A comparison of clinical trials investigating the efficacy of myopia control with an age-matched normal axial growth analysis: Physiological eye growth rate as a new benchmark for myopia treatment goal

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Purpose

Myopia control strategies such as low-dose atropine, multifocal contact lenses, and specially designed spectacle lenses are well evidenced for their use in myopia management. In clinical studies, treatment efficacy of myopia control methods are commonly calculated based on an untreated control group. However, this says little about whether the inhibition of axial length (AL) growth is sufficient.

This is where the **Age-Matched Myopia Control (AMMC)** [1] system comes in, by enabling a simple comparison of the observed annual AL growth rate with the age-matched physiological AL growth rate.

Methods

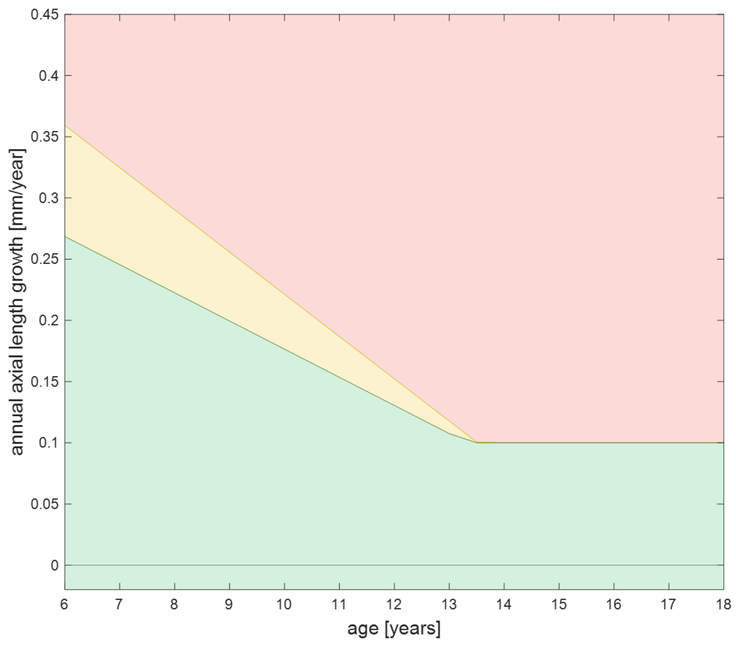
A literature review of clinical trials investigating different myopia control options (with or without a placebo group) in children was performed. For each clinical trial, participants' mean annual axial length growth per treatment year was calculated and plotted against participants' mean age after each year of treatment using the AMMC System. If data for a clinical trial were available for subsequent years, these were included.

The AMMC System classifies annual axial length growth rate as:

physiological AL growth rate → treatment success

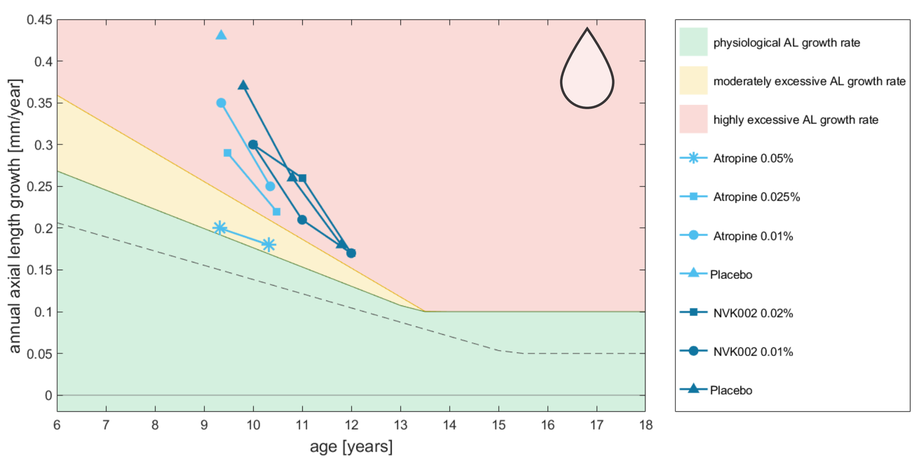
moderately excessive AL growth rate

highly excessive AL growth rate



Results

1)



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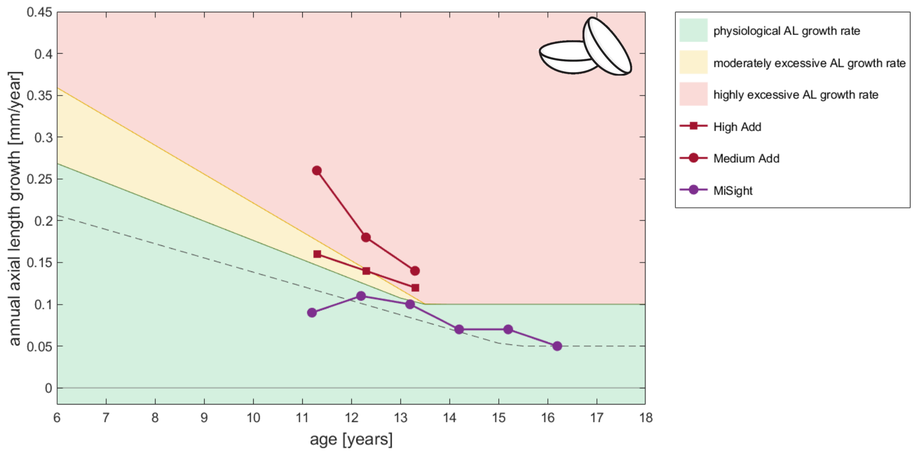

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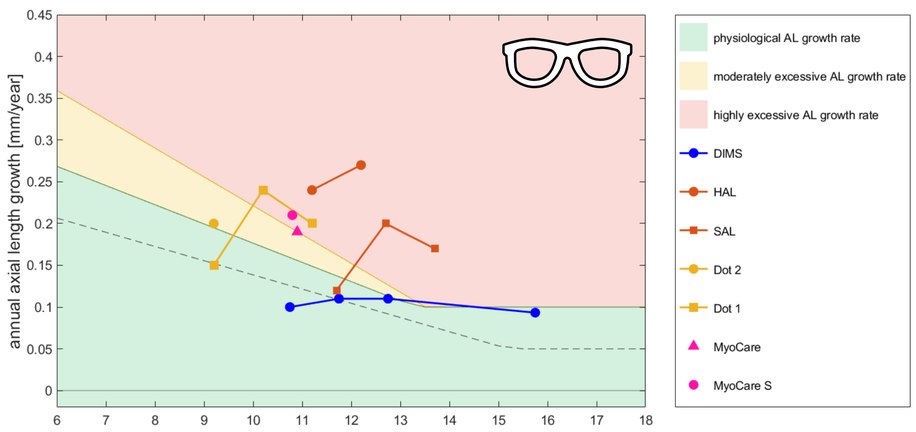
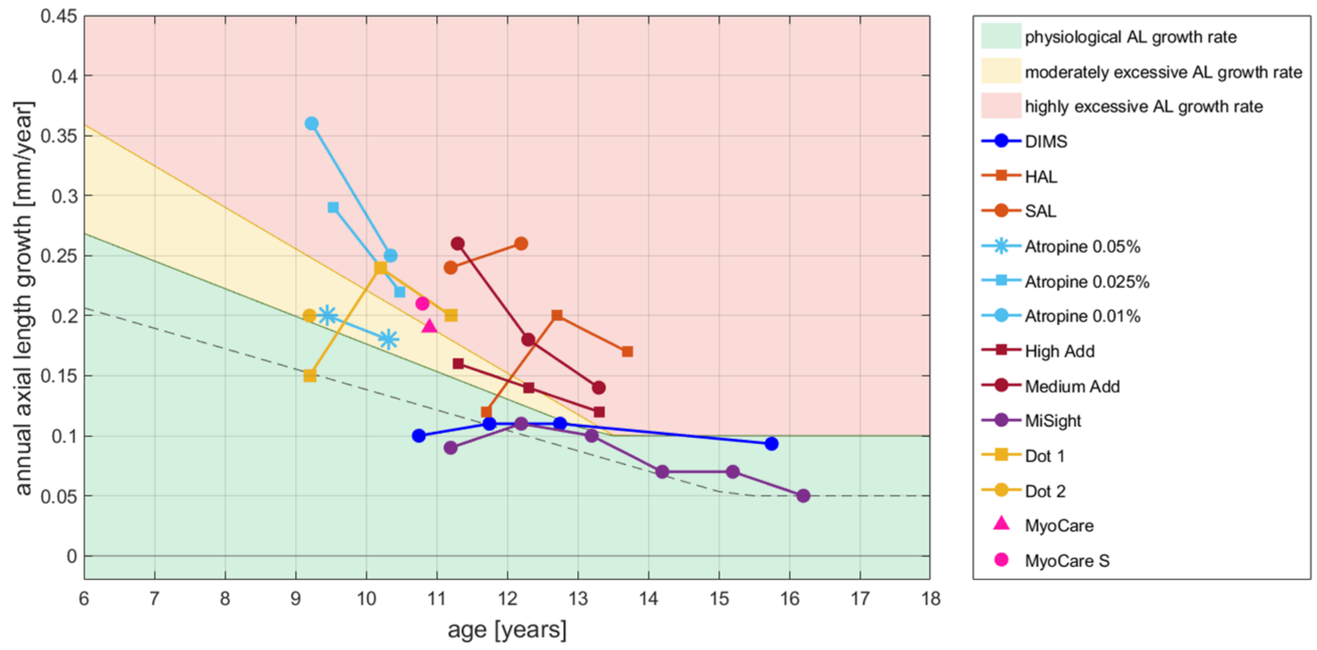


1) The results of the **LAMP study** [2] clearly show the dose dependent effect of atropine: The higher the dose, the closer the average annual growth to the green zone. However, only **0.05% atropine** delivered acceptable results regarding this treatment goal. Puzzlingly, contrary to the well-established finding of this dose-dependency, this effect was not seen in the study with **NVK002** [3], where 0.01% and 0.02% showed similar efficacy, which, however, did not reach the treatment goal.
2) Also, for multifocal contact lenses one can identify a dependency of near addition: Patients treated with **high addition contact lenses** [4] had moderately excessive AL growth in the first two years of treatment, but highly excessive AL growth in the third year, while **medium addition contact lenses** [4] showed highly excessive AL growth throughout all three years. **Dual-focus contact lens (MiSight)** [5] showed physiological axial length growth over six years of treatment.
3) Spectacle lens with **defocus incorporated multiple segments (DIMS)** [6] achieves the best results with an annual axial length growth rate that is in range of physiological axial length growth and this also over several years. Spectacle lens with **highly aspherical lenslets (HAL)** [7] and **diffusion optics technology (DOT) lens 1** [8] and provide sufficient axial length growth inhibition in the first year, but no longer in the following years. **Diffusion optics technology (DOT) lens 2** [9], **Myocare** and **MyoCare S** [10] lens do not achieve the treatment goal of physiological AL growth in the first year; long-term data are not yet available.



Conclusion

As children's physiological AL growth declines with age, the interpretation of reported clinical trial results must be made in the context of the age of the cohort. A simple comparison of AL growth or percentage inhibition of AL growth is therefore not useful when assessing different treatment options. Only spectacle lenses with DIMS and the dual-focus soft contact lens resulted in physiological AL growth in the long term. It is not possible to make any statements regarding the efficacy of the methods in children who do not meet the study-specific inclusion criteria, such as those with higher myopia or younger children.

Literature

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