

Promising results for myopic correction with overnight contact lens

**Dermot McGrath
in Rome**

MYOPIC patients who are not eligible candidates for refractive surgery may benefit from treatment with a new contact lens specially designed for overnight orthokeratology, according to an Italian optometrist.

Presenting the results of clinical trials with the lens to the 9th Winter Refractive Surgery meeting of the ESCRS, its creator Antonio Calossi said that the reverse-geometry gas permeable contact lens achieved safe and effective corneal remodelling without significant adverse reactions.

"These initial results suggest that the overnight wear of these customised multi-curve reverse-geometry lenses reduces patients' dependence on daytime wear of spectacles or contact lenses and allows them to achieve acceptable unaided vision for most of their daytime activities. Furthermore, the safety and efficacy of the procedure appear to be favourable without significant adverse reactions," he said.

Mr Calossi, in private practice in Florence, Italy, defined orthokeratology as the controlled application of rigid permeable contact lenses to bring about a reversible reduction or elimination of refractive error. According to the American Academy of Ophthalmology, optometrists developed the procedure in the 1960s. Although not in wide use in the United States, the procedure is gaining in popularity in China and other Asian countries.

The study included 50 eyes of 25 myopic patients aged from 11 to 44 years with a baseline spherical equivalent ranging from -1.0 D to -6.0 D, with-the-rule astigmatism up to +1.50 D and oblique astigmatism up to +0.75 D.

All patients enrolled in the study were fitted with the overnight contact lenses. Assessment criteria included uncorrected visual acuity, best-corrected visual acuity, manifest refraction, ultrasound pachymetry, corneal topography, corneal wavefront analysis, and biomicroscopic data. These data were collected at baseline, in the morning immediately following lens removal, 12 hours after lens

removal, and then after one night, one week, two weeks, one month, three months and six months of lens wear.

Results after one night

Mr Calossi noted that the cornea responded rapidly with significant ($p < 0.05$) central corneal flattening and improvement in visual acuity after the first night of contact lens wear.

"The corneal shape changed from prolate to oblate after one night of wear. By the end of one week, all corneal and visual changes had reached a maximal level and remained fairly stable during the day. These changes were sustained at the following visits," he said.

He added that there was a significant increase of corneal spherical aberration ($p < 0.05$) in the first week of treatment, but that biomicroscopy showed no significant ocular adverse events. Nor was any significant change observed in the central thickness of the cornea.

All of this seemed to point to the fact that the procedure was safe as well as efficacious, said Mr Calossi.

"For all the period of the study we observed a safety index of '1.0', which means that no patient lost any lines of BCVA. Specular microscope analysis showed no measurable changes in the endothelium and the confocal microscope did not show any significant structural, inflammatory or trophic alteration of corneal tissue," he added.

Infection risks with older overnight lens designs

Calossi noted that while orthokeratology had attracted its fair share of criticism in the past because of associated problems with corneal scarring and infection, recent advances in lens design and gas permeable material which allow oxygen to reach the cornea have gone a long way towards addressing these concerns.

"Infection is naturally one of our main concerns with this type of treatment. There are several published papers in the literature that show that if we don't fit the right lens and the right material, then there is an increased risk of infection. Interestingly, most of these cases of infection were reported in



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Asia with very few in North America," Mr Calossi noted.

One such paper published in 2004 found that some Chinese children who wore contact lenses overnight as part of an orthokeratology regimen developed corneal ulcers that resulted in corneal scarring and vision loss.

Alvin L. Young and colleagues at the Chinese University of Hong Kong reported this consecutive series of children with orthokeratology-related corneal ulcers who presented to their tertiary care centre.

The six children between the ages of nine and 14 wore rigid contact lenses 8 to 12 hours a night for the correction of myopia. All of the children developed bacterial eye infections that warranted medical treatment. All the infections were unilateral. Infection onset was between three and 36 months after initiating orthokeratology contact lens wear. Five of the six cases were positive for *Pseudomonas aeruginosa*. All of the affected eyes lost best-corrected visual acuity, according to the published report.

Little change in central pachymetry with new lens

While there are a number of FDA-approved gas permeable lenses on the market, Calossi explained that the innovation of his own design is that it attempts to mould the periphery of the cornea with a minimum compression in the centre of the lens.

He noted that the lack of change found in the central pachymetry data suggests that the overnight contact lens can successfully flatten the cornea without direct compression of the centre of the cornea.

"Our biomechanical hypothesis is that the central flattening might be secondary to a mid-peripheral steepening, induced by a displacement of the epithelium that results from the compression in the alignment zone of this lens," he said.

Mr Calossi said that the results of this study suggest that the corneal epithelium can be safely moulded or redistributed very rapidly in response to the tear film forces generated behind this reverse-geometry lenses design.

Antonio Calossi
calossi@tin.it

