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Orthokeratology (ORTHO-K) & Retinal Morphology In Progressive Myopia- A One Year Longitudinal Analysis

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ABSTRACT

Background: To investigate the changes in retinal nerve fiber layer (RNFL) thickness, ganglion cell layer (GCL) thickness, inner plexiform layer (IPL) thickness in progressive myopic patients after one year of treatment with orthokeratology (Ortho-K) lenses.

Methods: This prospective, longitudinal study enrolled 49 patients with age upto 20 years with progressive myopia (-1.00 D to -10.00 D & upto -1.00 Dcyl and a documented increase of at least -0.50 D in the past year). All participants were fitted with custom Ortho-K lenses. Ocular examinations were conducted on baseline and every three month and data recorded. Measurements included: best-corrected visual acuity (BCVA), Objective and subjective refraction , axial length (AL) using an IOL Master, and macular and optic disc optical coherence tomography (OCT) to measure RNFL, GCL, and IPL thicknesses. Statistical analysis was performed using paired t-tests and repeated measures ANOVA to compare changes from baseline.

Results: The mean age of study patients was 14.74 ± 3.121 years (range 5-20 years) and predominantly females (59.2% females Vs 40.8% males).The mean global NFL thickness at baseline was [99.96 ± 6.92 µm]. At the 12-month follow-up, the mean global RNFL thickness was [101.1 ± 7.12 µm]. The mean GCL+IPL thickness at baseline was [88.92 ± 7.25 µm]. After one year of Ortho-K wear, the mean GCL+IPL thickness was [89.94 ± 7.25 µm]. A paired t-test revealed no statistically significant difference between baseline and 12-month measurements (p= 0.162). Subgroup analysis of specific quadrants showed minor, non-pathological variations, which did not correlate with the changes in AL. No signs of retinal toxicity or structural damage were observed.

Conclusion: This study confirms that orthokeratology is a safe and effective approach for controlling myopia progression by maintaining stable axial length. It also demonstrates that Ortho-K lenses do not cause thinning of the RNFL, IPL, or GCL layers, suggesting a reduced risk of glaucoma development in progressive myopes who consistently wear Ortho-K lenses.

Keywords: *Schiff base, Aromatic amines, Ketones, Benzoxazipine.*

1. INTRODUCTION

Myopia, or nearsightedness, is a global public health concern with increasing prevalence, particularly among school-aged children. High myopia is a significant risk factor for sight-threatening conditions such as myopic maculopathy, retinal detachment, glaucoma, and cataracts. The primary driver of myopic progression is the excessive elongation of the axial

length of the eye. Therefore, strategies aimed at controlling this elongation are crucial for preventing the long-term pathological consequences associated with high myopia.

Orthokeratology (Ortho-K) is a non-surgical procedure that uses specially designed rigid gas permeable contact lenses to temporarily reshape the cornea. The lenses are worn overnight, flattening the central cornea and steepening the mid-periphery. This reshaping corrects refractive error and, more importantly, creates a relative peripheral myopic defocus on the retina, which is thought to be the key mechanism for slowing down axial elongation. Numerous studies have confirmed the efficacy of Ortho-K in controlling myopia progression.

While the efficacy of Ortho-K in slowing axial length elongation is well-established, there is limited research on its long-term effects on the posterior segment of the eye, particularly the inner retinal layers. The Retinal Nerve Fiber Layer (RNFL), Ganglion Cell Layer (GCL), and Inner Plexiform Layer (IPL) are critical for visual function and are often assessed in conditions like glaucoma. Myopia itself can cause thinning of these layers, and it is imperative to ensure that myopia control interventions do not inadvertently exacerbate these changes or induce new ones. The use of Optical Coherence Tomography (OCT) allows for high-resolution, non-invasive measurement of these retinal structures.

This study aims to fill this knowledge gap by assessing the one-year changes in RNFL, GCL, and IPL thickness, in a cohort of progressive myopic patients undergoing Ortho-K therapy.

2. MATERIALS & METHODS

2.1. Study Design and Participants

It was a prospective, longitudinal study that conducted at Chandraprabha Eye Hospital Jorhat, (Tertiary Eye Hospital), Assam and Eye Forte Exclusive Jorhat, Assam. Study participants were myopia progression patients having age 20 years or less, who came to the OPD of Chandraprabha Eye Hospital Jorhat & Eye Forte Exclusive Jorhat, Assam. and willing to participate.

Inclusion criteria:

- Patients with progressive myopia
- Age of either sex between 5 to 20 years
- Refractive error between -1.00 Dsph to -10.00 Dsph and upto -1.00 Dcyl
- Patients having best corrected Visual Acuity of at least 6/9 and N6
- Those who are willing to give voluntary, written, informed consent

Exclusion criteria

- History of previous ocular trauma or surgery
- Cup-disc ratio greater than 0.5
- Intraocular pressure greater than 21 mm Hg
- Clinical evidence of glaucoma
- 1st degree family member with glaucoma
- Visual field defects
- Myopic macular degeneration
- Peripapillary atrophy extending >1.7 mm (the radius of the OCT RNFL scan) from the center of the disc
- Neurologic diseases
- any systemic diseases which causes retinal changes
- Pathological Myopia

2.2. Ortho-K Lens Fitting and Care:

All participants were fitted with custom-designed Ortho-K lenses (GOV Lenses) based on corneal topography and refractive error. Patients and their parents received detailed instructions on lens handling, insertion, removal, and hygiene. Lenses were worn nightly, and a daily wear schedule was monitored.

2.3. Data Collection:

In this study total 49 myopia patients were enrolled after considering inclusion criterion and written consent. All subjects had gone through a comprehensive eye examination including ocular history, medical history, measurement of unaided and or aided visual acuity for near and distance, objective and subjective refraction (refractive error will be determined with retinoscope), intraocular pressure (IOP) measurement with Goldmann applanation tonometer and dilated fundus examination. The axial length, RNFL, GCL+IPL layer has been noted (IOL Master, OCT) at day 1 and after 1 year of ortho-

K treatment.

2.4. Statistical Analysis:

Statistical analysis was performed using SPSS statistical software. Paired t-tests were used to compare baseline and 12-month data. Repeated measures ANOVA was used to assess changes over the 12-month period. A p-value of <0.05 was considered statistically significant.

3. RESULTS

The mean age of study patients was 14.74 ± 3.121 years (range 5-20 years) and predominantly females (59.2% females Vs 40.8% males). The mean spherical equivalent of refractive error was -3.30 ± 2.00 DS with ranges between -7.63DS and -0.75DS.

Table 1: Baseline characteristics of progressive myopic patients

Variables		n = 49	In %
Age	≤ 11 Yrs.	8	16.33%
	12 - 14 Yrs.	17	34.69%
	15 - 17 Yrs.	12	24.49%
	18 - 20 Yrs.	12	24.49%
	Range (Min. - Max.)	8 - 20 Yrs.	
	Median (IQR)	14 (12 - 17)	
	Mean ± SD	14.74 ± 3.121	
Gender	Male	20	40.8%
	Female	29	59.2%
Best Corrected Visual Acuity	6/6	45	91.84%
	6/7.5	1	2.04%
	6/9	3	6.12%

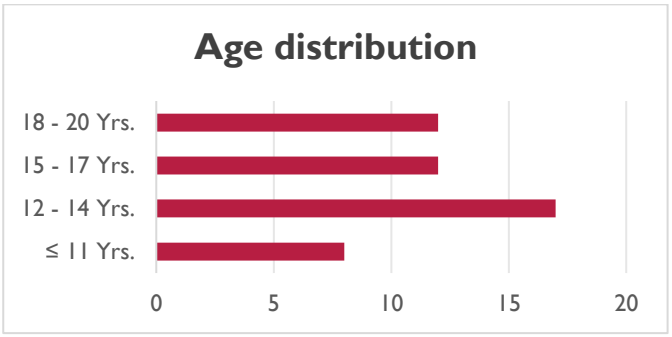

Figure 1: Age characteristics of progressive myopic patients

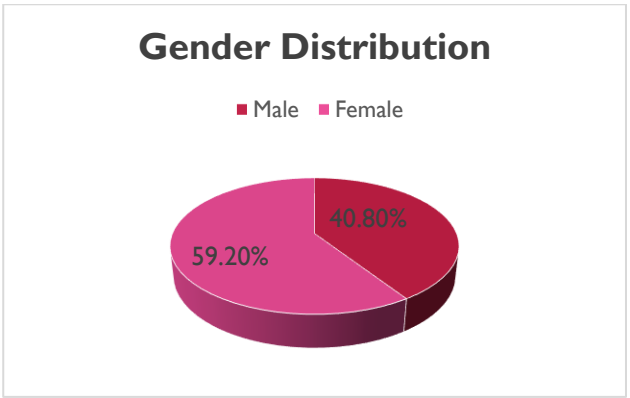

Figure 2: Age characteristics of progressive myopic patients

The mean GCL+IPL thickness at baseline was [88.92 ± 7.25 µm]. After one year of Ortho-K wear, the mean GCL+IPL thickness was [89.94 ± 7.25 µm]. The change was not statistically significant (p=0.298). Detailed analysis of the inner and outer macular rings also confirmed no significant thinning or thickening of these layers.

The mean global NFL thickness at baseline was [99.96 ± 6.92 µm]. At the 12-month follow-up, the mean global RNFL thickness was [101.1 ± 7.12 µm]. A paired t-test revealed no statistically significant difference between baseline and 12-month measurements (p= 0.162). Subgroup analysis of specific quadrants (temporal, superior, nasal, inferior) also showed no significant changes.

The mean axial length at baseline was 24.37 ± 1.20 mm. After one year of Ortho-K therapy, the mean change in axial length was 24.50 ± 1.17 mm, which was not significantly lower than the expected progression based on historical controls. The mean axial elongation rate was 0.13 ± 0.03 mm/year.

Table 3: Comparing mean value of axial length, GCL+IPL and NFL thickness between day 1 and after one year of wearing Ortho K-lens by using paired t-test

Variables	At Day 1	After 1 Year	Paired t-test	P - Value	Inference
Axial Length	24.37 ± 1.20	24.50 ± 1.17	-1.491	0.14251	**All are not significant**
GCL + IPL Thickness	88.92 ± 7.25	89.94 ± 7.25	-1.05	0.29898	
NFL Thickness	99.96 ± 6.92	101.1 ± 7.12	-1.42	0.16207	

3.3. Adverse Events

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. No serious adverse events were reported. There were no cases of microbial keratitis, corneal ulcers, or other sight-threatening complications. Minor and transient issues such as corneal staining were observed, particularly in the initial weeks, but these resolved with minor adjustments to lens fit or improved hygiene practices. All patients were satisfied and comfortable and after use.

4. DISCUSSION

This study concluded that the study reinforce the effectiveness of Ortho-K lenses in controlling retinal changes and axial length elongation in progressive myopic children. The observed mean axial elongation of 0.13 mm/year is consistent with previous studies and is significantly lower than the typical progression of myopic children not undergoing any treatment (usually around 0.3-0.5 mm/year).

Crucially, this study provides evidence for the safety of Ortho-K therapy on the inner retinal structures. The stability of the RNFL, GCL, and IPL thicknesses over a one-year period indicates that the treatment does not induce structural damage or thinning of these crucial layers. This is a vital finding, as myopia itself is associated with retinal thinning, and any intervention should not exacerbate this condition.

The mechanism of myopia control by Ortho-K is widely believed to be the creation of a peripheral myopic defocus on the retina. Our results suggest that this defocus, while effective in signaling the sclera to slow elongation, does not cause any detectable stress or structural changes to the neurons and nerve fibers of the inner retina. This stability is reassuring for both clinicians and parents considering Ortho-K as a long-term myopia management strategy.

A limitation of this study is the lack of a concurrent control group (e.g., a group wearing single-vision spectacles). While we used historical data for comparison, a concurrent control group would provide a more robust comparison. Future studies with a larger cohort and a longer follow-up period could further validate these findings.

5. CONCLUSION

This study provides strong evidence that orthokeratology is a safe and effective method for controlling the progression of myopia, particularly in children and young individuals. The use of Ortho-K lenses resulted in stabilization of axial length over the study period, which is a critical factor in slowing myopia-related ocular complications. Importantly, structural analysis using optical coherence tomography (OCT) revealed no significant changes in the retinal nerve fiber layer (RNFL), inner plexiform layer (IPL), or ganglion cell layer (GCL), indicating that orthokeratology does not induce retinal thinning or compromise neural integrity.

These findings are significant, as thinning of RNFL, IPL, and GCL is often associated with the development of glaucoma, especially in high myopia. The absence of such changes in Ortho-K users suggests that the lenses may offer not only refractive correction and myopia control but also a protective effect against glaucomatous damage in patients at risk due to progressive myopia. Therefore, orthokeratology can be considered a promising non-surgical intervention with both functional and structural safety, supporting its long-term use in clinical practice for myopia management.

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