Performance comparison of peripheral defocus spectacle lenses

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Background

Myopia prevalence is rapidly increasing worldwide, particularly in East and Southeast Asia, where up to 80% of young adults are myopic, with 20% of children having high myopia (≤ -6.00D).[1]

In Europe, approximately 30% of the population is myopic, with 2.7% affected by high myopia.[2] It is estimated that by 2050, 50% of the global population and 63% of the European population will be myopic.[1,3]

Myopia progression is influenced by genetic and environmental factors, with severe cases increasing the risk of complications such as retinal degeneration and glaucoma.[4,5] This has driven research into methods to slow myopia progression, including specialized contact lenses and spectacles like DIMS and HAL lenses.[6,7,8]

Method

This is a retrospective cohort study conducted at the Pediatric Ophthalmology Clinic of San Giuseppe Hospital in Milan, Italy.

The study included children with progressive myopia who wore either Defocus Incorporated Multiple Segments (DIMS) or Highly Aspherical Lenslets (HAL) spectacles for two years.

Axial Length (AL) and Spherical Equivalent Refraction (SER) were measured at baseline, and at one- and two-year follow-up visits.

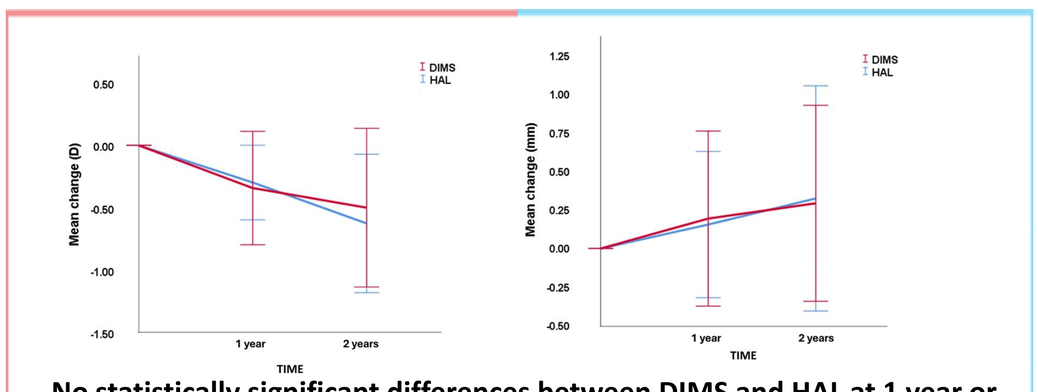
Statistical analysis aimed to assess the equivalence between the two lens types, with predefined equivalence margins of 0.25D and 0.50D for SER, and 0.20mm and 0.30mm for AL at the one- and two-year time points, respectively.

Results

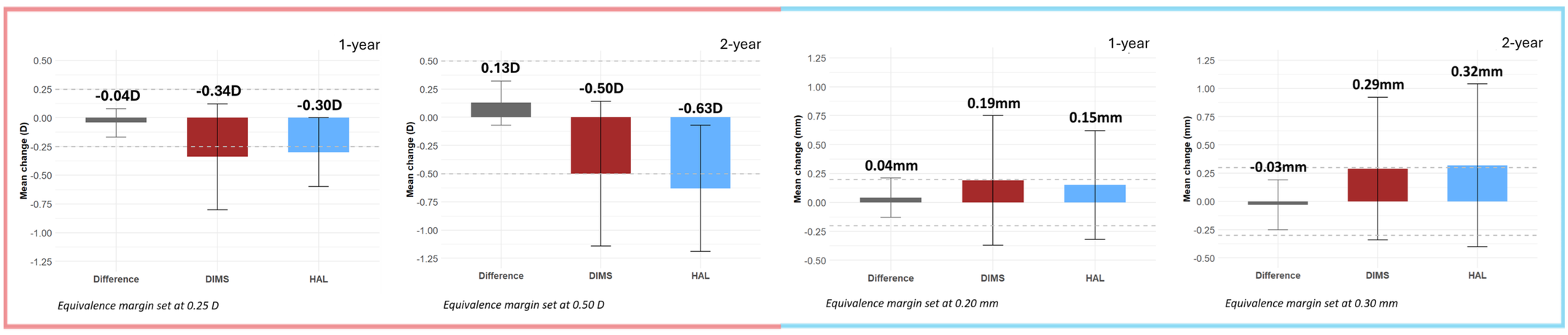
DIMS (N=73)
Age: 11.2 ±2.3 years
Females: 46.6%
Family history of myopia: 61.6%
Age at diagnosis: 7.7 ± 2.44 years
Previous atropine: 74.0%
SER: -3.4 ±1.63 D
AL: 24.9 ±0.99 mm

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 atropine: 41.1%
SER: -3.6 ±1.81 D
AL: 25.0 ±0.99 mm

Baseline characteristics: The two groups were well balanced for the endpoint variables measured at baseline.



No statistically significant differences between DIMS and HAL at 1 year or 2 year for SER (p = 0.801 and p = 0.052) or AL (p = 0.335 and p = 0.713).



At one year, the mean SER change was -0.34D and -0.30D for the DIMS and HAL groups respectively, with a difference of -0.04D (95% CI: -0.17 to 0.08), confirming equivalence within the 0.25D margin.

After two years, the SER changes were -0.50D and -0.63D for the DIMS and HAL groups respectively, resulting in a difference of 0.13D (95% CI: -0.07 to 0.32), which also fell within the equivalence margin of 0.50D.

At one year, the AL increase was 0.19 mm and 0.15 mm for DIMS and HAL groups respectively, with a difference of 0.04mm (95% CI: -0.13 to 0.21) between the groups, slightly exceeding the margin of 0.20 mm by 0.01 mm.

At two years, the AL increase was 0.29 mm and 0.32 mm for DIMS and HAL groups respectively, with a difference of -0.03mm (95% CI: -0.25 to 0.19) confirming equivalence within the pre-specified margin of 0.30 mm.

Discussion

- A comparison of the myopia control effects of DIMS and HAL spectacle lenses in European children and adolescents over a two-year period, using tests for equivalence not previously applied to this comparison.
- Our findings show that DIMS and HAL lenses are essentially equivalent in reducing myopia progression, as measured by changes in SER and AL over two years.
- Previous studies comparing DIMS and HAL spectacle lenses in Chinese children[9,10], found contrasting results, with Guo et al. reporting greater myopia control with HAL over DIMS after one year. However, the current study had a more balanced sample size and fewer methodological issues compared to Guo et al.[9], yielding lower progression rates for DIMS at one year with differences in SER and AL between DIMS and HAL being neither clinically nor statistically significant.
- Randomized controlled trials (RCTs) on DIMS and HAL spectacle lenses conducted before the COVID-19 pandemic reported lower progression rates, potentially due to selective recruitment and controlled settings that may overestimate real-world effects.[7,8]

Conclusions

In a European population, DIMS and HAL spectacle lenses are essentially equivalent in their ability to reduce myopia progression and axial length elongation over a two-year follow-up period. To the best of our knowledge, this is the first study of this type to be conducted on European participants. Future studies should consider conducting RCTs to reduce bias in group allocation, explore the lenses' effectiveness in less compliant populations, and assess the response of children with a history of atropine use to these lenses.

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