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CLINICAL INVESTIGATION

Decrease in intraocular pressure following orthokeratology measured with a noncontact tonometer

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Abstract
Purpose Orthokeratology for correction of myopia reduces corneal power by flattening corneal curvature and thinning central corneal thickness (CCT). Measurement of intraocular pressure (IOP) with a noncontact tonometer is known to be affected by CCT and corneal curvature. We investigated the influence of orthokeratology on such measurements of IOP.
Methods This was a prospective, interventional case series derived from a clinical trial of orthokeratology lenses in two hospitals. Both eyes of 45 subjects were fitted with reverse-geometry lenses, worn for more than 4 h overnight for 52 weeks. Uncorrected visual acuity, refraction, IOP (with a noncontact tonometer), CCT, and corneal curvature were measured.
Results Uncorrected visual acuity, spherical equivalent value, IOP, CCT, and the radius of corneal curvature were 0.93 ± 0.27, -2.87 ± 1.05 D, 13.5 ± 2.5 mmHg, 536.2 ± 39.6 μm, and 7.88 ± 0.25 mm, respectively, before orthokeratology, and 0.17 ± 0.34, -1.05 ± 1.18 D, 12.4 ± 2.7 mmHg, 528.6 ± 40.8 μm, and 8.10 ± 0.31 mm at 52 weeks after treatment. The changes in all parameters were significant, and the change in IOP was significantly correlated with that in CCT at 24 weeks and thereafter.
Conclusions Orthokeratology for myopia leads to a decrease in IOP measured with a noncontact tonometer, likely as a result of the associated decrease in CCT.

Keywords Intraocular pressure · Noncontact tonometer · Central corneal thickness · Corneal curvature · Orthokeratology

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Introduction

Intraocular pressure (IOP) is a fundamental ophthalmic index for evaluation of ocular health and diagnosis of ocular disorders in clinical practice. However, it is usually not possible to measure true IOP with a needling pressure indicator inserted into the eyeball. Instead, IOP is usually measured with either a Goldmann applanation tonometer or a noncontact tonometer (NCT). Such IOP measurements are affected by the physiological properties of the cornea, including central corneal thickness (CCT), corneal curvature, and corneal rigidity. A thinner CCT [1], flatter corneal curvature [2], and lower corneal rigidity [3, 4] are thus thought to result in an underestimation of the IOP. Such underestimation in individuals with myopia, whose risk of developing glaucoma is two- to sixfold higher [5], may result in failure to detect early glaucoma.

Orthokeratology, also known as corneal reshaping or corneal refractive therapy, is a method for temporarily changing refraction in myopic patients by the programmed application of specially designed rigid contact lenses [6].

Orthokeratology renders the cornea an asymmetric non-physiological oblate shape [7], depending on the extent of myopic correction [6, 8–13]. It also results in a decrease in corneal thickness and increase in the flattening of corneal curvature [10, 13–17] and might therefore be expected to lead to a decrease in NCT measurements of IOP.

Given the increasing popularity of overnight orthokeratology, it is important to investigate how this procedure affects IOP measurements. To clarify the influence of orthokeratology on IOP measurements, we performed a prospective study to investigate the dynamics of corneal shape and to compare IOP measurements before and after overnight orthokeratology for myopia.

Materials and methods

The study was a prospective, interventional case series derived from a clinical trial of BE lenses (see below) in two hospitals. Ninety eyes of 45 individuals (16 men, 29 women; mean age ± SD 27.2 ± 5.0 years, age range 20–37 years) attending the Department of Ophthalmology, Yamaguchi University Graduate School of Medicine, or the Department of Ophthalmology, Juntendo University School of Medicine, for correction of myopia by overnight orthokeratology were enrolled in the study. The subjects underwent an initial ocular examination to determine whether they matched the criteria listed in Table 1. The Human Research and Ethics Committees of both Yamaguchi University Hospital and Juntendo University Hospital approved the study protocol, and the study was performed in accordance with the Declaration of Helsinki. At the initial visit, the details of the study were explained, and, if the subject agreed to participate, an informed consent form was signed.

Table 1 Criteria for inclusion or exclusion of study subjects

Inclusion criteria
Of legal age (20 years) and able to volunteer
Understands rights as a research subject
Willing to sign a statement of informed consent
Willing and able to follow the study protocol
Best corrected visual acuity of ≤0 in log MAR units
Refractive spherical correction of between −1.00 and −4.00 D
Refractive with-the-rule cylindrical correction of between 0.00 and 1.00 D
Has realistic expectations of the outcome of treatment
Exclusion criteria
More than 38 years of age (to avoid presbyopia)
Ocular or systemic disorders that would normally contraindicate contact lens wearing
Refractive against-the-rule cylindrical correction of >0.50 D
Anterior eye clinical signs
Use of topical ocular medication
Previous corneal refractive surgery or keratoconus
Pregnant, lactating, or planning pregnancy during the study period

MAR minimal angle of resolution

Both eyes of each subject were fitted with orthokeratology lenses of reverse-geometry design (BE lenses, designed and developed by Mountford and Noack and supplied by Eiko, Nagoya, Aichi, Japan). The lenses were manufactured from Boston XO material (Polymer Technology, Wilmington, MA, USA) with a nominal Dk of 100×10^{-11} (cm^2/s) [mL O_2/(mL hPa)] and central thickness of 0.22 mm. The BE lenses were fitted with the appropriate lens-fitting software (BE Optimal Orthokeratology, version 4.0) supplied by the manufacturer. The lenses were selected initially on the basis both of the baseline apical radius of the corneal curvature, corneal eccentricity, and horizontal visible iris diameter, all of which were determined with a corneal topographer (model E300; Medmont, Vermont, VIC, Australia), as well as of the desired refractive change. Subjects returned to the clinic the morning after the overnight trial (within 1 h of waking) with the lenses in situ, and the topographic and refractive outcomes were entered into the software to select the appropriate lenses for dispensing. If the first overnight trial was unsuccessful, another BE lens was tried at least 1 week later. Subjects were instructed to wear the dispensed lenses for more than 4 h each night for 52 weeks and were examined at 12, 24, 36, and 52 weeks.

All subjects underwent a comprehensive ocular examination, including measurement of uncorrected and corrected visual acuity, autorefraction, CCT (with an SP-3000 pachymeter; Tomey, Nagoya, Aichi, Japan), and IOP (with an NT-4000 NCT; Nidek, Nagoya, Aichi, Japan) as well as autokeratometry and slitlamp examination. Visual acuity was measured with the use of a Landolt chart and converted to the logarithm of the minimal angle of resolution (log MAR). Data are presented as mean ± SD, and the data obtained after orthokeratology were compared with the baseline measurements (pretreatment) with the use of Dunnett's test. The relations between the changes in IOP from the baseline value and the changes in either CCT, spherical equivalent value, or radius of corneal curvature were evaluated with the use of Pearson's correlation coefficient. A P value of less than 0.05 was considered statistically significant.

Results

The mean best corrected visual acuity of eyes treated by overnight orthokeratology with a reverse-geometry lens was less than or equal to 0 in log MAR units during the

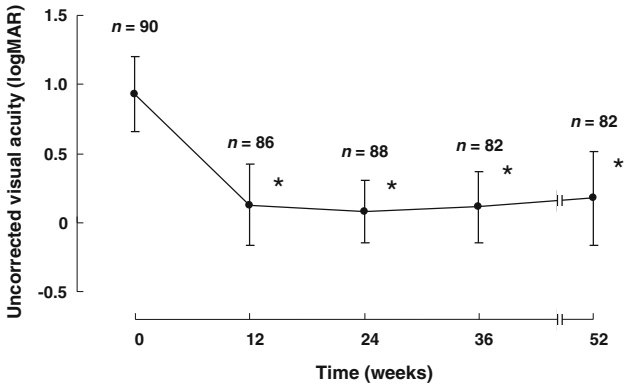

Fig. 1 Changes in mean uncorrected visual acuity during treatment of myopia by overnight orthokeratology with a reverse-geometry lens for 52 weeks relative to the baseline value. Data are mean ± SD. *$P < 0.01$ (Dunnett's test) versus baseline value (time 0)

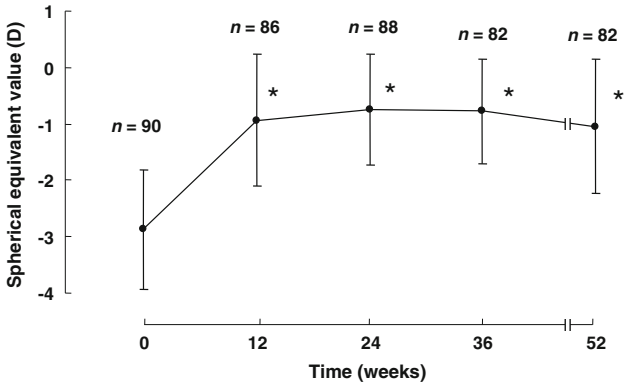

Fig. 2 Change in spherical equivalent value during treatment of myopia by overnight orthokeratology with a reverse-geometry lens for 52 weeks. Data are mean ± SD. *$P < 0.01$ (Dunnett's test) versus baseline value (time 0)

study period. As shown in Fig. 1, uncorrected visual acuity increased significantly ($P < 0.01$) from 0.93 ± 0.27 before treatment to 0.13 ± 0.29 mmHg (12 weeks), 0.08 ± 0.22 (24 weeks), 0.11 ± 0.26 (36 weeks), and 0.17 ± 0.34 (52 weeks) after treatment. Spherical equivalent values changed significantly ($P < 0.01$) from −2.87 ± 1.05 to −0.94 ± 1.17 mmHg (12 weeks), −0.75 ± 0.98 (24 weeks), −0.78 ± 0.93 (36 weeks), and −1.05 ± 1.18 (52 weeks) after treatment (Fig. 2). IOP decreased significantly ($P < 0.01$) from 13.5 ± 2.5 to 12.3 ± 2.9 mmHg (12 weeks), 12.1 ± 2.7 (24 weeks), 12.5 ± 2.8 (36 weeks), and 12.4 ± 2.7 (52 weeks) after treatment (Fig. 3). CCT also decreased significantly ($P < 0.01$) from 536.2 ± 39.6 to 528.5 ± 41.4 μm, 529.0 ± 40.7 (12 weeks), 528.3 ± 40.0 (24 weeks), and 528.6 ± 40.8 (36 weeks) after treatment (Fig. 4). Finally, the radius of corneal curvature increased significantly ($P < 0.01$) from 7.88 ± 0.25 to 8.09 ± 0.31 mm (12 weeks), 8.12 ± 0.31 (24 weeks), 8.11 ± 0.30 (36 weeks), and 8.10 ± 0.31 (52 weeks) after treatment (Fig. 5).

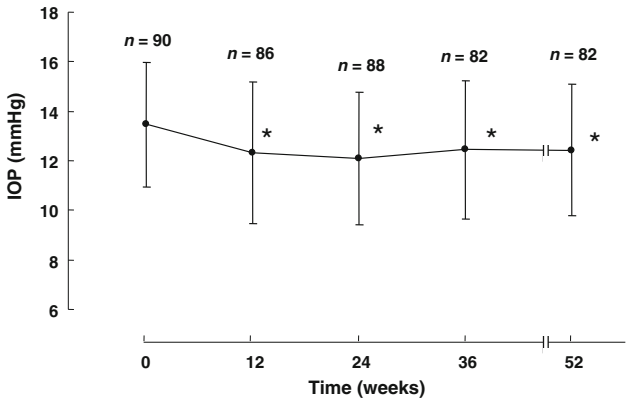

Fig. 3 Changes in IOP during treatment of myopia by overnight orthokeratology with a reverse-geometry lens for 52 weeks. Data are mean ± SD. *$P < 0.01$ (Dunnett's test) versus baseline value (time 0)

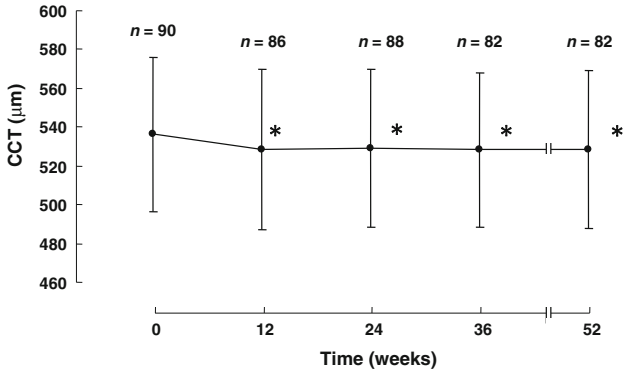

Fig. 4 Changes in CCT during treatment of myopia by overnight orthokeratology with a reverse-geometry lens for 52 weeks. Data are mean ± SD. *$P < 0.01$ (Dunnett's test) versus baseline value (time 0)

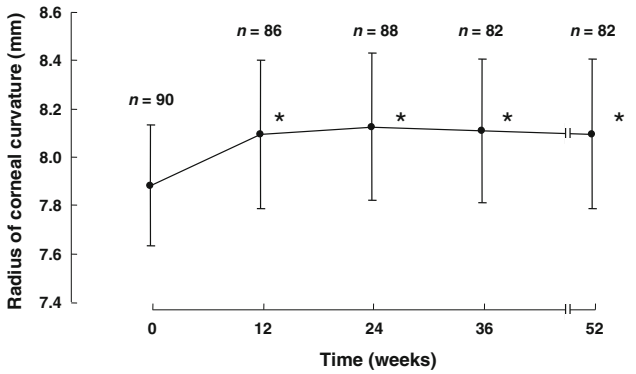

Fig. 5 Changes in the radius of corneal curvature during treatment of myopia by overnight orthokeratology with a reverse-geometry lens for 52 weeks. Data are mean ± SD. *$P < 0.01$ (Dunnett's test) versus baseline value (time 0)

We next analyzed the relation between the changes in IOP and those in either CCT, spherical equivalent value, or corneal curvature in order to explain the decrease in NCT measurements of IOP after orthokeratology. The changes

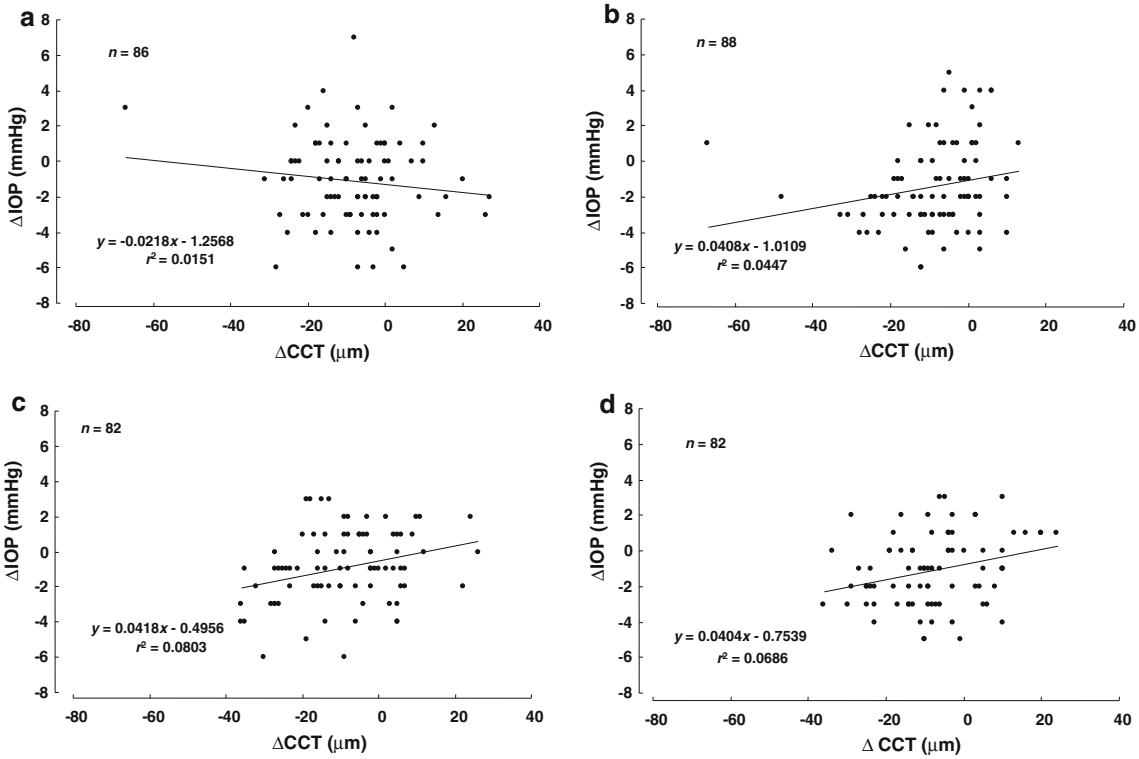

Fig. 6 Relation between the changes in IOP (ΔIOP) and those in CCT (ΔCCT) after orthokeratology. Changes were compared at 12 weeks ($r = -0.123$, $P = 0.26$) (**a**), 24 weeks ($r = 0.211$, $P < 0.05$) (**b**), 36 weeks ($r = 0.283$, $P < 0.01$) (**c**), and 52 weeks ($r = 0.262$, $P < 0.05$) (**d**)

in IOP were positively correlated with those of CCT at 24, 36, and 52 weeks (Fig. 6). However, there was no correlation between the changes in IOP and those in either the spherical equivalent value (data not shown) or radius of corneal curvature (Fig. 7).

Discussion

We have shown that overnight orthokeratology for correction of myopia resulted in a decrease in IOP as measured with an NCT. We also detected a significant correlation between the decrease in measured IOP and the decrease in CCT after overnight orthokeratology. However, we did not observe any relation between the changes in measured IOP and either the changes in refraction or the extent of flattening of the corneal curvature. Our data suggest that the decrease in IOP measured with an NCT induced by the wearing of a contact lens with a reverse-geometry design during overnight orthokeratology treatment for myopia is the result of the associated decrease in CCT.

In overnight orthokeratology, myopic patients wear contact lenses with a reverse-geometry design only during sleep; they are thus free from corrective instruments such as glasses or contact lenses during the daytime. However, orthokeratology does not change the probability of ocular complications related to myopia, such as retinal detachment, macular disorders, and glaucoma [18]. Indeed, it is important to obtain accurate readings of IOP in myopic eyes in order to screen for glaucoma in its early stages [5].

IOP measurements have been found to be decreased after laser in situ keratomileusis (LASIK) [19–21]. LASIK surgery involves the cutting of collagen bundles in the corneal stroma, resulting in a decrease in both the CCT and corneal rigidity and a consequent underestimation of IOP [20, 21]. We have now shown that overnight orthokeratology also results in a decrease in IOP as measured with an NCT, most likely because of the associated decrease in CCT. In general, the decrease in CCT associated with orthokeratology is 10–20 μm [10, 13–17], which is smaller than the changes induced by LASIK (80–100 μm) [21–23]. One view is that the refractive changes induced by overnight orthokeratology are predominantly attributable to the thinning of the corneal epithelium [13], which may not affect corneal rigidity. Although the precise mechanism underlying the decrease in IOP measurements with an NCT in eyes treated by orthokeratology remains to be determined, our present data suggest that the principal cause of the decrease in the measured IOP is the change in CCT.

Noncontact tonometry is a convenient and safe method of IOP measurement. An NCT allows the rapid measurement of IOP without direct contact with the corneal

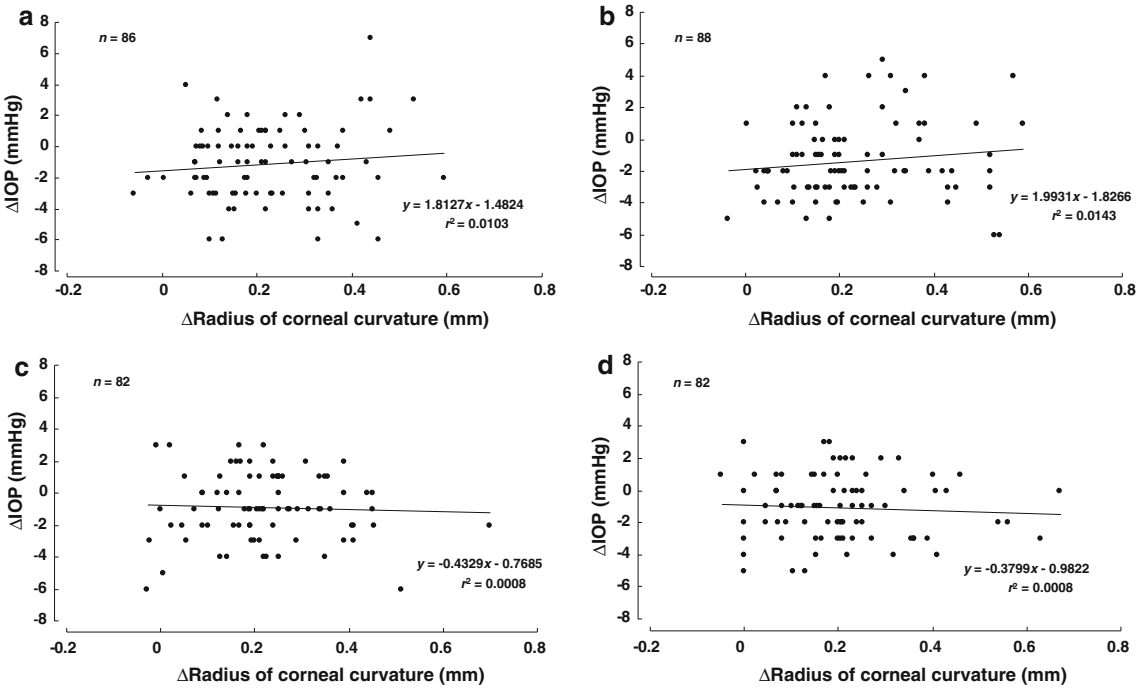

Fig. 7 Relation between the changes in IOP (ΔIOP) and those in the radius of the corneal curvature (ΔRadius of corneal curvature) after orthokeratology. Changes were compared at **a** 12 weeks ($r = 0.101$, $P = 0.35$), **b** 24 weeks ($r = 0.120$, $P = 0.27$), **c** 36 weeks ($r = -0.028$, $P = 0.80$), and **d** 52 weeks ($r = -0.027$, $P = 0.81$)

surface and yields values that correlate well with those obtained by Goldmann applanation tonometry [24, 25], which is the gold standard method and is extensively used in Western countries. A comparison of noncontact tonometry and Goldmann applanation tonometry for IOP measurements in healthy subjects revealed that CCT had a greater effect on NCT measurements than on those obtained by Goldmann applanation tonometry [26]. We have now shown that orthokeratology results in a decrease in IOP measured with an NCT. It remains to be determined whether orthokeratology might have a similar effect on IOP measurements by Goldmann applanation tonometry.

Our finding that orthokeratology results in a decrease in IOP measurements obtained with an NCT in myopic patients suggests that there is a danger of missing the early stages of glaucoma in such individuals. This possibility should thus be considered in clinical practice, especially given the increasing popularity of overnight orthokeratology.

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