Contact Lens Update
CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Article Review: Long-term Effect of Dual-focus Contact Lenses on Myopia Progression in Children: A 6-year Multicenter Clinical Trial

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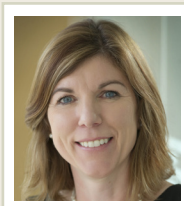

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The increase in worldwide prevalence of myopia has been very well documented,[1] resulting in a call for myopia control to become standard of care. The World Council of Optometry has paved the way, with a resolution statement regarding the incorporation of myopia control as standard of care for all optometrists.[2]

Once a young patient has been identified as having a myopic refractive error and the conversation has taken place with parents about the necessity for the implementation of myopia control, the practitioner is faced with decisions regarding which modality to choose. Of these, a widely available option is specially designed soft contact lenses.

At the time of publication, this paper outlines the results from the longest continuous myopia control soft contact lens study involving children. The children were enrolled for an initial three-year period, which was subsequently extended for a further three years, resulting in six years of data.

Long-term Effect of Dual-focus Contact Lenses on Myopia Progression in Children: A 6-year Multicenter Clinical Trial. Chamberlain P., Bradley A., Arumugam B., Hammond D., McNally J., Logan N., Jones D., Ngo C., Peixoto-de-Matos S., Hunt C., Young G. Optom Vis Sci, 2022. 99(3): p. 204-212.

The Study

As mentioned above, this six-year study was separated into two three-year parts. In Part One, children aged 8-12 years were enrolled and randomized (1:1) into a single-vision spherical contact lens (Proclear 1 Day) or the dual focus MiSight 1 Day lens (CooperVision Inc., Pleasanton, CA, USA). Children were recruited across four clinical sites globally (Canada, Portugal, Singapore, and United Kingdom), covering a wide range of ethnic backgrounds. One-hundred-and-nine children completed the initial three years of lens wear during Part One. In Part Two, participants were invited to continue for a further three years, with all participants wearing MiSight 1 Day lenses. Eighty-five participants completed the full six-years of the study.

The profile of subjects who took part in the clinical trial is typical of patients commonly seen in a primary eye care setting. In Part One, the age range at enrolment was 8-12 years and during Part Two, the age range was 11-16 years. The authors of the paper coded the two groups of children into T6 (who had been in MiSight for 6 years during Parts One and Two) and T3 (who had been in Proclear for 3 years during Part One, then switched to MiSight for the subsequent 3 years during Part Two).

As with all myopia control studies, the primary outcome measures were the standardized objective measurements of axial length (AL) and cycloplegic spherical equivalent refractive error (SERE). These are the same measurements that are commonly monitored in patients attending myopia control clinics. After the initial

measurements, fitting and follow-ups were completed. Follow-up appointments were scheduled every six months, which is similar to the regimen used clinically for children wearing soft contact lenses. A complete cycloplegic refraction and axial length measurements were performed annually.

The stand-alone results of Part One have been published previously, showing a significant difference in rate of change of myopia (both SERE and AL) in the two groups of children.[3] The myopia of those in Proclear 1 Day lenses progressed significantly more than those in the dual-focus MiSight 1 Day lenses.3 Moving into Part Two, the aims of the extended portion of the study were to continue monitoring the progression of both groups over the additional period of time, and to compare the rate of progression between the two groups (T3 and T6), with all children now wearing the MiSight lenses.

It is important to note that while Part One was a conventional, double masked, randomized clinical trial with a test group and a demographically matched control group, Part Two did not offer the option of a treatment vs control comparison and thus, conventional measures of efficacy could not be established. What Part Two of the study did offer was the option to consider an analysis of eye growth over time, and the impact of switching a child from no myopia control to a myopia control contact lens at a later stage in their myopia journey. This analysis provides answers to questions clinicians often have relating to: “ideally when should myopia control start?” and “is it ever too late to implement myopia control?”

Results

Across the entire six years of the study, there was a significant difference in the rate of myopia progression between the two groups. The T3 group progressed by an average of -1.55 ± 0.81D, whereas the T6 group progressed by an average of -0.92 ± 0.87D. As seen by the range of effect for the T6 group, some children did not progress at all. The results of the study indicate that 23% of the T6 group had only -0.25D of SERE change or less over the entire period of the study.

In considering progression experienced during the two three-year time periods, it was evident that the T6 group had a very similar SERE rate of changes for both Part One and Part Two: -0.51 ± 0.64D and -0.45± 0.41D respectively. The T3 group had a significantly slower rate of progression in Part Two than in Part One of the study: -0.29±0.52D and -1.24±0.61D respectively. The axial length changes mirrored these results, with an average increase in AL for the T6 group of 0.30mm and 0.22mm in Parts One and Two respectively, and 0.62mm and 0.18mm in Parts One and Two respectively for the T3 group. In other words, these results show that the myopia control effect was sustained over six years for those children who used the MiSight lenses for the entire study (T6) and, in those children who were in the control group during the initial three-year period (T3), still demonstrated a slowing of myopia progression once they were refit into MiSight lenses.

Clinicians who are concerned about fitting young children with contact lenses may wonder whether compliance with wearing time may be an issue. In this study there was excellent compliance, with children wearing the contact lenses an average of more than 12-hours per day and 6.5 days per week.

As with all studies there were many clinical tests performed, and while this paper is focussed on the myopia control aspect of the results, there are also other important findings. Visual acuity was very similar across both groups at the 36-month cross over point, being on average -0.02 logMAR for T3 and -0.03 logMAR for T6 children. At the six-year visit there was no difference in visual acuity between the two groups, with both averaging -0.02 logMAR. For those unfamiliar with logMAR notation, 0.00 logMAR equates to 20/20 acuity and -0.02 equates to an acuity better than 20/20.

Another important issue to consider is the ocular health of patients wearing contact lenses for an extended period. In this study, all children wore the hydrogel material for at least six days a week over six years. This

publication did not go into detail regarding the rates of adverse events or slit lamp findings but does direct the reader to another publication that outlines the positive results in depth; very few adverse events or physiological complications were observed.[4]

Application to clinical practice

This paper clearly demonstrates that young patients can be fit with MiSight 1 Day lenses at any point in their myopia journey, and there will be an impact on AL as well as SERE. The study did show that MiSight 1 Day lenses could help control myopia over an extended period however, there was a greater impact on those children who were fit at a younger age.

In summary, clinicians can be confident that myopia progression can be slowed by wearing approved soft contact lenses for myopia control and the sooner there is intervention, the better the eventual result.

REFERENCES

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