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## High myopia-partial reduction ortho-k: a 2-year randomized study.

[Charm J<sup>1</sup>, Cho P.](#)

[Author information](#)

### Abstract

#### PURPOSE:

To investigate if the combination of partial reduction (PR) orthokeratology (ortho-k) and spectacles for residual refractive errors in the daytime was effective to slow myopic progression in high myopic children.

#### METHODS:

High myopic children (aged 8 to 11 years) with spherical equivalent refraction at least -5.75 diopters (D) and myopia -5.00 D or more myopic were recruited and randomly assigned into PR ortho-k and control groups. Subjects in the PR ortho-k group were fitted with custom made four-zone ortho-k lenses with target reduction of 4.00 D for both eyes, and the residual refractive errors were corrected with single-vision spectacles for clear vision in the daytime. Control subjects were fully corrected with single-vision spectacles. Axial length of each eye of all subjects was measured with the IOLMaster at 6-month intervals by a masked examiner. This study was registered at [www.clinicaltrial.gov](#) with the identifier NCT00977236.

#### RESULTS:

Fifty-two subjects were recruited and randomized to the PR ortho-k and control groups. Twelve PR ortho-k and 16 control subjects completed the study. Compared with the residual refractive errors at the 1-month visit (after stabilization of ortho-k treatment), the median increase in noncycloplegic residual myopia at the 24-month visit was 0.13 D. In the control group, the median increase in myopia was 1.00 D at the end of the study. The mean  $\pm$  SD increases in axial length were  $0.19 \pm 0.21$  mm in the PR ortho-k group and  $0.51 \pm 0.32$  mm in the control group (95% confidence interval, -0.55 to -0.12; unpaired t test, p = 0.005).

#### CONCLUSIONS:

This single-masked randomized study showed that PR ortho-k effectively slowed myopic progression in high myopes. Axial length elongation was 63% slower in PR ortho-k-treated children compared with children wearing spectacles.

[Invest Ophthalmol Vis Sci.](#) 2012 Oct 11;53(11):7077-85. doi: 10.1167/iovs.12-10565.

## Retardation of myopia in Orthokeratology (ROMIO) study: a 2-year randomized clinical trial.

[Cho P<sup>1</sup>, Cheung SW.](#)

[Author information](#)

### Abstract

#### PURPOSE:

This single-masked randomized clinical trial aimed to evaluate the effectiveness of orthokeratology (ortho-k) for myopic control.

#### METHODS:

A total of 102 eligible subjects, ranging in age from 6 to 10 years, with myopia between 0.50 and 4.00 diopters (D) and astigmatism not more than 1.25D, were randomly assigned to wear ortho-k lenses or single-vision glasses for a period of 2 years. Axial length was measured by intraocular lens calculation by

a masked examiner and was performed at the baseline and every 6 months. This study was registered at ClinicalTrials.gov, number NCT00962208.

#### **RESULTS:**

In all, 78 subjects (37 in ortho-k group and 41 in control group) completed the study. The average axial elongation, at the end of 2 years, were  $0.36 \pm 0.24$  and  $0.63 \pm 0.26$  mm in the ortho-k and control groups, respectively, and were significantly slower in the ortho-k group ( $P < 0.01$ ). Axial elongation was not correlated with the initial myopia ( $P > 0.54$ ) but was correlated with the initial age of the subjects ( $P < 0.001$ ). The percentages of subjects with fast myopic progression (>1.00D per year) were 65% and 13% in younger (age range: 7-8 years) and older (age range: 9-10 years) children, respectively, in the control group and were 20% and 9%, respectively, in the ortho-k group. Five subjects discontinued ortho-k treatment due to adverse events.

#### **CONCLUSIONS:**

On average, subjects wearing ortho-k lenses had a slower increase in axial elongation by 43% compared with that of subjects wearing single-vision glasses. Younger children tended to have faster axial elongation and may benefit from early ortho-k treatment. (ClinicalTrials.gov number, NCT00962208.).

[Eye Contact Lens](#). 2013 Mar;39(2):153-7. doi: 10.1097/ICL.0b013e31827a0241.

## **Myopia control with orthokeratology contact lenses in Spain: a comparison of vision-related quality-of-life measures between orthokeratology contact lenses and single-vision spectacles.**

[Santodomingo-Rubido J<sup>1</sup>](#), [Villa-Collar C](#), [Gilmartin B](#), [Gutiérrez-Ortega R](#).

#### [Author information](#)

#### **Abstract**

#### **PURPOSE:**

To compare vision-related quality-of-life measures between children wearing orthokeratology (OK) contact lenses and distance single-vision (SV) spectacles.

#### **METHODS:**

Subjects 6 to 12 years of age and with myopia of -0.75 to -4.00 diopters and astigmatism less than or equal to 1.00 diopters were prospectively assigned OK contact lens or SV spectacle correction. A pediatric refractive error profile questionnaire was administered at 12- and 24-month intervals to evaluate children's perceptions in terms of overall vision, near vision, far distance vision, symptoms, appearance, satisfaction, activities, academic performance, handling, and peer perceptions. The mean score of all items was calculated as the overall score. Additionally, parents/guardians were asked to rate their child's mode of visual correction and their intention to continue treatment after study completion.

#### **RESULTS:**

Thirty-one children were fitted with OK contact lenses and 30 with SV spectacles. Children wearing OK contact lenses rated overall vision, far distance vision, symptoms, appearance, satisfaction, activities, academic performance, handling, peer perceptions, and the overall score significantly better than children wearing SV spectacles (all  $P < 0.05$ ). Near vision and handling were, respectively, rated better ( $P < 0.001$ ) and similar ( $P = 0.44$ ) for SV spectacles in comparison to OK contact lenses. No significant differences were found between 12 and 24 months for any of the subjective ratings assessed (all  $P > 0.05$ ).

Parents/guardians of children wearing OK contact lenses rated visual correction method and intention to continue treatment higher than parents of children wearing SV spectacles ( $P \leq 0.01$ ).

#### **CONCLUSION:**

The results indicate that the significant improvement in vision-related quality of life and acceptability with OK contact lenses is an incentive to engage in its use for the control of myopia in children.

*Cochrane Database Syst Rev.* 2011 Dec 7;(12):CD004916. doi: 10.1002/14651858.CD004916.pub3.

## **Interventions to slow progression of myopia in children.**

Walline JJ<sup>1</sup>, Lindsley K, Vedula SS, Cotter SA, Mutti DO, Twelker JD.

Author information

### **Abstract**

#### **BACKGROUND:**

Nearsightedness (myopia) causes blurry vision when looking at distant objects. Highly nearsighted people are at greater risk of several vision-threatening problems such as retinal detachments, choroidal atrophy, cataracts and glaucoma. Interventions that have been explored to slow the progression of myopia include bifocal spectacles, cycloplegic drops, intraocular pressure-lowering drugs, muscarinic receptor antagonists and contact lenses. The purpose of this review was to systematically assess the effectiveness of strategies to control progression of myopia in children.

#### **OBJECTIVES:**

To assess the effects of several types of interventions, including eye drops, undercorrection of nearsightedness, multifocal spectacles and contact lenses, on the progression of nearsightedness in myopic children younger than 18 years. We compared the interventions of interest with each other, to single vision lenses (SVLs) (spectacles), placebo or no treatment.

#### **SEARCH METHODS:**

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2011, Issue 10), MEDLINE (January 1950 to October 2011), EMBASE (January 1980 to October 2011), Latin American and Caribbean Literature on Health Sciences (LILACS) (January 1982 to October 2011), the metaRegister of Controlled Trials (mRCT) ([www.controlled-trials.com](http://www.controlled-trials.com)) and ClinicalTrials.gov (<http://clinicaltrials.gov>). There were no date or language restrictions in the electronic searches for trials. The electronic databases were last searched on 11 October 2011. We also searched the reference lists and Science Citation Index for additional, potentially relevant studies.

#### **SELECTION CRITERIA:**

We included randomized controlled trials (RCTs) in which participants were treated with spectacles, contact lenses or pharmaceutical agents for the purpose of controlling progression of myopia. We excluded trials where participants were older than 18 years at baseline or participants had less than -0.25 diopters (D) spherical equivalent myopia.

#### **DATA COLLECTION AND ANALYSIS:**

Two review authors independently extracted data and assessed the risk of bias for each included study. When possible, we analyzed data with the inverse variance method using a fixed-effect or random-effects model, depending on the number of studies and amount of heterogeneity detected.

#### **MAIN RESULTS:**

We included 23 studies (4696 total participants) in this review, with 17 of these studies included in quantitative analysis. Since we only included RCTs in the review, the studies were generally at low risk of bias for selection bias. Undercorrection of myopia was found to increase myopia progression slightly in two studies; children who were undercorrected progressed on average 0.15 D (95% confidence interval (CI) -0.29 to 0.00) more than the fully corrected SVLs wearers at one year. Rigid gas permeable contact lenses (RGPCls) were found to have no evidence of effect on myopic eye growth in two studies (no meta-analysis due to heterogeneity between studies). Progressive addition lenses (PALs), reported in four studies, and bifocal spectacles, reported in four studies, were found to yield a small slowing of myopia progression. For seven studies with quantitative data at one year, children wearing multifocal lenses, either PALs or bifocals, progressed on average 0.16 D (95% CI 0.07 to 0.25) less than children wearing SVLs. The largest positive effects for slowing myopia progression were exhibited by anti-muscarinic medications. At one year, children receiving pirenzepine gel (two studies), cyclopentolate eye

drops (one study), or atropine eye drops (two studies) showed significantly less myopic progression compared with children receiving placebo (mean differences (MD) 0.31 (95% CI 0.17 to 0.44), 0.34 (95% CI 0.08 to 0.60), and 0.80 (95% CI 0.70 to 0.90), respectively).

**AUTHORS' CONCLUSIONS:**

The most likely effective treatment to slow myopia progression thus far is anti-muscarinic topical medication. However, side effects of these medications include light sensitivity and near blur. Also, they are not yet commercially available, so their use is limited and not practical. Further information is required for other methods of myopia control, such as the use of corneal reshaping contact lenses or bifocal soft contact lenses (BSCLs) with a distance center are promising, but currently no published randomized clinical trials exist.

Am J Ophthalmol. 2013 Dec;156(6):1076-1081.e1. doi: 10.1016/j.ajo.2013.04.039.

## **Myopia control in children through refractive therapy gas permeable contact lenses: is it for real?**

Koffler BH<sup>1</sup>, Sears JJ.

Author information

**Abstract**

**PURPOSE:**

To compare the safety and efficacy of orthokeratology as a nonsurgical treatment for myopia in children with alternate methods, such as soft contact lenses, rigid gas permeable lenses, and spectacles, throughout multiple studies.

**DESIGN:**

Perspective with literature review.

**METHODS:**

Analysis of recent studies to determine the safety and effectiveness of orthokeratology versus soft contact lenses, rigid gas permeable lenses, and spectacles in children.

**RESULTS:**

In all of the studies reviewed, the use of orthokeratology lenses proved to reduce myopia, to improve visual acuity, and, with the exception of the SMART study, to reduce the rate of axial elongation.

Orthokeratology has been shown to be as effective as other methods in treating myopia and to be more effective at treating axial elongation. There were no major adverse events in any of the studies comparing orthokeratology with other methods of myopia treatment.

**CONCLUSIONS:**

Studies show that the use of orthokeratology is a safe and efficacious nonsurgical treatment for myopia and that it is capable of slowing axial elongation, making it an effective myopic treatment for children.

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## **The longitudinal orthokeratology research in children (LORIC) in Hong Kong: a pilot study on refractive changes and myopic control.**

Cho P<sup>1</sup>, Cheung SW, Edwards M.

Author information

### **Abstract**

#### **PURPOSE:**

Myopia is a common ocular disorder, and progression of myopia in children is of increasing concern. Modern overnight orthokeratology (ortho-k) is effective for myopic reduction and has been claimed to be effective in slowing the progression of myopia (myopic control) in children, although scientific evidence for this has been lacking. This 2 year pilot study was conducted to determine whether ortho-k can effectively reduce and control myopia in children.

#### **METHODS:**

We monitored the growth of axial length (AL) and vitreous chamber depth (VCD) in 35 children (7-12 years of age), undergoing ortho-k treatment and compared the rates of change with 35 children wearing single-vision spectacles from an earlier study (control). For the ortho-k subjects, we also determined the changes in corneal curvature and the relationships with changes of refractive errors, AL and VCD.

#### **RESULTS:**

The baseline spherical equivalent refractive errors (SER), the AL, and VCD of the ortho-k and control subjects were not statistically different. All the ortho-k subjects found post-ortho-k unaided vision acceptable in the daytime. The residual SER at the end of the study was  $-0.18 \pm 0.69$  D (dioptrē) and the reduction (less myopic) in SER was  $2.09 \pm 1.34$  D (all values are mean  $\pm$  SD). At the end of 24 months, the increases in AL were  $0.29 \pm 0.27$  mm and  $0.54 \pm 0.27$  mm for the ortho-k and control groups, respectively (unpaired t test;  $p = 0.012$ ); the increases in VCD were  $0.23 \pm 0.25$  mm and  $0.48 \pm 0.26$  mm for the ortho-k and control groups, respectively ( $p = 0.005$ ). There was significant initial corneal flattening in the ortho-k group but no significant relationships were found between changes in corneal power and changes in AL and VCD.

#### **CONCLUSION:**

Ortho-k can have both a corrective and preventive/control effect in childhood myopia. However, there are substantial variations in changes in eye length among children and there is no way to predict the effect for individual subjects.

Optom Vis Sci. 2004 Jun;81(6):407-13.

## **The Children's Overnight Orthokeratology Investigation (COOKI) pilot study.**

Walline JJ<sup>1</sup>, Rah MJ, Jones LA.

Author information

### **Abstract**

#### **PURPOSE:**

Innovations in contact lens materials and designs allow patients to wear contact lenses during sleep to flatten the cornea and temporarily to reduce myopic refractive error and improve unaided visual acuity. We conducted the Children's Overnight Orthokeratology Investigation (COOKI)pilot study, a case series,

to describe the refractive error and visual changes, as well as the slitlamp observations associated with overnight orthokeratology in children, over a period of 6 months.

**METHODS:**

Twenty-nine 8- to 11-year-old children with myopia between -0.75 and -5.00 D and <-1.50 D corneal toricity were fitted with corneal refractive therapy contact lenses (Paragon Vision Sciences, Mesa, AZ). They were examined within 1 hour of awakening and about 6 hours later at 1 day, 1 week, 2 weeks, 1 month, 3 months, and 6 months after the first night of contact lens wear. At each visit, the logarithm of the minimum angle of resolution (logMAR) visual acuity, manifest refraction, slitlamp examination, and corneal topography were performed.

**RESULTS:**

Twenty-three subjects completed the 6-month study. Three subjects decided not to wear contact lenses, two did not achieve acceptable fits, and one moved from the area. At the 6-month afternoon visit, the mean +/- SD uncorrected high-contrast visual acuity was +0.08 +/- 0.15 logMAR (Snellen equivalent, 20/24), and the mean +/- SD spherical equivalent refraction was -0.16 +/- 0.66 D. The corneas of three-fifths of the subjects showed mild staining at the morning visit, and one-third of the patients showed mild corneal staining at the afternoon visit. The most common type of stain was central punctate staining. No subjects experienced lasting adverse visual effects from cornea-reshaping contact lens wear during the study period.

**CONCLUSIONS:**

Overnight cornea-reshaping contact lenses are efficacious for young myopic patients, and no children experienced a serious adverse event during the study.

## Seven-year retrospective analysis of the myopic control effect of orthokeratology in children: a pilot study

Alan Kwok-Hei Mok<sup>1,2</sup>  
Cindy Sin-Ting Chung<sup>1</sup>

<sup>1</sup>Eye'ni, Hong Kong, People's Republic of China; <sup>2</sup>Department of Anatomy, LiKaShing Faculty of Medicine, The University of Hong Kong, Hong Kong, People's Republic of China

**Objectives:** To investigate retrospectively the difference in myopia progression, over about 7 years, between two groups of Hong Kong Chinese myopic children who wore overnight orthokeratology lenses or single-vision spectacles.

**Methods:** A total of 238 records of children wearing overnight orthokeratology lenses or single-vision spectacles from Eye'ni optical shop (Hong Kong) between January 1999 and December 2009 were reviewed. Refractive and central corneal curvature data with 6-year or a longer follow-up period of 70 patients were retrieved: 34 children (15 boys and 19 girls, aged  $9.2 \pm 1.8$  years) wore orthokeratology lenses and 36 (20 boys and 16 girls, aged  $10.2 \pm 2.0$  years) wore spectacles. Myopic progression was determined as the change of myopia from the baseline to the final visit.

**Results:** No statistically significant differences ( $P > 0.05$ ) in age, central flat corneal curvatures, baseline refractive error, or follow-up period were observed between the two groups. Average myopic progression of the overnight orthokeratology contact lens cohort ( $-0.37 \pm 0.49$  D) was significantly less ( $P < 0.001$ ) than of the single-vision spectacle group ( $-2.06 \pm 0.81$  D) over about 7 years.

**Conclusion:** Our preliminary 7-year data support the claim that overnight orthokeratology contact lenses may be a feasible clinical method for myopic progression control. Prospective and randomized investigations are warranted to overcome the limitations of this retrospective study.

**Keywords:** myopia, contact lens, orthokeratology, myopia progression

### Introduction

Orthokeratology contact lenses began to be fitted in the late 1960s. At this time, the technique suffered because only a small amount of myopia was corrected, the time for the correction to occur was long, and the technique was unpredictable. Changes in technology and design have made orthokeratology a predictable means of correcting low to moderate myopia safely, such that the technique is now used as an overnight modality in children. New materials with higher oxygen permeability and reverse geometry contact lens design allow myopic children to wear the contact lenses during sleep to temporarily flatten the central cornea (overnight orthokeratology). An orthokeratology lens flattens the central cornea while it steepens the mid-peripheral cornea. This rearrangement of the shape of the cornea induces peripheral myopic defocus. Several investigations<sup>1–3</sup> propose that peripheral myopic defocus may play a vital role in myopic progression; thus overnight orthokeratology is hypothesized to control myopic progression.<sup>4–8</sup> Two longitudinal clinical trials<sup>4,5</sup> have proposed that overnight orthokeratology may slow

Correspondence: Alan Kwok-Hei Mok  
Eye'ni G/F 63 Lee Garden Road,  
Causeway Bay, Hong Kong, People's  
Republic of China  
Fax +852 2882 2959  
Email mokkwokhei@gmail.com