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## A novel fitting algorithm for alignment curve radius estimation using corneal elevation data in orthokeratology lens trial

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#### ABSTRACT

*Purpose:* To evaluate a novel fitting algorithm for estimation of alignment curve (AC) radius during orthokeratology lens trial.

*Methods:* Fifty myopic children were recruited in this study. AC radii were estimated by both traditional method using flat K readings and eccentricity values and by a novel fitting algorithm, which was composed of 256 circle fittings using corneal elevation data from the corresponding AC region and a succedent toric fitting based on these calculated AC curvatures. Parameters of the final ordered lenses were determined by fluorescein analysis and corneal topography. The number of lens trials was recorded for each patient, and the consistencies of AC radius and astigmatism between the first trial lenses and the final ordered lenses were tested by Pearson correlations and Bland-Altman plots.

*Results*: The numbers of trials for the novel algorithm and traditional method were  $1.2 \pm 0.4$  times vs.  $1.8 \pm 0.7$  times, respectively, and Mann-Whitney test showed significant difference (z = -3.27, p = 0.001). AC radii of the first trial lenses estimated by the novel fitting algorithm were more close to that of the final ordered lenses, showing a R square value of 0.994 for the fitting algorithm and 0.927 for the traditional method, respectively. Similar results could also be noticed for astigmatism estimation.

*Conclusion:* AC radius and astigmatism of ortho-k lens could be better estimated by two steps of fitting algorithm using corneal elevation data, which may shorten the time needed for ortho-k lens trial and achieve better lens fitting status.

#### 1. Introduction

Myopia or nearsightedness describes the condition in which the eye is too long for its optical power, which may cause severe myopia-related pathologies, such as retinal detachments, [1] maculopathies, [2] posterior scleral staphylomas, [3] and choroidal neovascularization, [4] et al. Increased prevalence of myopia have been noticed around the world, with a recent study in the United States reporting a figure of approximately 42%, [5] and even as high as 95.5% in university students in China [6].

Overnight orthokeratology lenses (ortho-k lenses) have shown effects against myopia progression in multiple studies. In a randomized clinical trial (ROMIO study), Cho et al. found a slower increase in axial length by 43% in patients treated with ortho-k lenses compared with single-vision spectacle lenses, [7] and a similar result could be noticed for toric design. [8] The effect of ortho-k lens against myopia

progression was further summarized by a recent meta-analysis [9], showing a slower elongation of axial length by approximately 50%.

Despite of the efficacy of ortho-k lens, poor lens fitting may cause decentration of ortho-k lens, [10] severe corneal staining, loss of the meibomian gland, [11] or even severe keratitis, [12] resulting in failure of overnight ortho-k lens treatment. Traditionally, alignment curve radius of the first trial lens was chosen based on the central flat K reading and eccentricity value (e value) obtained from corneal topography, and final lens parameters were determined after several lens trials. While optimum lens fitting could be achieved within two or three trials in most cases, some patients may need more trials to finally target the best parameters of ortho-k lenses, which was time-consuming and may cause corneal staining and conjunctival congestions, leading to ocular discomforts and also clinical complains. In this study, a novel algorithm was proposed to precisely estimate the alignment curve (AC) radius for the first trial lens.

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#### 2. Materials and methods

#### 2.1. Human subjects

Fifty myopic children, who were referred to the Ophthalmology Department and Clinical Centre of Optometry of Peking University People's Hospital (Beijing, China) for ortho-k lens treatment from June 2016 to August 2016, were recruited in this study, with a mean age of 9.73  $\pm$  0.92 years (aged between 8 ~ 12 years). Detailed ocular examinations, including LogMAR uncorrected distance visual acuity (UDVA), slit lamp, non-contact tonometer, manifest and cycloplegic refractions, corneal topography (Sirius, Costruzione Strumenti Oftalmici, Florence, Italy), axial length (IOLMaster, version 4.0, Carl Zeiss Shanghai Co., Ltd., Germany) and indirect ophthalmoscope were performed to exclude any other ocular diseases. When performing corneal topography examinations, the patients were asked to widely open their eyes for better data sampling over anterior corneas. The criterions for image chosen were based on acquisition quality indices provided by Sirius system, with Scheimpflug images coverage not less than 95%, the percentage of edited images larger than 90%, and at least a 90% for well-centeredness of keratoscopy. Cornea topography was performed at least three times, and the best-sampled data set was chosen for further analyses. None of these children had previous surgeries or worn contact lenses. The inclusion criterion was moderate myopia with a spherical equivalent refraction between  $-2.00D \sim -4.00D$ , complicated with astigmatism less than 2.50D. Patients having astigmatism larger than 2.50D were excluded from the study. Myopic children with meibomain gland dysfunction (MGD), dry eye, or small palpebral fissure which resulted in obvious incomplete corneal data sampling even with a lid retractor on were excluded from the study. All children and parents were informed about the study, and the parents signed an informed consent document in accordance with the Helsinki Declaration, and the study was approved by Medical Ethics Committee of Peking University People's Hospital.

#### 2.2. Lens fitting methods

All children were randomly divided into two groups for ortho-k lens fitting (Euclid, USA), with 25 children in each group. The lens material was Boston Equalens II, with an oxygen permeability (DK) of  $85 \times 10^{-11}$  (cm<sup>2</sup>/s)(ml O<sub>2</sub>/ml·mmHg) measured by the polarographic method. Before lens fitting, cycloplegic manifest refraction, horizontal visible iris diameter (HVID, by Sirius), K readings at both flat and steep meridians (Sirius), and corneal eccentricity (Sirius) values were collected for trial lens selection. To avoid correlated effects between both eyes, only data from right eyes were collected.

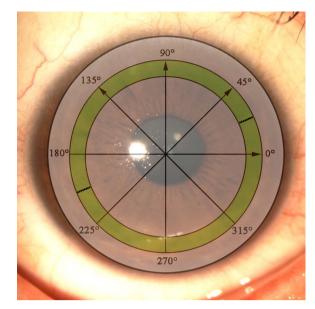
In group 1, alignment curve radius (AC, in this study referred to AC1, represented as powers) of the first trial lens for each patient was determined by the flat K reading (FK) and e value with a modified equation [13], which is applied for non-toric design:

$$ACI = FK - 3.465 e^2 - 0.3396 e + 1.26$$
(1)

Eyes with limbus-to-limbus corneal astigmatism larger than 0.75D or elevation difference larger than 30 microns between the flat and steep meridians at 8 mm ring were fitted with toric lenses, i.e., 1.00D toricity for 30 microns difference, and adding 0.25D for every 7 ~ 8 microns of increasing elevation difference. The flat AC radius of the first trial lens for toric design was determined as 0.25D or 0.50D flatter than the non-toric design, based on clinical experience. For comparison, AC radii calculated by the new algorithm described below were also recorded.

In group 2, AC radii of the first trail lens were determined by the following mathematic procedures, but the values determined by the traditional method described in group 1 were also recorded for further comparison. For each patient in group 2, a ".csv" file containing

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**Fig. 1.** Fitting procedures. The anterior corneal elevation data within the green region (AC1) were extracted from the exported matrix. At each meridian, a circle fitting was performed, e.g., at 23° and 203° meridians shown in this figure, 16 elevation values (16 black dots) were used. Then a toric fitting was performed based on fitted radii from all 256 meridians. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

anterior corneal elevation data was exported from Sirius system, with a matrix of 31 \* 256, containing 7936 data points within a polar coordinate, which was then imported into a customized Matlab program. The row vector of the exported raw matrix represents radii ranging from 0 mm to 6 mm, with a step of 0.2 mm, while the column vector represents 256 meridians ranging from 0° to 360°, with an interval of 1.4°, which starts from 3 o'clock, and rotates counterclockwise back to 0°, with the origin centered at corneal apex. To match different lens designs, the matrix was interpolated ("PCHIP" method) and transformed into a 61 \* 256 matrix for further calculating, with a minimum radius step of 0.1 mm. Briefly, corneal elevation data corresponding to the alignment curve (AC1) of ortho-k trial lens were extracted from the matrix, i.e., data within a ring with radius ranged from 3.6  $\sim$  4.3 mm (AC1) at all meridians (for a trial lens with a diameter of 10.6 mm) were extracted, according to the lens design, then a least-square circle fitting was repeated 256 times to calculate the best fitted radius at each meridian, followed by a least-square toric fitting using the calculated AC radii at all 256 meridians (Fig. 1). If the calculated astigmatism (difference between the flat AC and steep AC) was less than 0.75 D, a value 0.50 D steeper than the mean calculated AC radius was chosen as the AC radius for the first trial lens. For toric design in which the astigmatism of AC was larger than 0.75D, the flat AC radius for the first trial lens was determined as 0.50D steeper than the value calculated from the fitting algorithm, and astigmatism of AC region was determined as the difference between the flat AC and steep AC calculated by the algorithm.

#### 2.3. Lens fitting evaluation

Lens fitting evaluation was performed 0.5 h after lens insertion using fluorescein sodium. The optimum alignment curve radius was determined after several lens trials until a perfect "bull-eye" pattern was shown, with a central touch surrounded by a deep annulus of tear reservoir trapped in the reverse curve area. Corneal topography was also performed 40 min after the optimum trial lens insertion in order to confirm fitting status of the lens. A Jessen factor of  $+0.50D \sim +0.75D$  was applied for the final ordered lenses.

A SPSS statistics software package (version 22.0, IBM, Armonk, NY,

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