# Ten year results of overnight orthokeratology for myopia control

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# Background

Several studies have reported a possibility that orthokeratology (OK) can retard the progression of myopia in children. The 2-year studies showed that the inhibitory effect of OK on axial elongation was from 36 to 63%,<sup>1-4</sup> and a 5-year study showed that it was around 30%,<sup>5</sup> and a 7year study showed that it was 33%,<sup>6</sup> compared with control groups with single-vision spectacles or soft contact lenses (SCLs.) However, little is known about long-term effects of OK for more than 7 years.

## Purpose

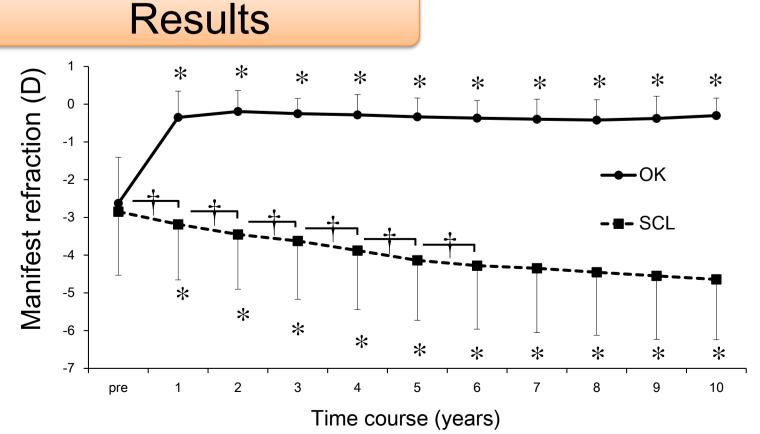
To investigate 10-year effects of OK on myopia progression in schoolchildren, and to compare the results with those of SCL wearers.

# Methods

- We retrospectively investigated the medical records of patients ( $\leq$  16 years) who were continuing overnight OK for more than 10 years.
- All patients used the α ORTHO-K<sup>®</sup> (ALPHA Corp., Aichi, Japan) five-zone reverse geometry lens.
- Examinations included were followings; Refraction, Uncorrected visual acuity (UCVA), Best-corrected visual acuity (BCVA), Prescription lens power, and Complication. We also calculated an estimated myopia progression in each eye as the sum of "change in lens power" and "residual refractive error.

Subjects	OK (104 eyes of 53 patients) Mean ± SD (range)	SCL (78 eyes of 39 patients) Mean ± SD (range)	P-value
Age (year)	11.5 ± 2.1(8 to 16)	13.4 ± 2.3(8 to 16)	< 0.0001*
Sex (male : female)	24 : 29	15 : 24	0.3631
Spherical Equivalent Refraction (D)	-2.63 ± 1.22 (-6.00 to -0.75)	-2.85 ± 1.68 (-6.875 to -0.50)	0.3076
Cylinder (D)	-0.20 ± 0.32 (-1.25 to 0.00)	-0.13 ± 0.28 (-1.25 to 0.00)	0.1513
UCVA (logMAR)	0.80 ± 0.28 (0.15 to 1.30)	0.89 ± 0.39 (0.22 to 1.70)	0.0683
BCVA (logMAR)	-0.12 ± 0.05 (-0.18 to 0.00)	-0.11 ± 0.06 (-0.18 to 0.00)	0.2144

SCLs used in this study were followings;1-Day Acuvue<sup>®</sup>, 1-Day Acuvue<sup>®</sup> TruEye<sup>®</sup>, Acuvue<sup>®</sup> Advance<sup>®</sup>, or Acuvue<sup>®</sup> Oasys<sup>®</sup> (Johnson & Johnson), Medalist<sup>®</sup>, Medalist<sup>®</sup> Plus, Medalist<sup>®</sup> Premier, Medalist<sup>®</sup> Premier Toric, or Medalist<sup>®</sup> FreshFit<sup>®</sup> (Bausch + Lomb), Menicon 1Day, 2 Week Menicon Premio, or 2 Week Menicon Premio Toric (Menicon), 2 Week Aquair<sup>®</sup> (CooperVision)



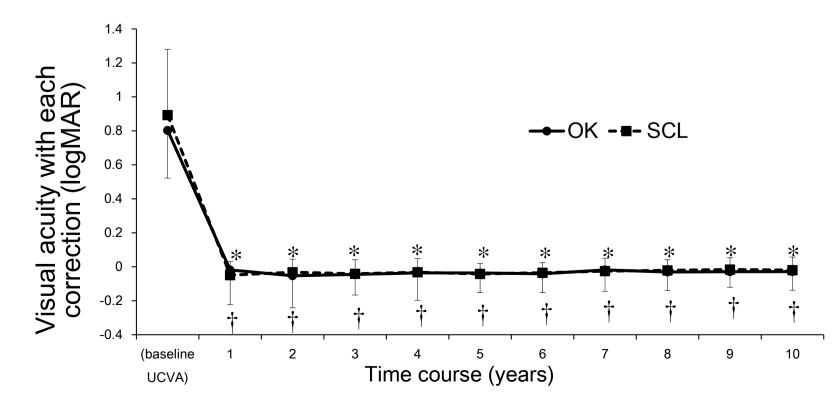


Figure 2. Time course of change in visual acuity with each correction method. The UCVA significantly improved (P < 0.001, general linear model) after the start of OK treatment and remained constant at the same level over the 10-year period. Similarly, visual acuity significantly improved after the patients started wearing SCL (P < 0.001), and remained constant at the same level thereafter. There was no significant difference in the time course of change in visual acuity between the two correction methods (P = 0.274).

Figure 1. Time course of change in manifest refraction in both groups.

Myopic refractive errors significantly improved after the start of OK treatment, and remained constant at the same level over the 10-year period, with a significant difference compared to the baseline value (P < 0.001, general linear model). In contrast, in the SCL group, myopic refractive errors gradually worsened over time, with significant differences over successive periods of 6 years (P < 0.05). There was a significant difference in the time course of change in manifest refraction between the OK and SCL groups (P < 0.001).

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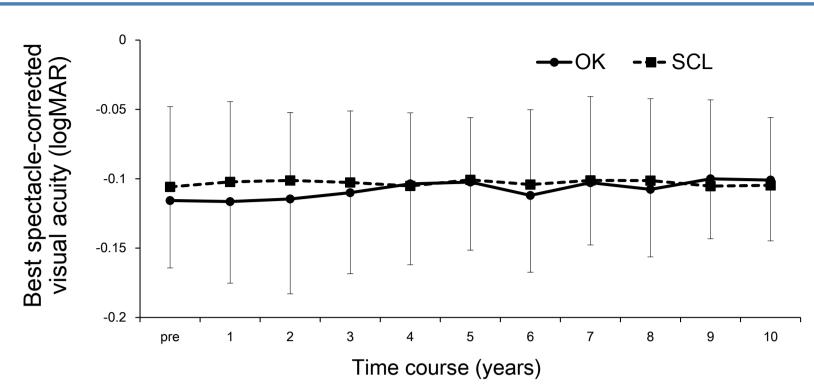


Figure 3. Time course of change in best spectacle-corrected visual acuity in both groups There was no significant change in best spectacle-corrected visual acuity over the 10-year period in either group (OK group, P = 0.110; SCL group, P = 0.998; general linear model), nor was there any significant intergroup difference in this aspect (P = 0.242).

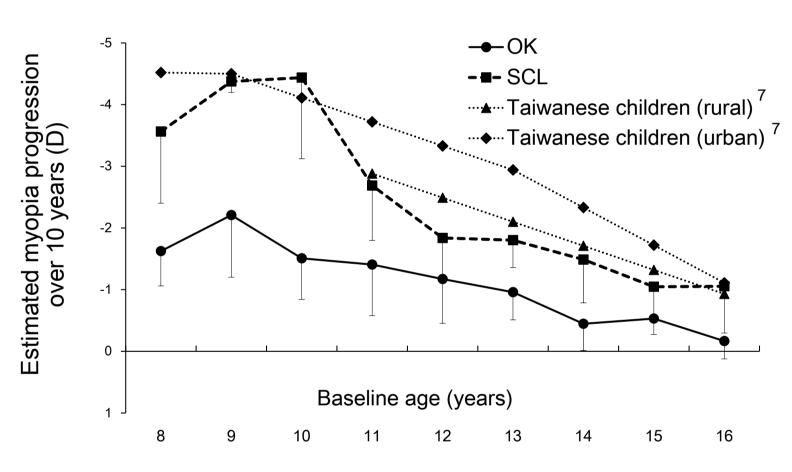


Figure 5. Comparison of estimated myopia progression over 10 years between the present and previous studies. Estimated 10-year myopia progression among the present subjects in the OK group was lower than that among Taiwanese children with myopia both in urban and rural areas.<sup>7</sup> Additionally, the estimated myopia progression among the present subjects in the SCL group was closer to the values observed among rural Taiwanese children than to those observed among urban Taiwanese children.

### Summary

### Conclusion

OK treatment was effective in slowing myopia progression over a 10-year treatment period and demonstrated a clinically acceptable safety profile among patients between the ages of 8 and 16 years. Long-term OK treatment is promising for controlling myopia progression in schoolchildren.

### References

- 1. Kakita T, et al. Invest Ophthalmol Vis Sci. 2011 2. Cho P, et al. Invest Ophthalmol Vis Sci. 2012

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[ Financial disclosure ]



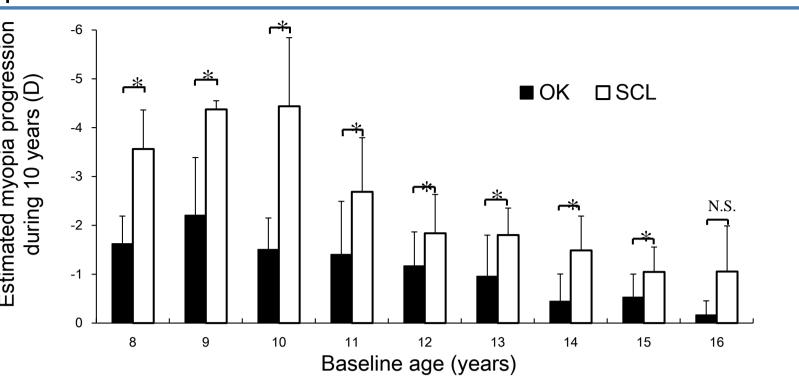


Figure 4. Comparison of estimated myopia progression over 10 years between the OK and SCL groups at each baseline age Estimated myopia progression in the OK group was apparently smaller than that in the SCL group, and there were significant mated myopia progression between the groups at all initial ages (P < 0.001 to P = 0.043, unpaired *t*-test) except at 16 years (P = 0.128).

	OK	SCL	Total
Acute conjunctivitis	25	23	48
Allergic conjunctivitis	48	29	77
Phlyctenular conjunctivitis	2	0	2
Superficial punctate keratopathy	32	33	65
Corneal erosion	1	1	2
Corneal infiltration and Keratitis	8	0	8
Blepharitis	0	3	3
Hordeolum	0	8	8
Chalazion	0	5	5
Others	3	1	4
Total	119	103	222

The details of adverse events during 10 years in both groups. In the OK group, a total of 119 adverse events were observed in 53 eyes. In the SCL group, a total of 103 adverse events were recorded in 43 eyes. There was no significant difference in the incidence of adverse events between the groups. Conjunctival complications such as acute and allergic conjunctivitis were the most frequent adverse events; superficial punctate keratopathy was also often observed in both groups. Corneal infiltration and keratitis were only observed in the OK group; however, there were no incidences of serious complications such as infectious keratitis. Evelid complications such as blepharitis, hordeolum, and chalazion were observed in the SCL group.

> Refractive error and VA significantly improved after OK, and maintained the improved level over the study period.

> Time course of changes in visual acuity in OK patients was almost equivalent to that in SCL wearers.

> Estimated myopia progression during 10 years was significantly smaller in OK patients than in SCL wearers.

> It was also smaller than previously reported myopia progression in Asian children with single-vision spectacles or standard SCLs.

Takao Ito and Hiroshi Murakami are employees of ALPHA Corporation.