OPHTAMYOP STUDY MYOPIA CONTROL IN FRENCH CHILDREN TREATED WITH DEFOCUS INCORPORATED MULTILPE SEGMENT SPECTACLE LENSES: INTERIM ANALYSIS

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Poster # C08

Purpose

The rising prevalence of myopia in Europe is a public health concern. This study assesses the safety and effectiveness of Defocus Incorporated Multiple Segment (DIMS) spectacle lenses for children with progressive myopia in France.

Methods

- Multicenter, retrospective and prospective observational study
- children aged 4-16 years with progressive myopia (-0.25D to -8.00D).
- Participants were recruited between April 2020 and April 2024 and prescribed DIMS spectacle lenses.
- Patients undergo evaluations at baseline and at 3, 6, 12, 18, and 24 months.
- Measurements include visual acuity, cycloplegic refraction, phoria, fundus examination, and axial length by optical biometry.
- Primary outcomes: changes in Axial Length (AL) and Spherical Equivalent Refraction (SER)
- Comparisons between baseline, M12, and M24 are performed using the Wilcoxon signed-rank test.

From Serious Game Orthoptic Simulator

Image APHP, Paris France

Image D. Bremond-Gignac, Paris France

Results

- 49 participants
- Mean age of 10.36 years (± 2.49 years)
- M:F Ratio 6:4
- 68.1% were between 8 and 12 years old
- 8.5% being younger than 8 years.
- Baseline measurements for the Right Eye (RE):
  - Spherical equivalent refraction (SER): -2.97 D ± 1.79 D
  - Axial length (AL):24.35 ± 0.89 mm.
- Close monitoring during adaptation
- No adverse events
- 46 completed the 24-month follow-up

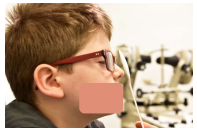
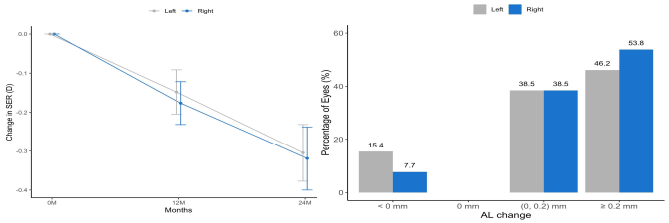


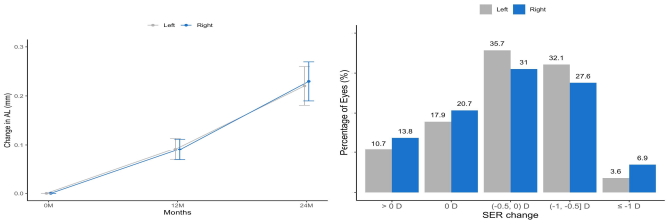
Image APHP, Paris France

Results

- The mean increase in AL from baseline to 24 months was 0.23 mm ± 0.20 mm for the RE.
- The progression analysis showed that 46% of subjects experienced an increase in AL of more than 0.2 mm by 24 months, while 38% had an increase of less than 0.2 mm.
- No correlation between baseline myopia severity and changes in AL



- The mean change in SER from baseline to 24 months was -0.32 D ± 0.44 D for the RE.
- Approximately 20% of subjects showed no change in SER by 24 months.
- About 30% had reductions up to -0.5 D and -1 D, with only a few experiencing reductions greater than -1 D.
- The changes in SER were similar across low and moderate myopia levels, but results for high myopia were less stable due to fewer observations



Discussion

- Progressive myopia is typically defined as an increase in spherical equivalent refraction (SER) of ≥-0.5 D over one year or ≥-0.25 D over six months and/or an axial length (AL) increase of ≥0.2 mm over one year.
- In our interim study of 49 patients, myopia progression was fastest in the 7-9 years age group (-0.34 D), followed by the 10-12 years group (-0.24 D).
- The 4-6 years group showed a progression of -0.31 D, though not statistically significant, while the 13-16 years group had the least progression at -0.22 D.
- Females show greater progression (-0.35 D) than males (-0.21 D).
- When analyzing data 24 months post-baseline, the mean axial elongation was approximately 0.2 mm/year in children aged 6, decreasing gradually to around 0.06 mm/year by age 13, with a slight increase thereafter.
- The limited number of patients demonstrates a robust trend of myopia control in children treated with the D.I.M.S. technology.

Conclusions

- Myopia is considered evolutive when refraction increases by 0.5D over 1 year or 0.25D over 6 months and/or when axial length by 0.2mm over 1 year.
- In our interim study, in 2 years, mean refraction change -0.32 +/- 0.44 D and mean axial length change 0.23 +/- 0.2 mm indicates a significant trend of myopia control.
- The D.I.M.S. technology appears safe as no adverse event were recorded.
- Small sample size limits generalisability of the results Further data with more patients enrolled are needed.

Conflict of Interest Declaration

- DBG :Cooper, Essilor, Hoya, J&J, Santen, Thea, Zeiss
- GLM: Essilor
- BM : Hoya, Santen, Thea
- JPC: Menicon, Precilens, Cooper
- MG (employee of Hoya)