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The safety of orthokeratology contact lens wear in slowing the axial elongation of the eye in children

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Purpose: To evaluate the safety of orthokeratology contact lens wear in slowing the axial elongation of the eye in myopic children.

Method: Safety data from three prospective studies, which evaluated the use of orthokeratology for slowing myopia progression in children in comparison to a parallel control group of single-vision spectacle lens wearers over a 2-year period, were pooled together for analysis. The primary and secondary safety endpoints are the comparisons of adverse events and slit-lamp findings grades ≥ 2 between orthokeratology and control groups, respectively.

Results: Collectively, data from 125 orthokeratology and 118 control subjects were analyzed in this study. Of these, 101 (81%) and 88 (75%) orthokeratology and control subjects completed the 2-year follow-up period, respectively. Nineteen orthokeratology subjects experienced 28 adverse events, of which 6 were significant, whereas just one adverse event was found in the control group; this difference was statistically significant ($p < 0.001$). Most adverse events found in the orthokeratology group were corneal in nature, primarily corneal abrasion/staining, accounting for around 40% of all and device-related adverse events. Of the 28 adverse events, only 18

(3 significant) are likely to be contact lens-related, leading to incidence rates of total and device-related adverse events per 100 patient years of lens wear (95% confidence intervals) of 13.1 (9.2–18.2) and 8.4 (5.4–10.7), respectively. No significant differences were found between groups in the total number of slit-lamp findings with grades ≥ 2 ($p > 0.05$).

Conclusions: Around 13% of eyes wearing overnight orthokeratology contact lenses are likely to experience an adverse event over one year of lens wear, with this figure being lower when considering device-related adverse events alone. No serious adverse events were found, with most being non-significant. These results inform eye care practitioners on the safety of orthokeratology lenses when prescribed for slowing myopia progression to myopic children.

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