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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Poster # - C10

Purpose

- Treatment efficacy of myopia control options are calculated with reference to an untreated control group in most clinical trials.
- Apart from ethical aspects of leaving myopic children untreated in a control group, such comparisons say little about whether the inhibition of axial length (AL) growth as intended by the myopia control treatment is already sufficient to stop progression.
- There is a physiological eye growth (AL growth) even in eyes that remain emmetropic. This growth is superimposed by the excessive growth in the progressive myopic eye. Physiologic AL growth seems to be comparable throughout different ethnicities.

Methods

A Literature review of clinical trials investigating myopia control options (with or without a placebo group) was performed

Participants' mean annual AL growth was calculated and plotted against participants' mean age after each year of treatment using the AMMC System.

The **Age-Matched Myopia Control (AMMC)** system[1] [WO2023143711 Jan 2022] allows comparison of the observed annual AL growth with an age-matched physiological AL growth of an emmetropic population. This empowers practitioners to work towards a target value (much like target IOP in Glaucoma treatment). The AMMC System classifies annual AL growth rate as:

- **physiological AL growth rate → treatment success**
- **moderately excessive AL growth rate**
- **highly excessive AL growth rate**

Conclusions

- Only Atropine, dual-focus soft contact lenses, and DIMS lenses showed lasting treatment effects over consecutive years, while other methods even reversed in efficacy. Seemingly similar designs or dosings do not necessarily lead to similar treatment outcomes.
- It is unreasonable to conclude treatment efficacy also for children not meeting study-specific inclusion criteria, which often have limited overlap.
- There is high variability in control and treatment groups across studies. Despite ethical concerns about placebo groups, placebo-controlled trials remain necessary until common standards for inclusion criteria are established.
- Axial length (AL) as the primary criterion over refractive error, given its recognition as the primary outcome in myopia studies should become commonplace. The lack of published baseline AL prevents assessment of presence of axial myopia.

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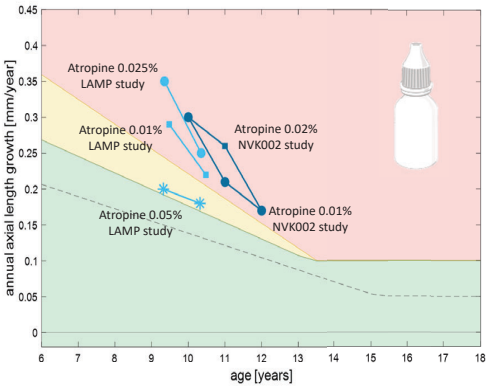
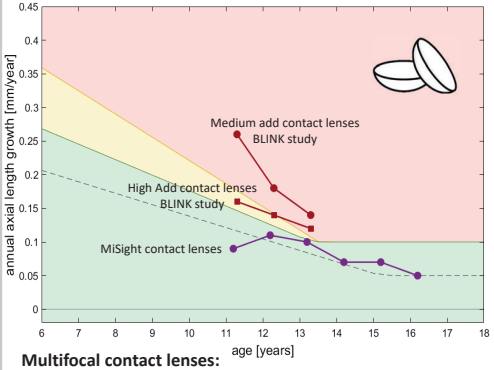
Results



Atropine treatment:

LAMP study[2] shows a dose dependent effect of atropine. Only 0.05% atropine delivered acceptable results regarding the treatment goal (AMMC yellow zone).

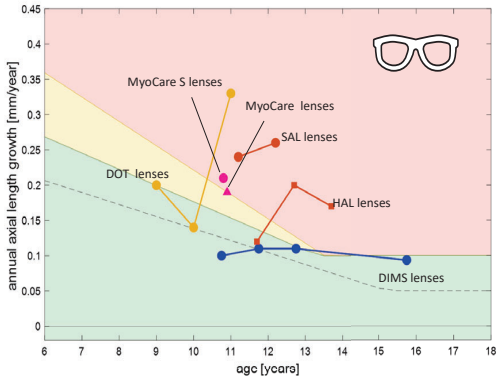
A dose dependent effect of atropine was not seen in the study with NVK002[3]: 0.01% and 0.02% showed similar efficacy, and both doses did not reach the treatment goal (AMMC red zone) and remained highly excessive.



Multifocal contact lenses:

A dose dependency of near addition exists: **High addition contact lenses**[4] lead to moderately excessive AL growth (AMMC yellow zone) 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 (AMMC red zone) throughout all three years of treatment.

Dual-focus contact lens (MiSight)[5] reached the treatment goal (AMMC green zone) over the whole six years of treatment.



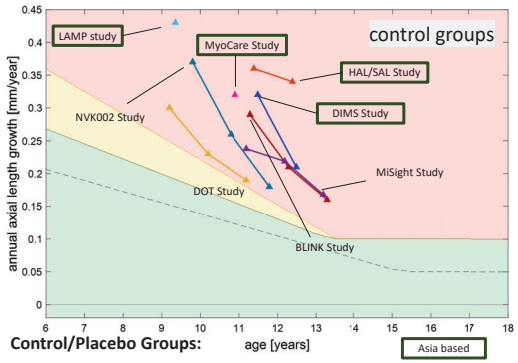
Myopia control spectacle lenses:

A substantial difference in the long-term treatment efficacy of the various designs exist: **Defocus Incorporated Multiple Segments (DIMS)**[6] reached the treatment goal (AMMC green zone) over the whole period of the study with lasing efficacy.

Highly Aspherical Lenslets (HAL)[7] **(HALT lens)** provides sufficient AL growth inhibition after the first year, but not in the following years. (The alternative SAL design is no longer available.)

Diffusion Optics Technology (DOT) lens[8] shows sufficient growth inhibition after first and second year but **allows a return to excessive growth in the following year.**

MyoCare and **MyoCare S**[10] lens did not achieve the treatment goal after the first year; long-term data are not yet available.

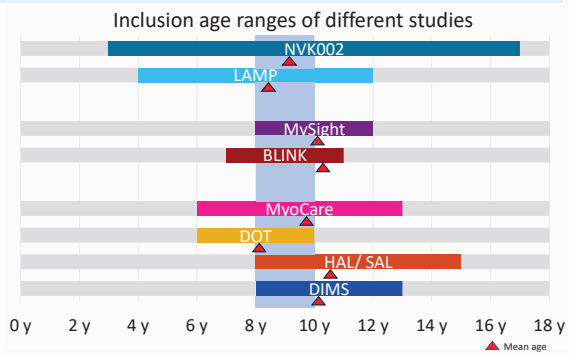


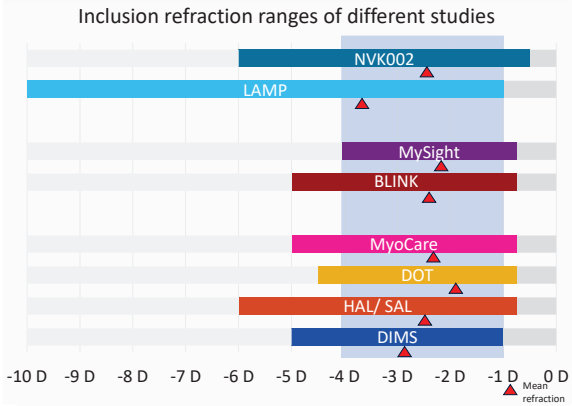
Control/Placebo Groups:

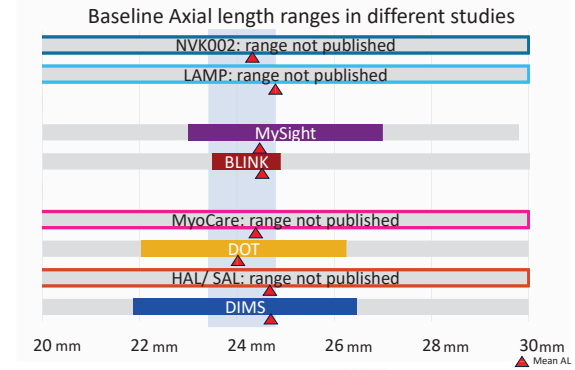
AL growth is generally reduced with age.

Control groups of the different studies do not show a uniform distribution of AL growth.

Asian studies show a higher AL growth rate in myopic controls.







References

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