Retardation of Myopia in Orthokeratology (ROMIO) Study: a 2-year randomized clinical trial

1. Pauline Cho and
2. Sin-Wan Cheung, *

Author Affiliations

1. School of Optometry, The Hong Kong Polytechnic University, Hong Kong
2. The Hong Kong Polytechnic University, School of Optometry, Kowloon, Hong Kong

1.* The Hong Kong Polytechnic University, School of Optometry, Kowloon, Hong Kong, sopeggy@polyu.edu.hk

Abstract

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

Methods: A hundred and two eligible subjects, age 6 to 10 years, with myopia between 0.50 to 4.00D and astigmatism not more than 1.25D were randomly assigned to wear ortho-k lenses or single-vision glasses for a period of two years. Axial length was measured with the IOLMasterTM (Zeiss) by a masked examiner and was performed at the baseline and every six months. This study was registered at ClinicalTrials.gov, number NCT00962208.

Results: Seventy-eight subjects (37 in ortho-k group and 41 in control group) completed the study. The average axial elongation, at the end of two years, were 0.36±0.24mm and 0.63±0.26mm 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 7 to 8 years) and older (age 9 to 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 slower increase in axial elongation by 43% compared to subjects wearing single-vision glasses. Younger children tended to have faster axial elongation and may benefit from early ortho-k treatment.

Copyright © 2012 by Association for Research in Vision and Ophthalmology