

Contact Lens Update

CLINICAL INSIGHTS BASED IN CURRENT RESEARCH

Orthokeratology and myopia control – the ROMIO study

April 18, 2016



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The ROMIO study was the first concurrently controlled, single-masked, randomised clinical trial of orthokeratology (OK) for myopia control.¹ A previous study by the same group had shown a 47% reduction in axial elongation in children wearing OK over two years, when compared to an historical spectacle wearing control group.² Interest in myopia control through the use of contact lens is increasing due to the documented rise in the incidence of childhood myopia across many countries.³ Application of successful myopia control strategies in the progressing paediatric myope can translate into lower rates of myopia-associated pathologies such as cataract, retinal detachment and myopic maculopathy in adulthood.^{4,5,6}

Cho P, Cheung SW. Retardation of myopia in Orthokeratology (ROMIO) study: a 2-year randomized clinical trial. Invest Ophthalmol Vis Sci 2012;53:7077-85.

Methods

A total of 102 children of Chinese ethnicity, aged 6 to 10 years of age with low to moderate myopia (0.50-4.00D) were enrolled and randomised into OK or single vision distance spectacle wear for two years. Axial length was measured at baseline and every six months for two years. The examiner performing the axial length measurements was masked to the participant's treatment. Unmasked examiners assessed ocular health, corneal topography and cycloplegic refractive outcomes over the study period, undertaking the routine OK management schedule for each participant with visits after one day, one week, one month and every three months of wear.

All OK-wearing participants were fit with spherical four zone lenses made from a high Dk gas permeable material (Menicon Z Night Lenses; DK 163 ISO; NKL Contactlinsen, The Netherlands) with the fitting performed according to manufacturer's instructions.

After data collection was completed, the increase in axial length over the study period was analysed to classify the group into slow (0.36mm per year, equivalent to 1.00D) rates of myopia progression.

Results

In total 78 children completed the study. Of the 51 children assigned to the spectacle wearing (control) group, 41 were analysed (nine were lost to follow up and one had an ocular health problem). Fourteen of the 51 OK-wearing children were excluded from analysis (nine due to OK fitting problems and five due to ocular health problems).

Children in the spectacle wearing control group (n=41) were 9.39 ± 1.00 years of age, with myopia OD 2.23 ± 0.84 D and habitual acuity of OD 0.07 ± 0.11 logMAR. At each six month interval the control group had significantly

higher mean axial elongation than the OK group ($p < 0.05$), and after two years had increased a total of 0.63 ± 0.26 mm. The control group showed faster progression of myopia in the first year than in the second.

The OK-wearing study group ($n=37$) were 9.23 ± 1.06 years of age, with myopia OD 2.05 ± 0.72 D and logMAR habitual acuity of OD 0.02 ± 0.10 logMAR, which was 2-3 letters better than the spectacle wearing group. At each six month interval the OK group had significantly lower axial elongation than the control group, and after two years had increased 0.36 ± 0.24 mm. (Control to OK group at two years; $p=0.001$) The OK group showed less myopia progression in their final six months ($p=0.002$) compared to the previous 18 months. This, combined with changes in the rate of the control group's progression, meant that the overall myopia control effect in each of the six month periods was 55%, 32%, 29% and 54% compared to the control group. The overall myopia control effect was 43% over two years.

Children who were less than nine years of age at baseline were the fastest progressors in both groups. There was no association between increase in axial length and initial level of myopia in either group. Fast myopia progression was found in 65% of these younger children in the control group, compared with 20% in the OK group. Older participants meeting the classification for fast progression numbered 13% in the control and 9% in the OK group. The proportion of fast progressors was significantly higher in younger compared to older control group participants ($p=0.002$), but fast progressor proportion by age was similar in the OK group ($p=0.61$).

Minimal adverse events

Ok-related adverse ocular health outcomes were minimal. Of the five dropouts due to ocular health issues in the OK group, three had sinus allergies resulting in persistent inferonasal corneal staining; one had significant conjunctival hyperaemia due to care procedure noncompliance and one developed a chalazion after 21 months of wear. There were no reported cases of microbial keratitis.

Conclusion

This paper demonstrates OK's long term myopia controlling effect of 43% in paediatric progressing myopes, which has been confirmed more recently by further studies.^{7,8} The finding here of faster myopia progression in younger age groups has also been reinforced by a meta-analysis of twenty studies with spectacle wearing control groups.⁹ From a clinical perspective, the sooner a myopia control strategy is implemented, the greater potential there is to make clinically significant differences to a myopic child's refractive and long term eye health outcomes.^{4,5} Meta-analyses of sixteen different interventions for myopia control – spectacle, contact lens and pharmaceutical – classify OK's myopia controlling treatment effect as moderate (0.25-0.50D/year), being similar to low dose atropine (0.01%), peripheral defocus-modifying soft contact lenses and prism bifocal spectacle lenses, and exceeded only by moderate (0.1%) and high (0.5 or 1%) atropine.¹⁰ The structure and outcomes of this study form the basis of an expanding area of research in myopia control. Increasing knowledge and industry product development in this field will ultimately translate into improved refractive and long term eye health outcomes for children with progressing myopia.

REFERENCES

1. Cho P, Cheung SW. Retardation of myopia in Orthokeratology (ROMIO) study: a 2-year randomized clinical trial. *Invest Ophthalmol Vis Sci* 2012;53: 7077-85.
2. Cho P, Cheung SW, Edwards M. The Longitudinal Orthokeratology Research in Children (LORIC) in Hong Kong: A pilot study on refractive changes and myopic control. *Current Eye Res* 2005;30: 71-80.
3. Holden BA, Fricke TR, Wilson DA, *et al*. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *Ophthalmol* 2016 (epub ahead of print).
4. Flitcroft DI. The complex interactions of retinal, optical and environmental factors in myopia aetiology. *Prog Retin Eye Res* 2012;31:

622-60.

5. Brennan NA. Predicted reduction in high myopia for various degrees of myopia control. *Cont Lens Anterior Eye* 2012;35 S1: e14-e15.
6. Jones D, Luensmann D. The prevalence and impact of high myopia. *Eye Contact Lens* 2012;38: 188-96.
7. Si JK, Tang K, Bi HS, *et al.* Orthokeratology for myopia control: a meta-analysis. *Optom Vis Sci* 2015;92: 252-7.
8. Sun Y, Xu F, Zhang T, *et al.* Orthokeratology to control myopia progression: a meta-analysis. *PLoS One* 2015;10: e0124535.
9. Donovan L, Sankaridurg P, Ho A, *et al.* Myopia progression rates in urban children wearing single-vision spectacles. *Optom Vis Sci* 2012;89: 27-32.
10. Huang J, Wen D, Wang Q, *et al.* Efficacy comparison of 16 interventions for myopia control in children: A network meta-analysis. *Ophthalmol* 2016;123: DOI 10.1016/j.ophtha.2015.11.010.