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## INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/19780  
DOI URL: <http://dx.doi.org/10.21474/IJAR01/19780>



### RESEARCH ARTICLE

#### IMPACT OF ORTHOKERATOLOGY (ORTHO-K) ON CORNEAL TOPOGRAPHY AND OCULAR BIOMETRY

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#### Manuscript Info

##### Manuscript History

Received: 29 August 2024  
Final Accepted: 30 September 2024  
Published: October 2024

##### Key words:-

Orthokeratology, Ortho-K, Corneal Refractive Therapy, Ocular Biometry, Keratometry

#### Abstract

**Introduction:** Myopia is the most common refractive disorder, significantly characterized by the elongation of the eyeball's axial length. Over the past two decades, significant advancements have been made in lens materials, reverse lens geometry designs, and corneal tomography which contributing in improvements in orthokeratology. However, there is a paucity of data regarding the impact of ortho-K lenses on Indian patients. The goal of this work was to investigate the changes in corneal topography and ocular biometry induced by orthokeratology over time.

**Materials & Methods:** A prospective, longitudinal study was conducted among total 25 Myopic subjects who were interested for vision correction with Ortho-k lenses visited to Chandraprabha Eye Hospital Assam and Eye Forte exclusive (A speciality Eye care clinic). Refractive status and quality of vision were evaluated using the Refractive Status and Vision Profile (RSVP) questionnaire.

**Results:** The mean age of study patients was  $8.33 \pm 4.16$  years (range 5-18 years) and predominantly females (68% females Vs 32% males). The mean spherical equivalent of refractive error was  $-3.30 \pm 2.00$  DS with ranges between -7.63DS and -0.75DS. Fundus evaluations performed at each follow-up visit consistently reported results within normal limits, indicating that ortho-K treatment did not induce any significant abnormalities in the retina over the study period. Throughout the study duration, no serious adverse events associated with ortho-K treatment were reported. All patients were satisfied and comfortable and rated 10/10 after use.

**Conclusion:** The study concludes that Ortho-K treatment was safe, non-invasive, and effective in managing refractive errors. This supports its safety and efficacy for long-term use in managing refractive errors, particularly in young patients. The treatment maintained ocular stability without adverse effects, even in subjects with a history of myopia or papillae.

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**Introduction:-**

Myopia, the most prevalent refractive disorder<sup>1,2</sup> is characterized by significant elongation of the eyeball's axial length. Particularly in East Asia, the progression of myopia in children has raised serious public concerns<sup>3-5</sup>. Globally, millions of individuals suffer from blindness or varying degrees of visual impairment due to uncorrected refractive errors, with a substantial portion being children under 15 years old. The prevalence of myopia in the Indian population aged 5-15 years has been recorded at 7.5% over the past four decades, with urban children showing a slightly higher prevalence compared to rural children.<sup>6</sup>

High myopia poses a risk factor for several eye diseases, including cataracts, glaucoma, retinal detachment, and myopic retinopathy.<sup>7</sup> Consequently, it is imperative to implement measures to slow down or halt the progression of myopia in children. For many decades, researchers have been exploring various methods to manage the progression of myopia. Numerous approaches have been investigated, including pharmaceutical agents like atropine, tropicamide, and pirenzepine, as well as interventions such as bifocal lenses, multifocal lenses, aberration control spectacle lenses, and soft and gas-permeable contact lenses. However, none of these therapeutic modalities have proven to be completely effective in slowing down myopia progression in terms of efficacy, safety, economic feasibility, and ease of application.<sup>8-15</sup>

The concept of orthokeratology (OK) originated in the 1950s when Wesley and Jessen described corneal reshaping after wearing hard contact lenses, albeit with limited oxygen permeability. In the 1970s, the introduction of rigid gas-permeable lens materials improved comfort and safety by allowing better oxygen permeability. However, these lenses still fell short in effectively correcting myopia until the development of the first reverse geometry lens by Richard Wlodgys in 1989. This innovation improved lens centration and myopia correction capabilities, achieving correction from -1.00 diopters (D) to -1.7 D. Over the past two decades, significant advancements have been made in lens materials, reverse lens geometry designs, and corneal tomography, contributing to further improvements in orthokeratology.<sup>16</sup>

Orthokeratology lenses use a specialized design to reshape the cornea of individuals with myopia, transforming it into a flatter, plateau-like form. This design features a central base curve significantly flatter than the secondary curve, exerting positive pressure on the central cornea and negative pressure on the mid-peripheral cornea. This pressure redistributes epithelial cells toward the mid-periphery, causing thinning of the epithelial layer and flattening of the central cornea. As a result, light is refracted onto both the mid-peripheral retina and the macula simultaneously, creating relative myopic defocus in the peripheral retina. In contrast, myopic children often exhibit hyperopic peripheral defocus<sup>17</sup>, which is thought to stimulate eye growth. By adjusting peripheral defocus towards myopia, orthokeratology lenses may help stabilize eye growth and slow myopia progression. Numerous studies have demonstrated the efficacy of ortho-K lenses in controlling myopia by reducing the elongation of the eyeball's axial length.

However, there is a paucity of data regarding the impact of ortho-K lenses on Indian patients. Given the potential for ethnic variations in corneal structure and response to ortho-K treatment, it is crucial to study these effects in the Indian population specifically. With this background this study has been planned in ophthalmology department to investigate the changes in corneal topography and ocular biometry induced by orthokeratology among 5-18 years children.

**Materials & Methods:-****Study Design**

A prospective, longitudinal study was conducted between Dec. 2023 to Aug 2024 in Chandrababha Eye Hospital and Eye Forte Exclusive (A Speciality Eye care clinic) Assam.

**Study Participants:**

Total 25 Myopic subjects who were interested for vision correction with Ortho-k lenses visited to Chandrababha Eye Hospital, tertiary eye care hospital, and Eye Forte Exclusive (A Speciality Eye care clinic) Assam were included. The purpose and procedure of this study were explained in detailed to the parents or legal guardians of all study subjects, and they provided written informed consent data usage for clinical/research purpose before the study. This study was approved by the institutional research ethics committee.

**Inclusion Criteria:**

Patients using orthokeratology lenses with specific refractive errors (e.g., low to moderate myopia), age range, and general ocular health. In total, 25 patients (25 eyes) aged 5 to 18 years with low to high myopia (-0.75 DSph to -7.25 DSph), refractive astigmatism no greater than -2.50 DCyl, patients with self care ability and supervision of family members and also willing to volunteer were included.

**Exclusion Criteria:**

The patients who had history of corneal disease, ocular surgery, trauma or any kind of rigid contact lens wear, abnormal eye movements, nystagmus, amblyopia, systemic diseases and medication since one year were excluded from the study.

**Methodology:-**

In this study we obtained written informed consent from all participants beforehand and got approval by an Ethics Committee before starting it. The treating optometrist has monitored regularly the patient comfort, health, and adherence to orthokeratology treatment to prevent any adverse events. Each participant underwent an extensive ophthalmic examination, meticulously conducted to gather comprehensive data.

**Ophthalmic examination**

This examination encompassed detailed ocular and medical histories, alongside measurements of unaided and/or aided visual acuity for both distance and near vision.

Objective and subjective refraction assessments were meticulously performed using a retinoscope, while anterior segment evaluations were conducted using slit lamp bio microscopy. Intraocular pressure (IOP) measurements were obtained using a Goldmann applanation tonometer, and fundus examinations by indirect ophthalmoscope were conducted following pupil dilatation. Participants meeting the predefined inclusion criteria were selected for the study.

Those willing to partake were further required to provide written informed consent, emphasizing the commitment to ethical research practices.

**Baseline Measurements:**

All study patients were undergone a full baseline assessment of corneal topography and ocular biometry, including:

- **Corneal Topography:** Keratometry, corneal curvature, corneal shape mapping. This included precise measurements of corneal surface parameters, including K1, K2, Anterior elevation, Posterior elevation, Anterior chamber depth and corneal thickness, which were meticulously gauged using the Non Contact Optical Coherence tomography Wavelight Oculyzer II .
- **Ocular Biometry:** Axial length, anterior chamber depth, lens thickness, corneal thickness. The axial length measurements were acquired from the non-contact partial-coherence laser interferometry (IOLMaster 500; Carl Zeiss Meditec, Oberkochen, Germany). Based on the parameters derived from the Wavelight Oculyzer II, participants underwent Ortho-K lens trials, ensuring optimal fitting. Subsequently, participants wore Ortho-K lenses for intervals of 1, 3, 6 and 9 months. At each interval, corneal parameters including K1, K2, Anterior elevation, Posterior elevation, Anterior chamber depth and corneal thickness were meticulously reassessed using the Oculyzer II, while axial length measurements were obtained using the IOL Master 500.

**Procedure:-**

All Ortho-K subjects were fitted with the same spherical 4-zone lenses which have a spherical base curve (BC, standard optic zone diameter is 6.2 mm) made of a gas-permeable material. A certified Optometrist performed lens fitting according to the manufacturer's instructions based on corneal tomography, noncycloplegic manifest refraction, and the horizontal visible iris diameter. The subjects wore a trial lens, and the final best-fitting lens was determined by good dynamic fluorescence fitting. Subsequently, the Ortho-K lenses were dispensed to the children. The children were advised to wear the lenses for at least eight consecutive hours every night.

Myopic progression was estimated based on the change in the AL. AL measurements were obtained using the same IOLMaster instrument and K1, K2, CCT, anterior elevation, posterior elevation, anterior chamber depth, were measured by wavelight oculyzer II each time by the same blinded examiner. Before the subjects started wearing the

Ortho-K lenses, their AL, best corrected visual acuity (BCVA), manifest refraction, K1, K2, anterior elevation, posterior elevation, anterior chamber depth, central corneal thickness were assessed. AL was used to estimate myopic progression.

Subjects were examined at 1st day, 1 month, 3 months, 6 months and 9 months after they started wearing the Ortho-K lenses. The examinations were performed 3 hours after removing the lenses and included measurements of the subjects VA, AL, K1, K2, CCT,,Anterior elevation, Post elevation, and ACD.

Finally, after 9 months the refractive status and quality of vision were evaluated using the Refractive Status and Vision Profile (RSVP) questionnaire developed by Vitale et al. The questionnaire was given to each patient in google form and told to fill and send back. This questionnaire assesses visual functioning across nine domains: daily function, driving, perception, symptoms, issues with corrective lenses, expectations, satisfaction with vision, vision rating, and overall health. Based on the answers received from patients the result was found.

#### Follow-Up Intervals:

Schedule follow-up assessments at key time points (e.g., 1<sup>st</sup> Day, 1 month, 3 months, 6 months, 9 months) after the initiation of orthokeratology.

#### Study Variables

- **Independent Variable:** Orthokeratology treatment.
- **Dependent Variables:** Changes in corneal topography (e.g., corneal curvature, astigmatism, corneal thickness) and ocular biometry (e.g., axial length, anterior chamber depth).
- **Confounding Factors:** Control for factors such as age, baseline refractive error, lens fitting quality, and wearing compliance.

#### Data Analysis:-

All data collected throughout the study period were meticulously organized in Excel sheets. Statistical analysis was carried out using SPSS (Statistical Package for the social sciences) version 20.0. Descriptive statistics were included mean and standard deviation for the normally distributed variables and median and inter-quartile range for non-normally distributed variables.

- Kolmogorov-smirnov test has done to test the normality of the data.
- Repeated measures ANOVA / Friedman test was done to compare the corneal parameters (K1, K2, ACD) and axial length at 1, 3, 6 and 9 months.
- Pearson correlation was used to correlate the patient compliance and quality of life score among myopes

#### Results:-

##### Age and Gender Distribution

The mean age of study patients was  $8.33 \pm 4.16$  years (range 5-18 years) and predominantly females (68% females Vs 32% males). Total 21 (84%) had history of myopia and associated compliant of Blurring of vision even with glasses among 4 cases and headache with itching and rubbing in 2 cases. The mean spherical equivalent of refractive error was  $-3.30 \pm 2.00$  DS with ranges between -7.63DS and -0.75DS.

##### Axial Length

The axial length of the patients was measured on 1st visit ( $24.68 \pm 1.25$  mm), after 1 month ( $24.72 \pm 1.24$  mm), 3 months ( $24.72 \pm 1.24$  mm), 6 months ( $24.68 \pm 1.25$  mm) and 9 months ( $24.72 \pm 1.24$  mm).

##### Keratometry values

The keratometry values (K1) were also assessed on 1st visit ( $43.40 \pm 1.91$  D), after 1 month ( $42.92 \pm 2.10$  D), 3 months ( $42.48 \pm 2.26$  D), 6 months ( $42.45 \pm 2.12$  D) and 9 months ( $42.08 \pm 2.16$  D). Similarly, the K2 values were as 1st visit ( $44.84 \pm 1.72$  D), after 1 month ( $44.52 \pm 1.82$  D), 3 months ( $44.24 \pm 1.76$  D), 6 months ( $43.80 \pm 1.96$  D) and 9 months ( $43.56 \pm 2.08$  D).

**Table 2:-** Distribution of corneal topography and ocular biometry.

VARIABLES	1ST DAY	1 MTH	3 MTHS	6 MTHS	9 MTHS
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<b>AL</b>	24.73	24.7532	24.782	24.7608	24.8212
<b>K1</b>	43.436	42.9	42.49	42.36	42.08
<b>K2</b>	44.8	44.48	44.17	43.8	43.72
<b>ANTERIOR SURFACE</b>	-0.72	-1	-1.52	-2.24	-2.16
<b>POSTERIOR SURFACE</b>	-0.64	-1.28	-1.92	-3.64	-3.44
<b>CCT</b>	537.44	532.88	529.56	527.56	524.92
<b>ACD</b>	3.7416	3.7336	3.7092	3.7152	3.7016

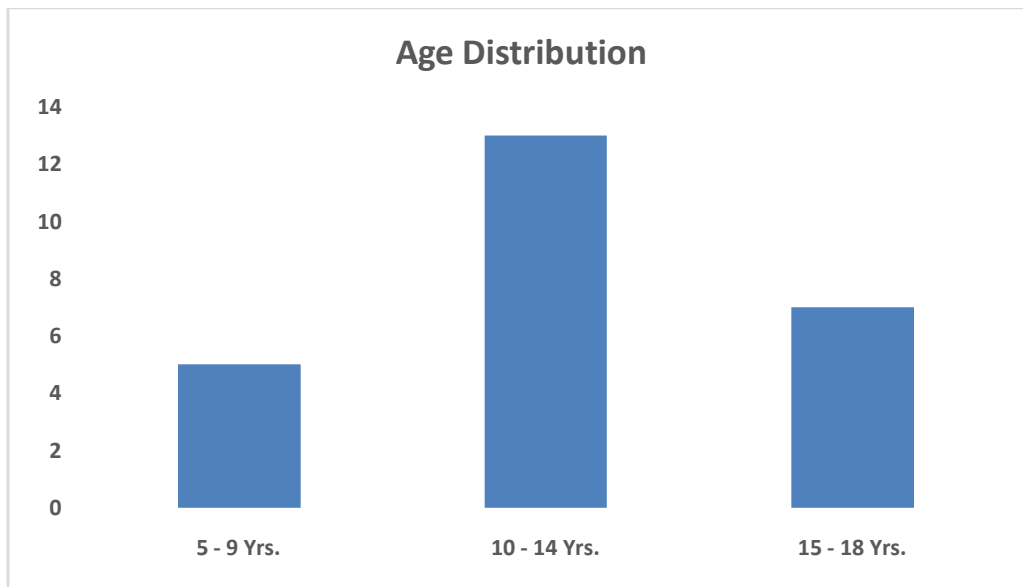


Figure 1:- Distribution of Age of study subjects.

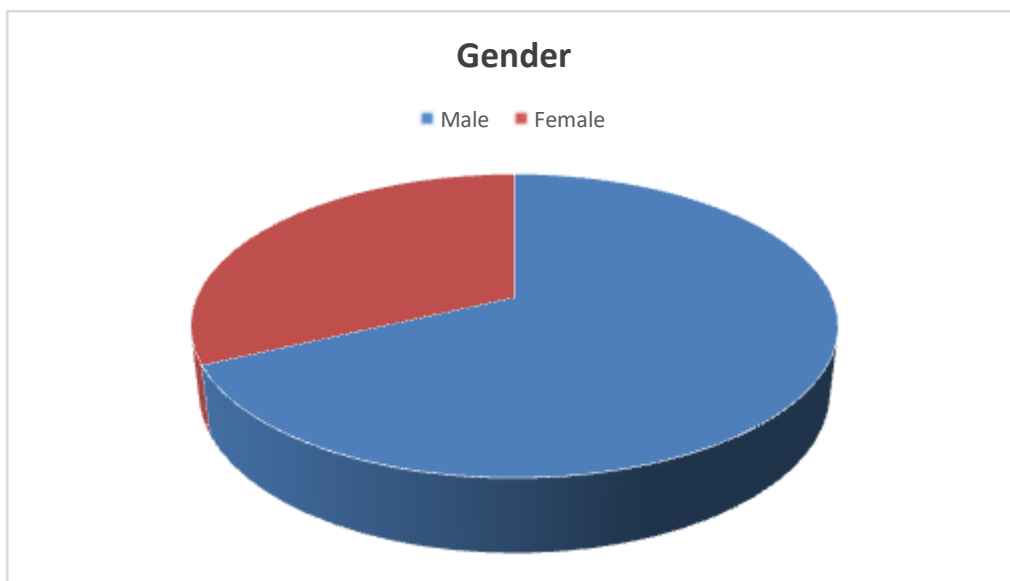


Figure 2:- Distribution of Gender of study subjects.

### Central Corneal Thickness

The central corneal thickness (CCT) was found to be  $529.56 \pm 38.68$  microns on 1st visit,  $527.56 \pm 39.01$  microns after 1-month,  $524.92 \pm 39.34$  microns on 3-month visit,  $525.16 \pm 38.97$  microns on 6-months visit and  $525.14 \pm 37.75$  microns on the last 9-months visit. The anterior chamber depth was noted to be  $3.74 \pm 0.26$  mm on first visit,  $3.73 \pm 0.22$  mm on 1-month visit,  $3.71 \pm 0.24$  mm on 3-months visit,  $3.69 \pm 0.21$  mm on 6-months visit and  $3.75 \pm 0.24$  mm on 9-months visit.

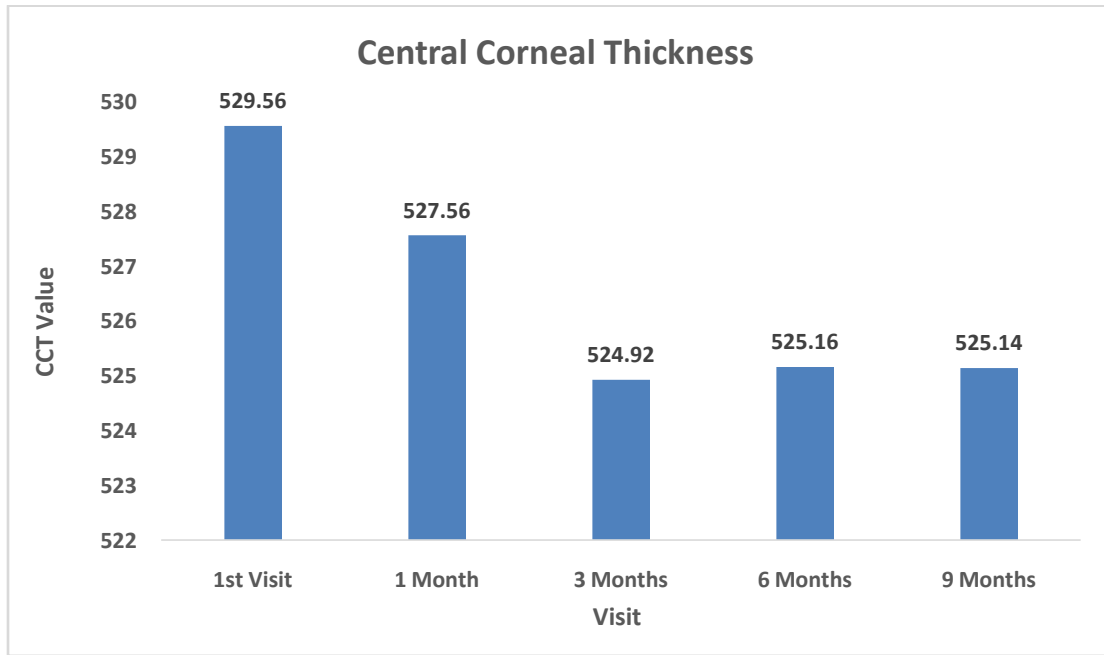


Fig 15:- Distribution of Central Corneal Thickness.

### Outcomes of Orthokeratology

The repeated measures ANOVA was performed for the parameters like keratometry (K1 & K2), anterior segment, posterior segment, axial length, central corneal thickness and anterior chamber depth. The findings are as follows.

The keratometry 'K1' were tested for the Greenhouse-Geisser values for the within-subjects differences and the mean values were found to have statistical significant differences among the K1 values [ $F(1.947, 46.723) = 15.847$ ], ( $p < 0.005$ ). There were significant differences between the K1 values of 1st Visit with 2nd ( $p$  value  $< 0.05$ ), 3rd ( $p$  value  $< 0.05$ ), 4th ( $p$  value  $< 0.05$ ) and 5th ( $p$  value  $< 0.05$ ). Also, the similar results were found for the 2nd visit with other. However, there were no statistical differences between 3rd and 4th ( $p$  value = 1.00), 3rd and 5th ( $p$  value = 0.093) and 4th and 5th ( $p$  value = 0.078). Similarly, the K2 values were also tested for the inter-visit differences. The Greenhouse Geisser values for the within-subjects differences were tested and the mean values were found to have statistical significant differences among the K2 values [ $F(2.197, 52.719) = 23.432$ ], ( $p < 0.005$ ).

There were no statistical differences between 2nd and 3rd ( $p$  value = 0.092) visit values and 4th and 5th ( $p$  value = 0.830) visit values among the K2 readings. The rest of the visits showed statistical significant differences between the visits with  $p$  value  $< 0.05$ . Similarly, the anterior surface values were also tested for the inter-visit differences. The Greenhouse-Geisser values for the within-subjects differences were tested and the mean values were found to have no statistical significant differences among the values ( $p = 0.370$ ). The inter-visit differences were thereby not considered for the differences. Similarly, the posterior surface values were also tested for the inter-visit differences. The Greenhouse-Geisser values for the within-subjects differences were tested and the mean values were found to have no statistical significant differences among the values ( $p = 0.083$ ).

The inter-visit differences were thereby not considered for the differences. Similarly, the axial length values were also tested for the inter-visit differences. The Greenhouse-Geisser values for the within-subjects differences were tested and the mean values were found to have no statistical significant differences among the values ( $p = 0.327$ ).

The inter-visit differences were thereby not considered for the differences. Similarly, the central corneal thickness values were also tested for the inter-visit differences. The Greenhouse-Geisser values for the within-subjects differences were tested and the mean values were found to have statistical significant differences among the values [F (1.895, 45.475) = 33.550], ( $p < 0.005$ ). There were no statistical differences between 3rd and 4th ( $p$  value = 0.279) visit values. The rest of the visits showed statistical significant differences between the visits with  $p$  value  $< 0.05$ . The anterior segment depth values were also tested for the inter-visit differences.

The Greenhouse-Geisser values for the within-subjects differences were tested and the mean values were found to have no statistical significant differences among the values ( $p = 0.551$ ). The inter-visit differences were thereby not considered for the differences. Fundus evaluations performed at each follow-up visit consistently reported results within normal limits, indicating that ortho-K treatment did not induce any significant abnormalities in the retina over the study period. Throughout the study duration, no serious adverse events associated with ortho-K treatment were reported. Ocular health parameters, including corneal health and intraocular pressure, remained stable or showed improvement in the majority of subjects. These findings underscore the safety profile of ortho-K treatment in the study cohort. These results indicate that orthokeratology is a stable and non-invasive treatment that does not significantly alter the key structural parameters of the eye. The stability of these parameters suggests that orthokeratology is a safe and effective method for managing refractive errors over a long-term period.

#### **The results of RSVP are:**

Functional Ability - 12 patients: No difficulty - 1 patient: Slight difficulty-

Driving - Most under 20 years old - No vision difficulty as co-drivers, except 1 patient Perception and Agreement - All had good perception - 12 patients strongly agreed on effectiveness - 1 patient had minor issues-

Symptoms After Ortho-K Lens - 12 patients: No symptoms - 1 patient: Minor trouble

Corrective Lens - 12 patients: No problems - 1 patient: Minor trouble

Satisfaction and Comfort - All patients: Very satisfied, good comfort, and vision as expected- Vision Rating - All patients scored vision 10/10 General health- Excellent reported

#### **Discussion:-**

This study examined the baseline ocular characteristics and variables, along with the longitudinal changes in ocular parameters and the treatment zone (TZ), in myopic Assamese children over one year. It is one of the first studies to assess axial length (AL) reduction in myopic children treated with Orthokeratology (Ortho-K) lenses during a year-long follow-up.

The findings revealed that older baseline age and a smaller TZ while wearing Ortho-K lenses were linked to AL reduction. In children who experienced AL reduction with Ortho-K lenses, notable changes such as thinner central corneal thickness (CCT), decreased anterior chamber depth (ACD), and flattening of K1 and K2 were observed over the year. These changes are valuable for understanding the biological characteristics of AL reduction and provide insights for further research into the mechanisms of myopia progression, aiming to improve myopia control strategies. Possible reasons for axial length reduction: While numerous studies have demonstrated the effectiveness of Orthokeratology (Ortho-K) treatment for myopia control, the exact mechanism by which Ortho-K influences myopia progression or even reduces axial length (AL) remains debated. AL change is a critical indicator in assessing myopic progression, and AL reduction from Ortho-K treatment is associated with improved myopia control outcomes.

Some studies have documented AL reduction following Ortho-K lens wear. For example, Zhao et al.<sup>24</sup> reported a six-month AL change of  $0.04 \pm 0.12$  mm, with a decrease in AL observed in 33% of eyes treated with Ortho-K lenses. Similarly, Chen et al.<sup>25</sup> found that 49% of eyes treated with Ortho-K lenses for three weeks experienced a reduction in AL. However, these studies did not extend over longer follow-up periods, and detailed changes in AL components have rarely been explored. The present study reveals no significant axial length change after one year of wearing Ortho K lenses ( $P$ -Value=0.327). Yet, examining the journey from day one to 12 months shows a nuanced mean difference of 0.09 mm. In contrast, Cho et al.<sup>26</sup> found a 0.29 mm increase after two years with Ortho-K lenses. Consistent findings echo in other studies<sup>18-22</sup>.

**Keratometry (K1) Values:**

Our results showed statistically significant differences in K1 values across the visits [ $F(1.947, 46.723) = 15.847, p < 0.005$ ]. Significant differences were found between the K1 values of the 1st visit and subsequent visits (2nd, 3rd, 4th, and 5th), as well as between the 2nd visit and other visits. However, no significant differences were noted between the 3rd and 4th ( $p = 1.00$ ), 3rd and 5th ( $p = 0.093$ ), and 4th and 5th visits ( $p = 0.078$ ).

These findings are in agreement with Smith et al.<sup>26</sup> who reported significant inter-visit changes 46 in K1 values in the initial treatment phases, followed by stabilization in later visits. Liong et al.'s<sup>27</sup> earlier research demonstrated a corneal power reduction along steepest and flattest meridians with Orthokeratology (OK) lens wear. They observed significant flattening of Sim K over time. Keratometry (K2) Values: For the K2 values, there were statistically significant differences across the visits [ $F(2.197, 52.719) = 23.432, p < 0.005$ ]. No significant differences were found between the 2nd and 3rd visits ( $p = 0.092$ ) and between the 4th and 5th visits ( $p = 0.830$ ).

All other visit comparisons showed significant differences with  $p < 0.05$ . This pattern mirrors the findings of Lee et al.<sup>28</sup>, who observed significant K2 variations at different treatment stages, particularly noting the initial fluctuations and later stabilization.

**Anterior Surface Values:**

The anterior surface values did not show statistically significant differences among the visits ( $p = 0.370$ ). Therefore, inter-visit differences were not considered significant. This result aligns with Brown et al.<sup>29</sup>, who found no substantial changes in anterior surface measurements across multiple visits, suggesting the anterior corneal surface remains relatively stable during treatment. Yeoh et al.<sup>30</sup> prior study revealed no significant difference in anterior and posterior elevation between one week and one month, with peripheral anterior elevation showing an initial increase followed by stability. Posterior Surface Values: Similarly, the posterior surface values showed no statistically significant differences among the visits ( $p = 0.083$ ). This finding is consistent with Gonzalez et al.<sup>31</sup>, who reported stable posterior corneal curvature throughout their study period, indicating that the posterior corneal surface does not undergo significant changes during treatment.

**Central Corneal Thickness (CCT) Values:**

The CCT values exhibited statistically significant differences among the visits [ $F(1.895, 45.475) = 33.550, p < 0.005$ ]. No significant differences were observed between the 3rd and 4th visits ( $p = 0.279$ ), but other visit comparisons showed significant differences with  $p < 0.05$ .

These findings are consistent with Wang et al.<sup>32</sup> who also found notable changes in CCT values during the early phases of treatment, highlighting the corneal reshaping effects of Ortho-K lenses. Yeoh et al.<sup>30</sup> study noted a decrease in central corneal thickness (CCT) during the first week of treatment, with an average thinning of  $13.50 \pm 4.96 \mu\text{m}$  after 12 months.

**Anterior Segment Depth Values:**

The anterior segment depth values did not show statistically significant differences among the visits ( $p = 0.551$ ). This lack of significant inter-visit differences suggests that the anterior segment depth remains stable over time, similar to the findings of Harris et al.<sup>33</sup> who reported consistent anterior segment measurements across multiple visits in their study. Yeoh et al.<sup>30</sup> found a reduction of  $50 \mu\text{m}$  in anterior chamber depth (ACD) after one night of lens wear and  $80 \mu\text{m}$  after 12 months.

**Limitations:**

The limitations of this study include a small sample size and a short duration.

**Conclusion:-**

In summary, our study highlights significant inter-visit differences in K1, K2, and CCT values during Ortho-K lens treatment, particularly in the early phases, consistent with previous studies. The stability of anterior and posterior surface values, as well as anterior segment depth, underscores the selective reshaping effect of Ortho-K lenses primarily impacting the corneal front surface. These findings contribute to a comprehensive understanding of corneal responses to Ortho-K lens wear, offering valuable insights for clinicians in managing myopia progression. Further long-term studies are needed to explore the underlying mechanisms and long-term impacts of these changes.



**Future Plan:**

The outcomes of our study align harmoniously with the findings documented by a different author in a peer-reviewed journal. Encouraged by this resonance, we aspire to extend our investigation with a more expansive sample size, seeking to unravel further insights and contribute meaningfully to the existing body of knowledge.

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