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# Performance comparison of peripheral defocus spectacle lenses



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*On behalf of: Prof. Paolo Nucci, Dr Andrea Lembo, Dr Massimiliano Serafino, and Dr Roberto Caputo*

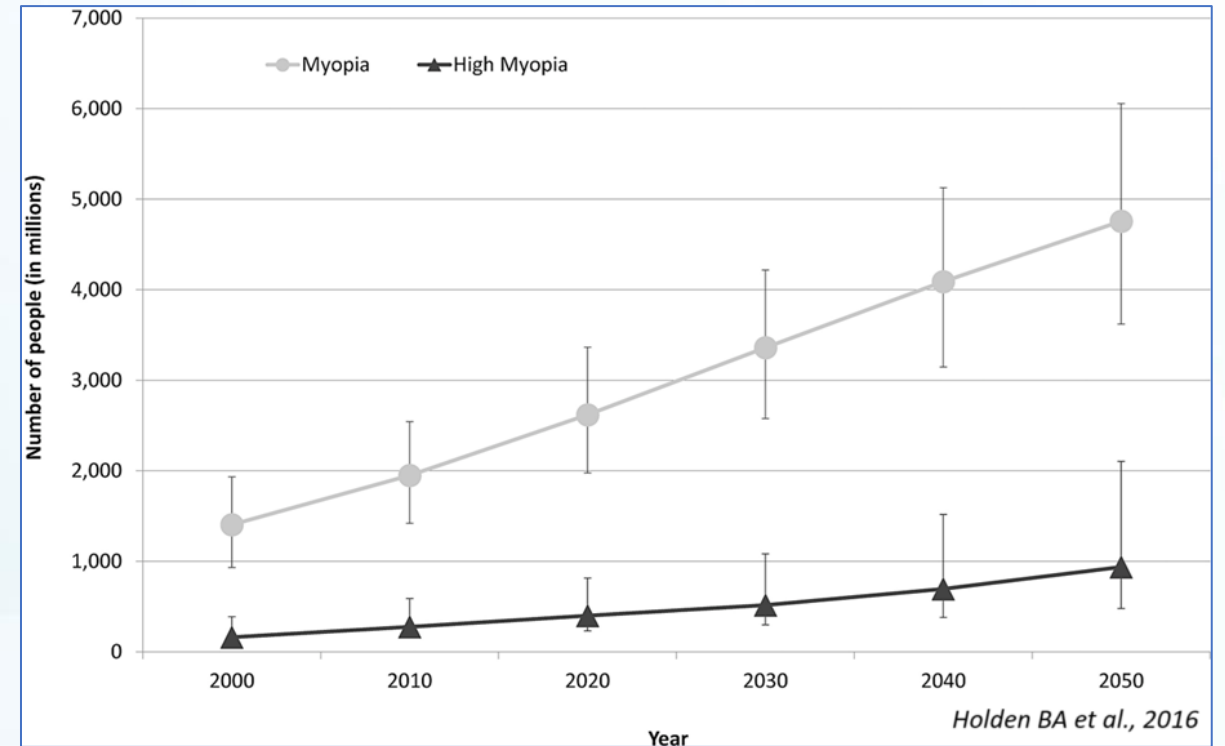
# Disclosures

Irene Schiavetti has received fees for consultancy work from AccMed, Amgen, Biogen, Dreams Lab, D.M.G. Italia, Eyepharm, Fondazione Ricerca Fibrosi Cistica, Forum Service, Hippocrates Research SRL, Hippocrates Sintech SRL, Horizon, HOYA, Lingomed, Siit.

*Acknowledgment is given to HOYA for supporting attendance at the conference.*

# Background

- Myopia prevalence is rising rapidly, projected to impact **50% of the global population by 2050**<sup>1</sup>.
- New generation lens designs, like **Defocus Incorporated Multiple Segments (DIMS)** and **Highly Aspherical Lenslets (HAL)**, offer innovative approaches to slow myopia progression by providing myopic defocus in the mid-peripheral area.
- However, while DIMS and HAL have been studied in **Chinese populations**<sup>2</sup>, their performance in European children remains unexplored.

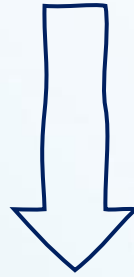


1. Holden BA, Fricke TR, Wilson DA, et al. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. *Ophthalmology*. 2016;123(5):1036-1042.

2. Yang B, Liu L, Cho P. Effectiveness of orthokeratology and myopia control spectacles in a real-world setting in China. *Cont Lens Anterior Eye*. 2024;47(3):102167.

# Objective and outcome

**Objective:** To show the equivalence between **DIMS** and **HAL** spectacles in slowing down myopia progression.



*Endpoints: Spherical equivalent refraction (SER) and axial length (AL)*

**Outcome:** Comparison between groups in SER and AL change after one-and two-year follow-ups

# Methods

- **Study design:** A retrospective cohort study conducted at the Pediatric Ophthalmology Clinic of San Giuseppe Hospital in Milan, Italy.
- **Participants:** Children with progressive myopia who wore either DIMS or HAL spectacles for two years.
- **Measurements:** Assessment of AL and SER at baseline and at one- and two-year follow-ups.
- **Statistical analysis:** The predefined equivalence margins were set at 0.25D and 0.50D for SER, and 0.20mm and 0.30mm for AL at one and two years, respectively.



## Inclusion criteria:

- Children/adolescents aged 6-17 years with developmental myopia
- European ethnicity
- Myopia with SER  $\leq$ -0.50D
- Two continuous years wear of either DIMS or HAL
- Attended one- and two-year follow-up visits

## Exclusion criteria:

- Genetic syndromes suspected (e.g., Stickler, Marfan etc.)
- Other eye diseases (such as glaucoma, juvenile cataracts or retinal abnormalities, any form of strabismus)

# Results: Baseline characteristics

- **146 patients** enrolled in the study (73 in each group) between January 2021 and April 2024.
- No statistically significant differences at baseline in SER ( $p = 0.22$ ) and AL ( $p = 0.38$ ) between the right and left eyes → only data from the **right eye** were used for the inferential analysis.

## DIMS (N=73)

Age: 11.2 ±2.3 years

Females: 46.6%

Family history of myopia: 61.6%

Age at diagnosis: 7.7 ± 2.44 years

Previous treatment with atropine: 74.0%

SER: -3.4 ±1.63 D

AL: 24.9 ±0.99 mm



## HAL (N=73)

Age: 11.4 ±2.4 years

Females: 53.4%

Family history of myopia: 74.0%

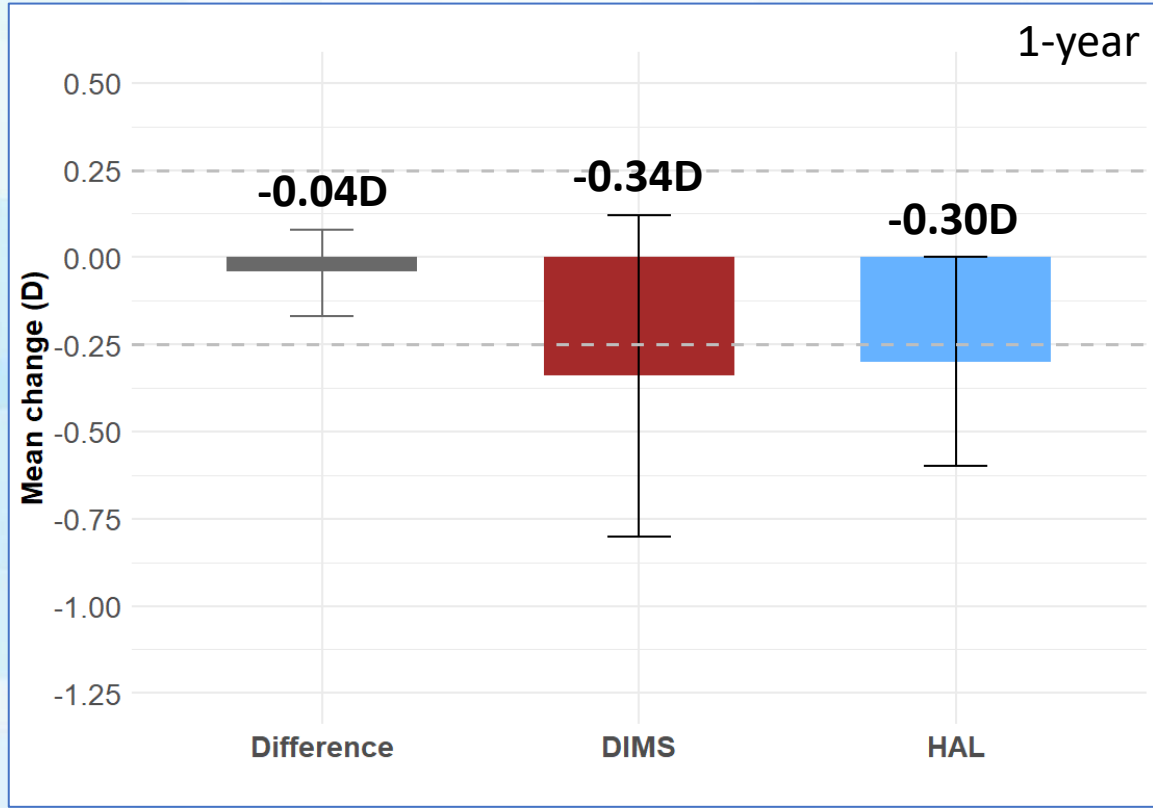
Age at diagnosis: 7.6 ± 2.16 years

Previous treatment with atropine: 41.1%

SER: -3.6 ±1.81 D

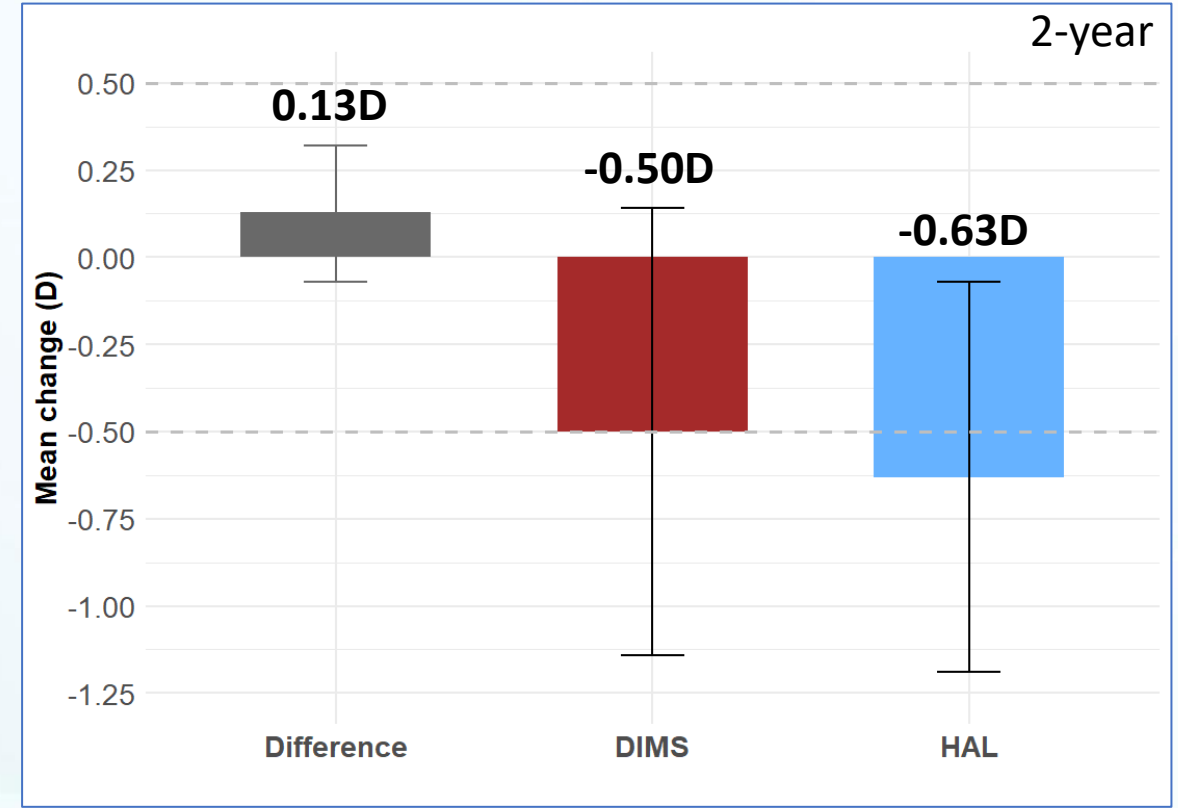
AL: 25.0 ±0.99 mm

# Results: Equivalence analysis for SER



*Equivalence margin set at 0.25D*

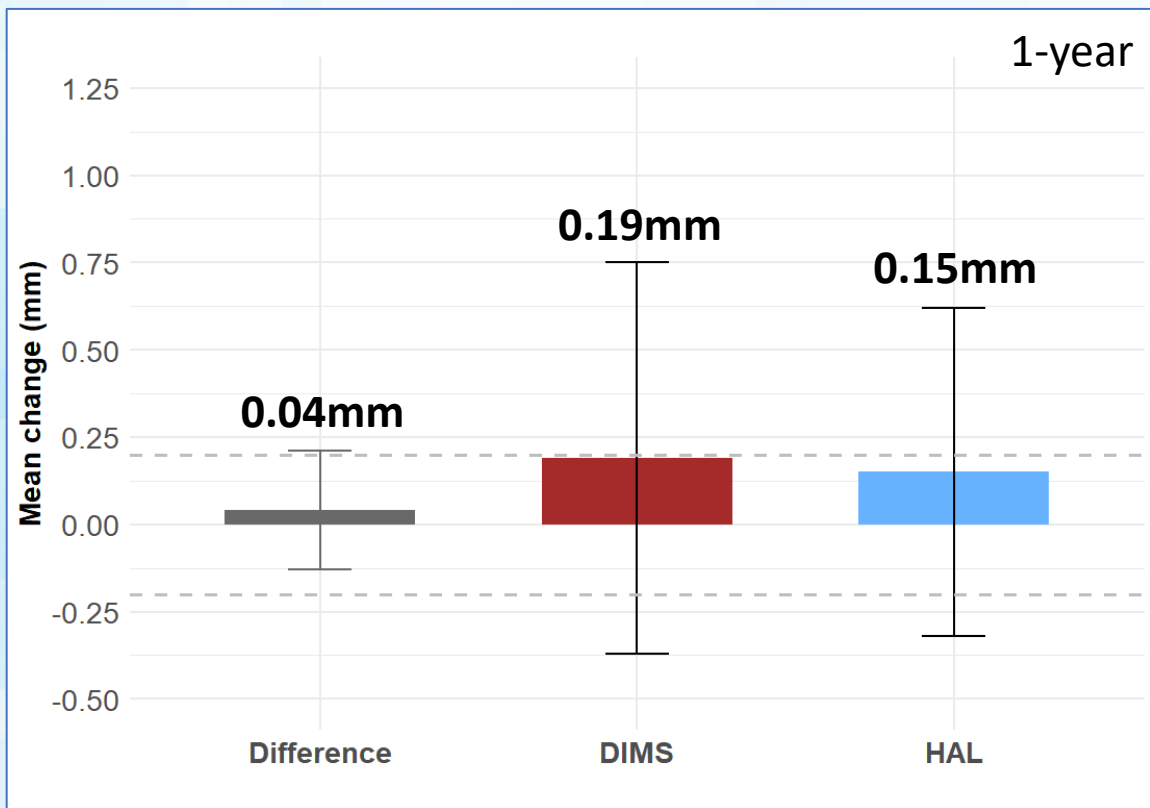
**DIMS and HAL lenses can be considered equivalent at 1 year follow-up.**



*Equivalence margin set at 0.50D*

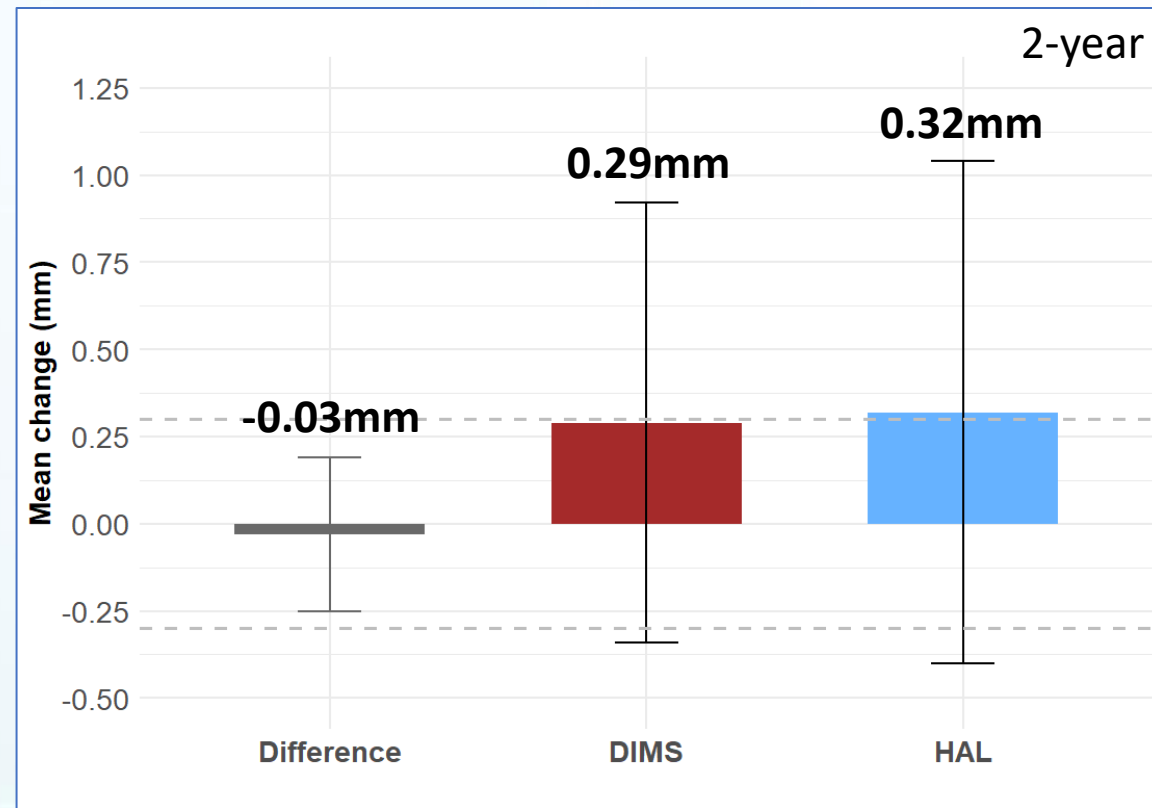
**DIMS and HAL lenses can be considered equivalent at 2 year follow-up.**

# Results: Equivalence analysis for AL



*Equivalence margin set at 0.20mm*

**DIMS cannot be considered equivalent to HAL at 1 year follow-up.\***



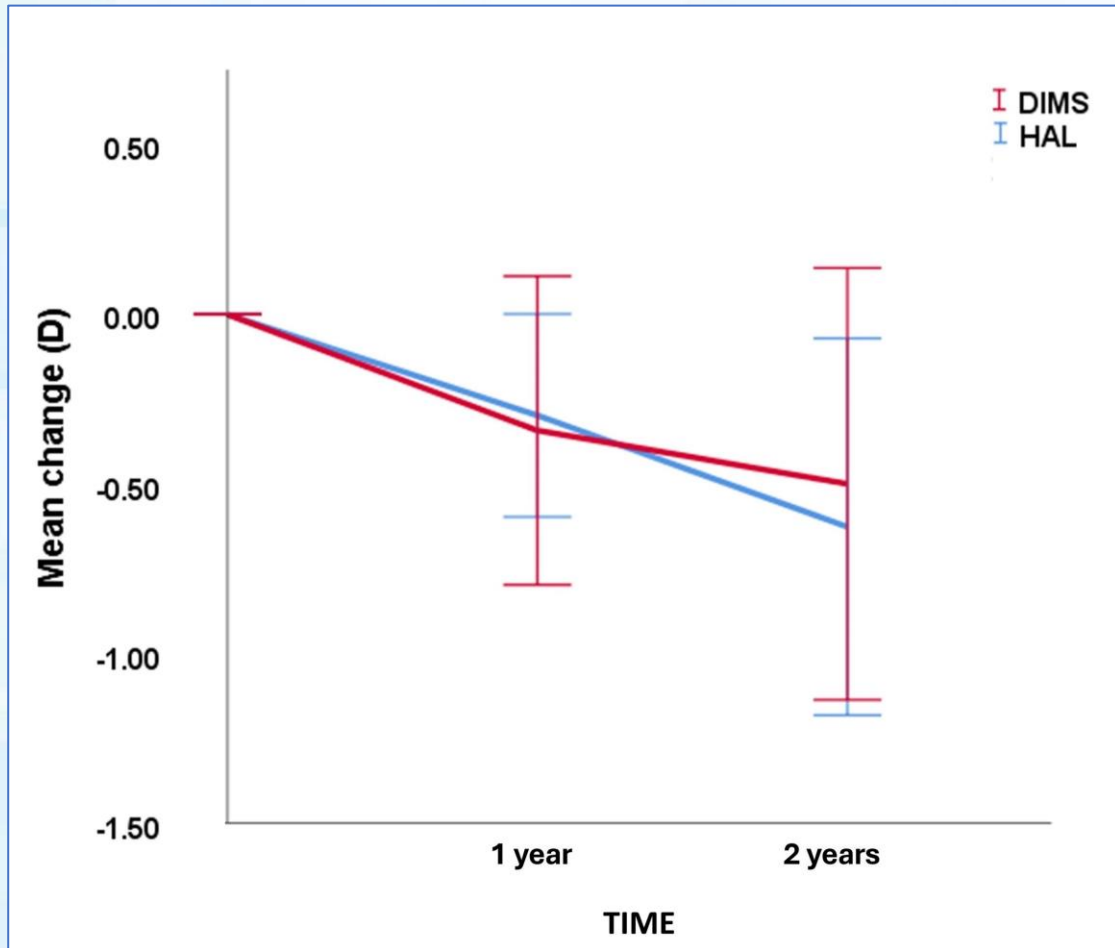
*Equivalence margin set at 0.30mm*

**DIMS and HAL lenses can be considered equivalent at 2 year follow-up.**

\* 0.21mm upper limit of the 95%CI exceed the 0.20mm equivalence margin

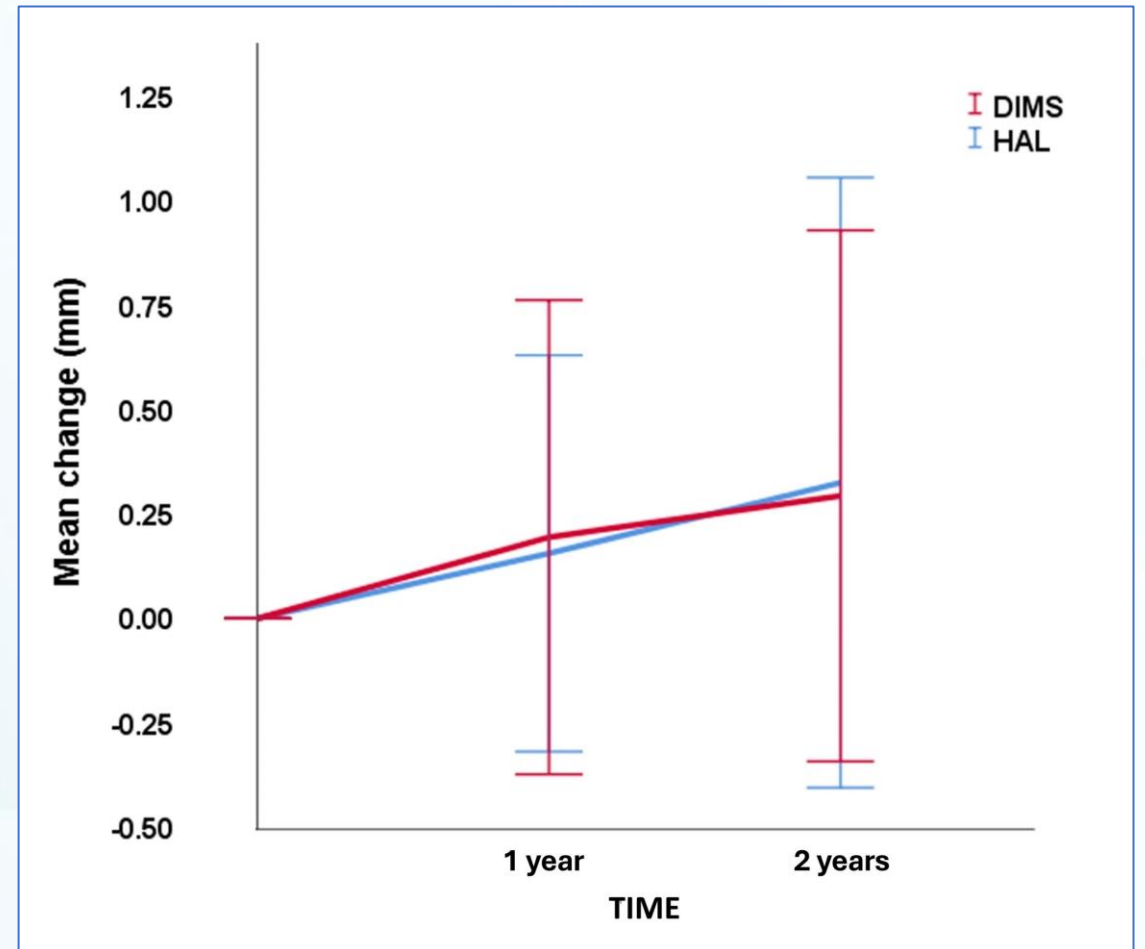


# Results: Mean changes over time



SER

No statistically significant difference in mean change between DIMS and HAL both at 1 year and 2 years (Mann-Whitney U Test, respectively  $p=0.801$  and  $p = 0.052$ ).



AL

No statistically significant difference in mean change between DIMS and HAL both at 1 year and 2 years (Mann-Whitney U Test, respectively  $p=0.335$  and  $p = 0.713$ ).

# Conclusion and future directions

- \* In our sample DIMS and HAL spectacle lenses are essentially equivalent in reducing myopia progression and axial length elongation at both one- and two-year follow-up periods.

## *In the future:*

- An RCT may reduce potential bias in group allocation.
- Explore the effectiveness of DIMS and HAL lenses in less compliant populations (not necessary attending both one-and two-year follow-up visits) to improve the generalizability of the results.
- Extend the follow-up period to assess the long-term efficacy.
- Investigate whether children with a history of atropine use respond differently to DIMS or HAL lenses compared to those who have never used atropine.

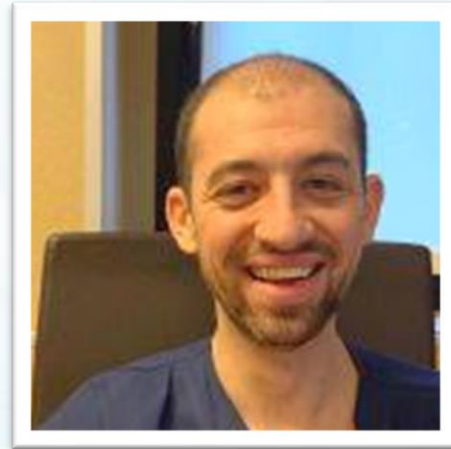


\*Take home message

# Thanks to my Collaborators



**Prof. Paolo Nucci**



**Dr. Andrea Lembo**



**Dr. Massimiliano Serafino**



**Dr. Roberto Caputo**



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***... And thank you for your attention***