A groundbreaking contact lens therapy has potential to impact the fast-growing issue of myopia (nearsightedness) among children, based on research presented at the American Academy of Optometry's 95th Annual Meeting. The prevalence of myopia is projected to increase from approximately 2 billion people worldwide in 2010 to almost 5 billion people in 2050.

Speaking to optometrists and scientists in Anaheim, Calif., CooperVision Senior Manager of Clinical Research Paul Chamberlain shared two-year interim results from a clinical trial assessing a specially-designed, dual-focus myopia control 1-day soft contact lens in reducing the rate of progression of juvenile-onset myopia. The design for myopia control has not been approved in the United States.


The findings indicated that use of the dual-focus contact lens -- which has alternating visual correction and treatment zones -- was effective in slowing myopia progression: 59% as measured by mean cycloplegic spherical equivalent (SE) and 53% as measured by mean axial elongation of the eye when compared to the children in the control group wearing a single vision 1-day contact lens. Mean cycloplegic SE progression and mean axial length were significantly less in the test group by 0.54D (95% CI: 0.40D-0.68D) and by 0.24mm (95% CI: 0.30mm to 0.19mm), respectively, over a two-year period.

This is the first prospective randomized controlled study to offer conclusive data for such a high degree of continued efficacy in myopia management using a 1-day soft contact lens at the two-year mark. The contact lens-based approach does not induce common side effects exhibited by some alternative pharmacological therapies.

The dual focus lens was well accepted by children, and did not affect their daily activities such as school work, reading, playing outside, and computer use when compared to the control group. Children in both the test and control groups indicated a higher satisfaction with contact lenses over spectacles.

Parents of study participants also had a very positive response, noting their children could mostly manage their lens wear independently. Prior to dispensing contact lenses, less than half of the parents were extremely at ease with their child wearing contact lenses, but this increased significantly to 79% after just one month and remained high through the two-year mark. Throughout the study, 8 out of 10 parents rated their children 'extremely happy' with the overall experience.

"Myopia's prevalence has exploded in the past several decades, moving from affecting low double-digit percentages of the general population to now compromising vision for the vast majority of young adults in some countries, especially in East Asia," said Arthur Back, Chief Technology Officer for CooperVision and a leading voice on myopia management.

"Myopia, mostly beginning during the preteen and early teen years, causes more than just blurred vision and the need for vision correction. The long-term consequences for individuals and communities is also well-documented, as it can increase the likelihood of conditions later in life such as glaucoma, cataract, retinal detachment and myopic maculopathy if not addressed. Initiating treatment for myopia in childhood represents a meaningful commitment by parents in the near- and long-term health and well-being of their children. The CooperVision dual-focus 1-day lens used in this study provides a new approach that's proving effective at 24 months."

**Slowing Cycloplegic SE Progression and Axial Length Growth**

In the study, mean spherical equivalent autorefraction at baseline was -2.02D (SD: 0.77) and -2.19D (SD: 0.81) for the test and control subjects, respectively. There was no significant difference in demographic factors between the groups at baseline. At two years, 60 subjects were evaluated in the control and 55 in the test groups.

Mean cycloplegic spherical equivalent was significantly lower in the test group by 0.40D (95% CI: 0.30D-0.51D) at 12 months and by 0.54D (95% CI: 0.40D-0.68D) at 24 months, respectively, when compared to the control group.
Mean axial length growth was less in the test group by 0.15mm (95% CI: 0.19mm to 0.11mm) at 12 months and by 0.24mm (95% CI: 0.30mm to 0.19mm) at 24 months. A highly significant correlation between SE and axial length change was found for the control and test groups.

**Rapidly Changed Parental Attitudes**

Prior to dispensing contact lenses, only 47% of parents were extremely at ease with their child wearing contact lenses, but this increased significantly to 79% after one month and grew to 84% at 24 months. Parents reported minimal involvement and assistance with lens handling after one month of contact lens wear by their children.

For lens removal, minimal parental assistance was required throughout the trial (4% of parents providing more than one assist in the first week and none at 24 months). Reminders by parents to insert or remove lenses were infrequent. At 24 months, 82% of parents rated their children 'extremely happy' with overall experience of the dual-focus contact lens.

**Positive Acceptance and Quality of Vision Among Children**

There was no difference in wearing time during the week and during the day between children wearing the dual-focus 1-day lens and a single vision 1-day contact lens. Quality of vision reported by the children was similar between the control and the test groups.

Average wear time at 24-months was 6.5±0.5 days/week and 13.1±1.4 hours/day during the week and 12.1±1.4 hours/day during the weekend. There was no significant difference between groups. At least 8 out of 10 children in each group rated their vision as 'seeing really well' for the following vision satisfaction assessments: school work, outdoor activities, and playing video games. Fewer subjects in the control than test group noticed ghosting (14% vs 49%, respectively), but only 5% of the control and 11% of the test group reported 'slightly annoying' ghosting.

Ocular comfort during contact lens wear in both groups was excellent, with 95% of children in the control group and 98% of children in the test group reporting that they could never or sometimes feel their contact lenses. When test and control subjects were asked how they liked wearing their type of vision correction, 78% and 80% of children respectively rated contact lenses 'the best'.

Source:
CoopervVision