to +50% above the age-appropriate physiological AL growth rate. The 'red zone' reflects a highly excessive AL growth rate that is more than +50% above the age-matched physiological AL growth rate. For children older than about 13 years the limit of physiological AL growth rate has been set at 0.10 mm/year for practical reasons and to avoid misleading apparent accuracy, as this reflects the degree of agreement in repeated AL measurements with currently available biometers.[31] Male and females are considered separately as they show different AL growth patterns.

Figure 1A,B also shows some fictitious sample data to illustrate the unique approach. It points out how:

a. The same value for the annual AL growth (here: 0.2 mm/year) delivers a different conclusion depending on the age.
b. The same inhibition of AL growth (here: 50%) of a treated eye (solid circles) compared with a control eye (unfilled squares) is nevertheless not comparable and also delivers different conclusions for the treated as well as the untreated eye.

Further subgroups of the dataset at hand were formed based on age at baseline (younger or older than 10 years) and AL at baseline: 'moderate baseline AL' denotes AL between 50th and 98th percentile; 'high baseline AL' stands for AL above 98th percentile of reference curve.[20] This percentile was chosen because it corresponds to high myopia in adulthood (>25.5 mm).

Statistics

AL growth rate of only right eyes were used for analysis. To quantify treatment effectiveness, the percentage treatment success of each group and subgroups was calculated. Statistical analysis of AL growth rate was performed by calculating difference between individual AL growth rate and the age-matched boundary of green zone and compared between DIMS and SV group (also in subgroups) by means of two-sample t-tests using Matlab R2022b (MathWorks, Natick, Massachusetts, USA). As a criterion of statistical significance, a $p<0.05$ was used.

RESULTS

Figure 2 shows annual AL growth rates after 1 year, with all eyes individually plotted against the actual age and the respective median of age and AL growth rates separately for males (figure 2A) and females (figure 2B). Figures 3 and 4 show the same data but colour-coded according to age at baseline (figure 3) or AL at baseline (figure 4) as described above with respective medians of age and AL growth rates of the different subgroups.

Overall, eyes with DIMS spectacle lenses are 65% (61% of male, 70% of female) within the range of physiological AL growth rate, while eyes with SV spectacle lenses are overall 16% (16% of male, 16% of female) within the range of physiological AL growth rate (online supplemental table 1). Twenty-two out of 79 eyes (28%) with DIMS spectacle lenses showed highly excessive AL growth, which is less than for eyes with SV spectacle lenses (64 of 81, 79%). Consequently, the median of AL growth rate and age of eyes with DIMS spectacle lenses lands in the green zone while for eyes with SV spectacle lenses it lands in red zone. Likewise, overall, eyes with DIMS spectacle lenses had significantly ($p<0.0001$) less difference of annual AL growth to boundary of green zones than eyes with SV spectacle lenses (online supplemental table 2). The same results are obtained by evaluating the four subgroups: (1) younger than 10 years at baseline, (2) older than 10 years at baseline, (3) moderate baseline AL and (4) high baseline AL. Always the eyes with DIMS spectacle lenses are to a greater extent in the range of physiological growth than the eyes with SV spectacle lenses (online supplemental table 1, figures 3 and 4). Likewise, the difference in axial growth to the green zone boundary is always significantly smaller in the

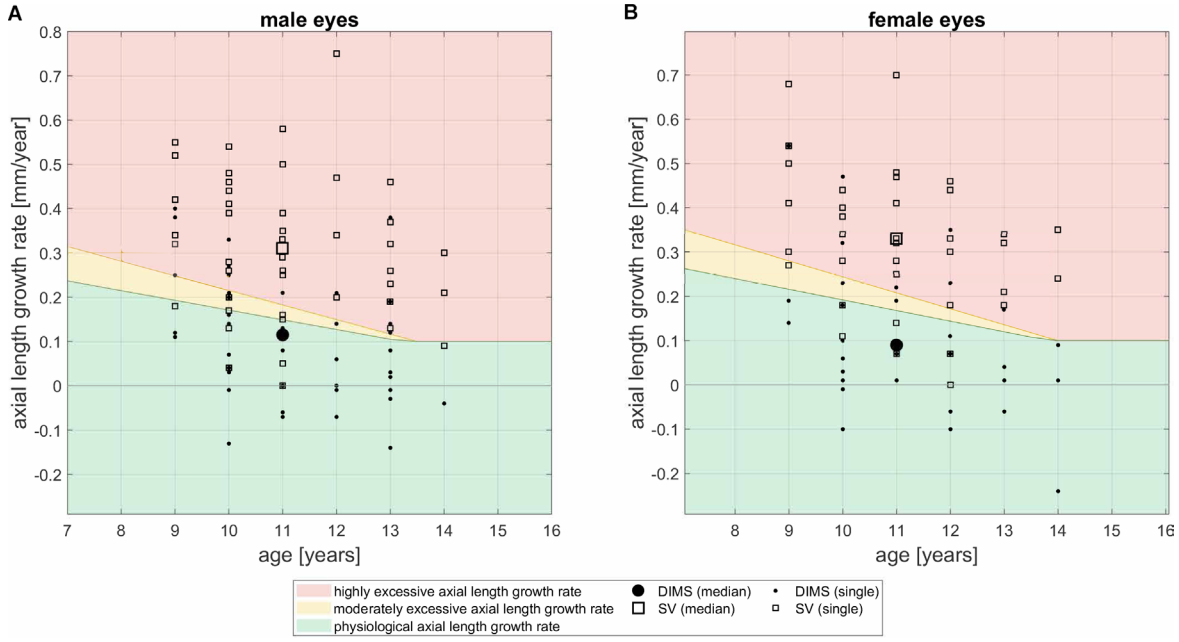

Figure 2 Individual annual AL growth rates after one year and respective median of age and AL growth rate for eyes with DIMS spectacle lenses (points) and eyes with SV spectacle lenses (squares), (A) male eyes, (B) female eyes. DIMS, defocus incorporated multiple segments; SV, single vision.

DIMS group than in the SV group (at least $p<0.001$; online supplemental table 2).

Strikingly, within the SV group, the eyes of children older than 10 years at baseline showed a higher proportion of highly excessive AL growth rate than the eyes of children younger than 10 years at baseline (total: 89% vs 74%; online supplemental table 1). For the eyes with DIMS spectacle lenses, the difference in proportions of older and younger children having highly excessive AL growth rates is only evident to a minor and thus negligible extent (30% vs 26%), with at the same time overall lower proportions of eyes with highly excessive AL growth rate.

Similarly, when eyes according their baseline AL were assessed separately, within the SV group a greater proportion of eyes with high baseline AL than the eyes with moderate baseline AL showed highly excessive AL growth rates (total: 89% vs 68%; online supplemental table 1)—again, for eyes with DIMS spectacle lenses this observation could only be made to a minor and

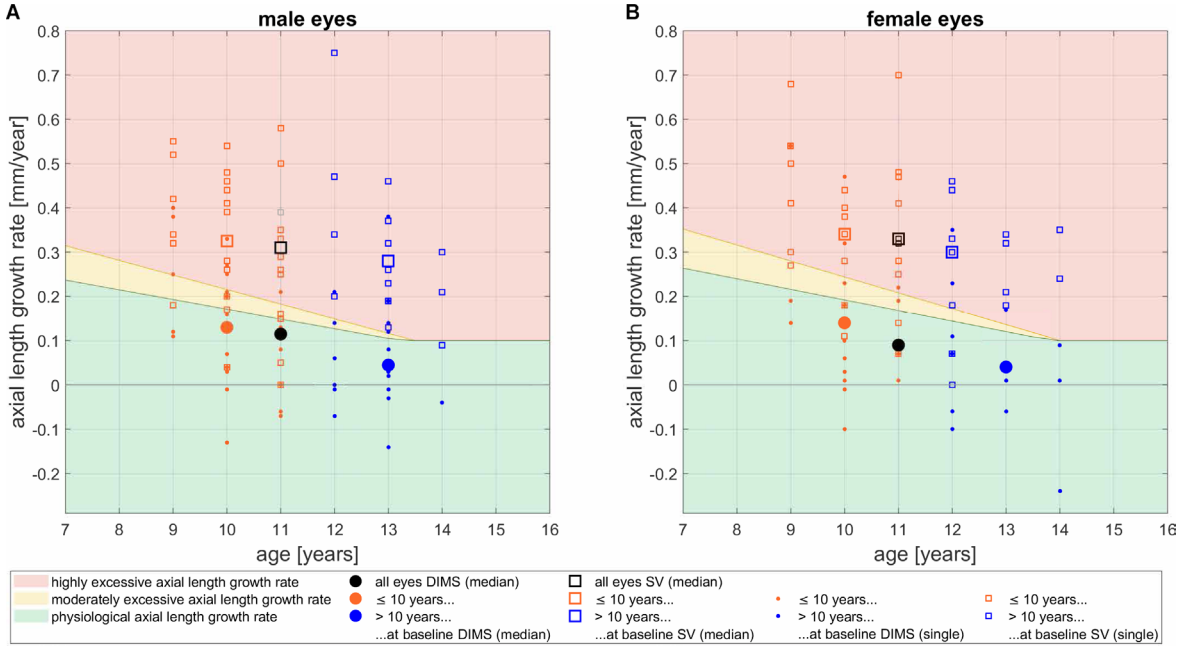

Figure 3 Individual annual AL growth rates after one year and respective median of age and AL growth rate for eyes with DIMS spectacle lenses (points) and eyes with SV spectacle lenses (squares), for different age groups; orange: eyes younger than 10 years at baseline and thus younger than 11 years after one year of treatment, blue: eyes older than 10 years at baseline and thus older than 11 years after one year of treatment, black: median of all eyes. (A) male eyes, (B) female eyes. DIMS, defocus incorporated multiple segments; SV, single vision.

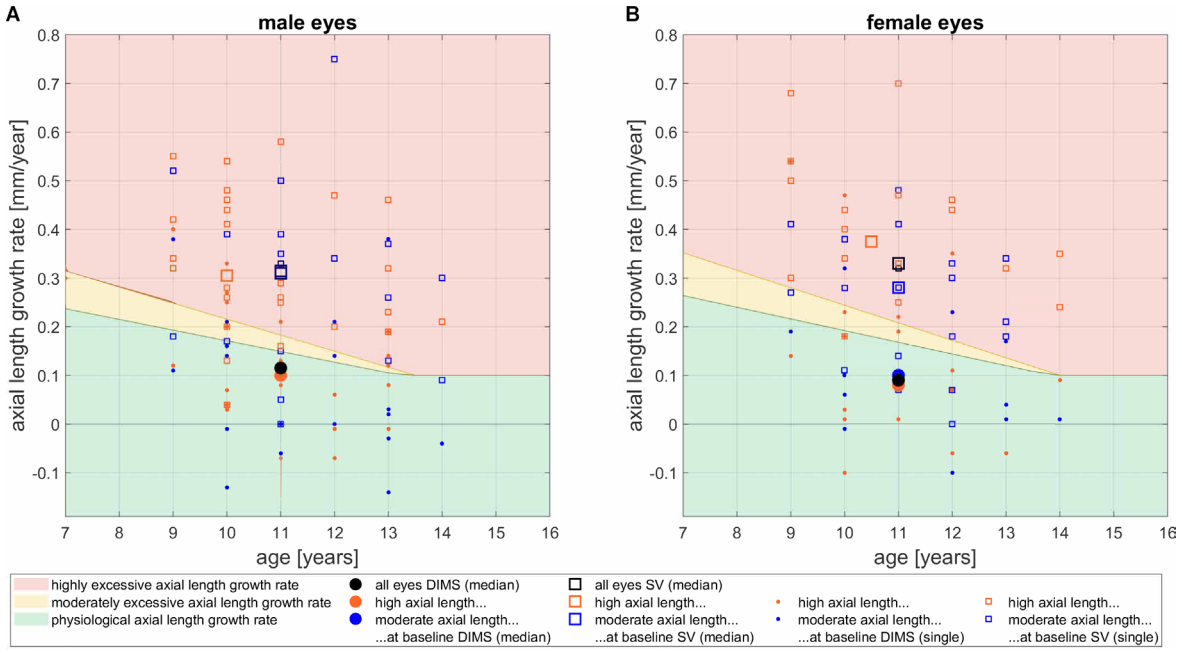

Figure 4 Individual annual AL growth rates after one year and respective median of age and AL growth rate for eyes with DIMS spectacle lenses (points) and eyes with SV spectacle lenses (squares) in two different groups according to baseline axial length; blue: eyes with moderate baseline axial length, orange: eyes with high baseline axial length black: median of all eyes. (B) Male eyes. Note that the median for all eyes (black) and for eyes with moderate AL at baseline (blue) coincide, which is why the blue point is hidden by the black point, (B) female eyes. DIMS, defocus incorporated multiple segments; SV, single vision.

therefore negligible extent (29% vs 27%), with overall lower proportion of eyes with highly excessive AL growth rate.

The distribution of moderate and high baseline ALs was fairly equal in both groups (47% and 53% for DIMS; 46% and 54% for SV). In both groups, there were more children younger than 10 at baseline than older than 10 at baseline (58% and 42% for DIMS; 67% and 34% for SV).

DISCUSSION

Axial length growth newly interpreted

Analysis of the data already available from Lam *et al*[14] using the AMMC system confirms the most important finding, namely that by wearing DIMS spectacle lenses, AL growth can be reduced in a clinical relevant amount. Lam *et al*[14] found eyes with DIMS spectacle lenses having 67% less AL growth than those with SV spectacle lenses after 1 year, which stabilised at 62% after 2 years. The annual AL growths observed in the DIMS group corresponded on average to the physiological AL growth related to the mean age of all children. This should be considered as 100% success of the treatment.

We can now specify, that after 1 year AL growth rate can be reduced to such an extent that in nearly two-thirds (65%) it is within the range of physiological growth rate. With respect to this treatment goal, the DIMS spectacle lenses demonstrated effectiveness regardless of age and baseline AL in this selected

Table 1 Overview and comparison of different myopia treatments (DIMS spectacle lenses, HAL spectacle lenses, atropine 0.01% and atropine 0.02%) regarding to the inclusion criteria of age and SER, mean axial length growth and age after the first year and to which zone in the AMMC this results into

		Inclusion criteria		Mean values after first year	
				Axial length growth (mm)	Age (years)
Study	Intervention and sample size of treated group	Age (years)	SER (D)	Resulting zone in AMMC	
Lam *et al* (2020)[14]	DIMS spectacle lenses n=79 eyes	8–13	−1.00 to −5.00	0.11	11.2
				Physiological AL growth rate	
Bao *et al* (2022)[36]	HAL spectacle lenses n=58 children	8–13	−0.75 to −4.75	0.13	11.7
				Physiological AL growth rate	
Chamberlain *et al* (2019)[37]	MiSight soft contact lens n=116 eyes	8–12	−0.75 to −4.00	0.09	11.1
				Physiological AL growth rate	
Zadnik *et al* (2023)[38]	Atropine 0.01% n=213 eyes	6–10	−0.50 to −6.00	0.30	10.0
				Highly excessive AL growth rate	
Zadnik *et al* (2023)[38]	Atropine 0.02% n=355 eyes	6–10	−0.50 to −6.00	0.30	10.0
				Highly excessive AL growth rate	

AL, axial length; AMMC, age-matched myopia control; DIMS, defocus incoporated multiple segments; HAL, highly aspherical lenslets; SER, spherical equivalent refractive error.

study group. A study group with extended/other inclusion criteria could show further knowledge about effectiveness.

A nevertheless highly excessive AL growth rate was observed for 28% of eyes with DIMS spectacle lenses. In such cases a combination treatment with atropine eye-drops should be considered, as it has been reported that the additional administration of low-dose atropine eye-drops enhances the myopia progression inhibiting effect of optical methods,[32] which is what DIMS spectacle lenses are. In addition, if treatment success with the DIMS spectacle lenses is low, compliance should be inquired about, or more precisely, the daily wearing time of the lenses. Several studies suggest that the myopia-inhibiting effect of optical treatment methods depends on the daily wearing time.[33 34] For everyday practice, we recommend starting with the DIMS spectacle lenses first, monitoring AL growth after 1 year and then deciding whether a combination treatment is necessary. If a combination treatment was started directly, about three-quarters of the children would be treated unnecessarily with atropine.

Interestingly, 16% of eyes with SV spectacle lenses, that is, without any myopia-inhibiting option, achieved the treatment goal of physiological AL growth rate. These were more likely to be those eyes with moderate baseline AL: 27% of eyes with SV spectacle lenses and moderate baseline ALs ended up within the range of physiological AL growth rate. Remeasurement of AL as early as 6 months in those children whose parents are sceptical about any myopia treatments is certainly justifiable.

Physiologically, AL should stabilise in the age of 10–15 years.[22 29] In myopic children, however, it is more common, that the eye still elongates at that age.[20 35] Therefore, it is particularly interesting to look at this group and the effect of DIMS spectacle lenses at this age. The present analysis proves that also in children older than 10 years at baseline, the DIMS spectacle lenses efficiently inhibit AL growth, with more individual AL growth rates being in the range of physiological growth rate than in the SV group and significantly less difference to the boundary of green zone than in the SV group.

Moreover, eyes with SV spectacle lenses of children that were older than 10 years at baseline were more likely to show highly excessive AL growth rates after 1 year than eyes with SV spectacle lenses younger than 10 years at baseline. The same and even to a greater extent applies to eyes with SV spectacle lenses and high baseline AL versus moderate baseline AL. This suggests that it is almost negligent and ethically questionable to use SV spectacle lenses to correct (progressive) myopia in older children and children with already high ALs. Even when physiological growth is eventually achieved, each year that an increased growth rate has occurred contributes to the eye becoming longer and developing pathologies. Therefore, DIMS spectacle lenses or another proven effective treatment method should be started as early as possible, as each year of excess axial growth unnecessarily lengthens the eye further.

Benefit and worth of the AMMC system

For the first time, the AMMC systems gives ophthalmologists and optometrists the chance to quantify the treatment success. This has practical consequences for whether current treatment can be continued or needs to be intensified. Regarding the results of studies, the AMMC can be used to demonstrate the effectiveness of myopia treatments for any age. After checking whether the child to be treated meets the inclusion criteria of the study, the parents can be informed accordingly.

Table 1 shows a comparison of the inclusion criteria of age and SER and the results of studies with different myopia treatments (DIMS spectacle lenses,[14] highly aspherical lenslets spectacle lenses,[36] MiSight soft contact lens,[37] atropine 0.01% and atropine 0.02%[38]) after the first year of treatment. For each it is given in which zone of the AMMC this results into (mean AL growth plotted vs mean age after the first year of treatment).

Outlook

In summary, the AMMC system is suitable for use in everyday practice to assess the individual AL growth rate of any child and allows a quick decision about treatment success. For own application, an online version of the AMMC is available free of charge (https://myopia-solutions.com).

Furthermore, AMMC is also suitable to picture study results from a different perspective. For future studies on myopia treatments, we propose to add AL as an inclusion criterion, and to distinguish between moderate myopia (baseline AL between 50th and 98th percentile) and high myopia (baseline AL>98th percentile). The distribution of moderate and high myopia both within a study arm and between study arms should be equal.

Contributors BG created the concept, conducted data analysis and wrote the manuscript. CSYL has gathered original data and written the scientific paper, which this paper is based on and reviewed and revised the manuscript. NV reviewed and revised the manuscript. HK created the concept, reviewed and revised the manuscript and acts as guarantor.

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Competing interests BG has received honoraria for lectures and reimbursement for attending and travel to meetings by HOYA Vision Care. CSYL is one of the inventors for the DIMS spectacle lens and received royalties from HOYA Vision Care. NV is employee of HOYA Vision Care, Research and Development Department. HK has received consulting fees, honoraria for lectures and reimbursement for attending and travel to meetings by HOYA Vision Care.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Human Subjects Ethic Subcommittee, Departmental Research Committee, The Hong Kong Polytechnic University, Hong Kong (30 July 2014, reference number: HSEARS20140630003). Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available on reasonable request.

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