Relationship Between Recovery Rate in Refractive Amblyopia and Ocular High-Order Aberrations: The HARD Pilot Investigation

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Background: *Higher-order aberrations (HOAs) are known to influence retinal image quality and may affect the functional improvement of amblyopic eyes. This study aimed to explore the association between best-corrected visual acuity (BCVA) recovery rate and specific HOA parameters obtained using a next-generation wavefront aberrometer.*
Methods: *A prospective case series was conducted involving children aged 3–7 years diagnosed with refractive amblyopia (Snellen equivalent <0.8). Each participant was monitored for a minimum of 6 months following complete optical correction. BCVA and HOAs were assessed with the iDesign aberrometer under non-cycloplegic and cycloplegic conditions at baseline, and at 3-month intervals thereafter. The relationship between BCVA improvement rate over 6 months and average HOA parameters was analyzed. Based on recovery velocity, subjects were categorized into fast and slow recovery groups for comparative analysis of HOA values.*
Results: *A total of 24 eyes from 12 children [mean age: 4.46 years (range, 3–6)] were evaluated. The baseline mean BCVA was 0.335 logMAR (Snellen equivalent 0.46), improving to 0.193 logMAR (Snellen equivalent 0.64) after 6 months of full optical correction. A significant correlation was identified between recovery rate and pre-cycloplegic tetrafoil values ($p = 0.045$). Children in the faster recovery group exhibited significantly lower baseline tetrafoil aberrations.*
Conclusion: *Specific HOA components, particularly tetrafoil aberrations measured by an advanced aberrometer, may serve as potential indicators of visual recovery speed in refractive amblyopia. These findings suggest that HOA assessment could contribute to the development of customized optical interventions, such as HOA-corrected contact lenses, for persistent cases of refractive amblyopia.*

BACKGROUND

Amblyopia is a common visual developmental disorder, affecting approximately 1.6%–3.6% of the general population and resulting primarily from inadequate foveal stimulation during the critical period of visual maturation[1–4]. Clinically, amblyopia is classified into three main types: refractive, strabismic, and deprivation amblyopia, among which the refractive type accounts for the majority of cases[5, 6]. Higher-order aberrations (HOAs) have been identified as a potential optical factor contributing to monocular idiopathic amblyopia[7, 8]. Vincent et al. reported significant differences in HOA values between amblyopic and fellow eyes, highlighting the possible optical basis for visual quality differences[9]. However, many earlier investigations were limited by small sample sizes and by the use of earlier-generation aberrometers, which produced inconsistent and variable results[1, 7–13].

Recent advances in optical imaging have enabled more precise evaluation of HOAs and their functional implications. A novel study employing an HOA-correcting, real-time, closed-loop adaptive optics perceptual learning system demonstrated significant improvements in both best-corrected visual acuity (BCVA) and contrast sensitivity

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among adolescents with refractive amblyopia (mean age, 16 years), suggesting that HOAs may influence the recovery dynamics of amblyopic eyes[14].

Wavefront aberrometry has also been widely applied in refractive surgery to optimize postoperative optical performance and enhance visual outcomes[15, 16]. The iDesign aberrometer (Abbott Medical Optics Manufacturing, Milpitas, CA, USA), based on the Hartmann–Shack principle, represents a new-generation system designed to minimize HOAs and improve postoperative visual quality through wavefront-guided refractive surgery. Studies have shown that procedures utilizing iDesign yield high levels of patient satisfaction and superior optical outcomes[15–21]. Owing to its higher spatial resolution and greater number of detection points, iDesign provides more precise and reproducible HOA measurements compared with previous devices[16].

To the best of our knowledge, no previous cohort study has investigated HOAs in pediatric amblyopic eyes using iDesign technology. We hypothesized that the HOA parameters measured by this advanced aberrometer may serve as predictive indicators of recovery velocity in refractive amblyopia. Therefore, the present prospective study aimed to evaluate the correlation between BCVA recovery rate and HOA metrics obtained with iDesign in children with refractive amblyopia following full correction of low-order aberrations during the critical developmental period.

MATERIALS AND METHODS

Patients

This prospective, single-center, longitudinal study was carried out at Chang Gung Memorial Hospital (Taipei, Taiwan) between August 2015 and December 2017. Children aged 3–7 years diagnosed with refractive amblyopia (Snellen equivalent <0.8) were enrolled.

Ophthalmic Examination

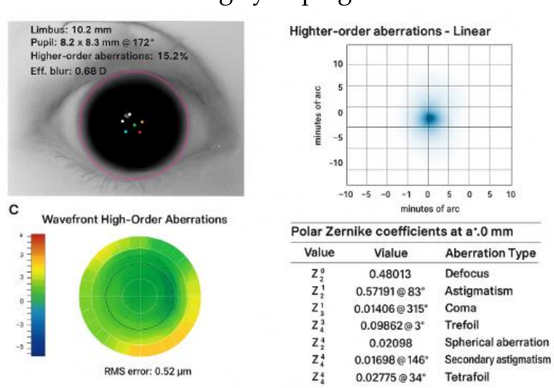
All participants underwent comprehensive ophthalmic evaluations at baseline and at regular 3-month follow-up intervals. The assessment included uncorrected distance visual acuity (UDVA), best-corrected visual acuity (BCVA), slit-lamp biomicroscopy, and objective refraction measurements performed before and after cycloplegia using an autorefractometer (Auto Ref/Keratometer-1a/ARK-1; Nidek Co., Ltd., Aichi, Japan). High-order aberrations (HOAs) were evaluated with the iDesign aberrometer (Abbott Medical Optics Manufacturing, Milpitas, CA, USA) under both non-cycloplegic and cycloplegic conditions. These measurements were obtained at baseline and every 3 months. In addition, fundus photography and axial length measurements were performed at baseline and every 6 months, while macular optical coherence tomography (OCT) (Optovue RTVue XR Avanti; Optovue Inc., Fremont, CA, USA) was conducted annually.

Cycloplegia was induced using 1% tropicamide and 10% phenylephrine, each instilled three times at 10-minute intervals. After at least 1 hour from the first instillation, adequate cycloplegia was confirmed by verifying a dilated pupil without a light reflex using a penlight.

HOA Measurement Parameters

HOAs were analyzed using a 4-mm pupil diameter on the iDesign system (Figure 1).

Figure 1: Illustration of data collection procedure. The figure presents the left eye of a 5-year-old female patient evaluated using the iDesign system at baseline following cycloplegia.



(A) Displays refraction parameters including dioptric power, total RMS error (µm), total effective blur (D), percentage of higher-order aberrations (HOA), and system status. (B) Demonstrates the point spread function along with HOA-derived effective blur (D). (C) Shows a twodimensional wavefront HOA map indicating the RMS error (μm). (D) Lists the polar Zernike coefficients (μm) calculated at a 4.0 mm pupil diameter.

Participants were instructed to blink immediately before each scan and to fixate on the target throughout measurement. Each eye was scanned five times, and the optimal data were selected by an experienced refractive ophthalmologist (C-F Liu) following the manufacturer's recommendations—preferring scans with larger pupil size, higher wavefront signal quality, and refractive values closest to objective cycloplegic refraction. The mean HOA value from the consecutive 3-month measurement intervals for each eye was used in the final statistical analysis.

Treatment Protocol

All patients received full optical correction based on the cycloplegic refraction determined by autorefractometry. Spectacles were remade whenever the difference between the current and measured refractive error exceeded 0.25 diopters (spherical or cylindrical). Parents were thoroughly instructed regarding full-time spectacle wear, and adherence was verified at every follow-up visit.

Grouping Criteria

Eyes were classified into fast and slow recovery groups based on BCVA improvement speed. The fast-recovery group included eyes showing BCVA improvement greater than or equal to the median value, while those with improvements below the median were assigned to the slow-recovery group.

Exclusion Criteria

Participants were excluded if they met any of the following conditions:

(1) Follow-up duration shorter than 6 months.
(2) Poor-quality or incomplete HOA data despite repeated measurements.
(3) Implementation of occlusion therapy on the fellow eye during follow-up.
(4) Refusal to accept full optical correction for personal reasons.
(5) Spectacle-wear compliance below 90% (as reported by parents during each visit).
(6) Diagnosis of strabismus or any other ocular pathology affecting visual function.

Statistical Analysis

All analyses were conducted using SPSS software (version 20.0; SPSS Inc., Chicago, IL, USA). The relationship between BCVA improvement and the mean HOA value for each eye was examined using Spearman's rank correlation coefficient (Spearman's ϱ).

For group comparisons, independent-samples t-tests and chi-square tests were employed for continuous and categorical variables, respectively. When expected frequencies were less than 5, Fisher's exact test was applied. Statistical significance was defined as a two-tailed p-value < 0.05.

RESULTS

A total of 56 eyes from 28 children were initially recruited for the study.

Among these, 16 eyes (8 participants) were excluded due to loss to follow-up after baseline evaluation, 4 eyes (2 participants) due to the presence of strabismus, 6 eyes (3 participants) because of persistently poor-quality HOA data despite repeated measurements, and 6 eyes (3 participants) owing to the initiation of occlusion therapy during follow-up.

After applying exclusion criteria, 24 eyes from 12 children were included in the final analysis. The mean (±SD) age of the participants was 4.46 ± 0.17 years (range: 3–6 years), comprising 12 boys and 12 girls. The demographic characteristics of the study population are presented in Table 1.

Correlation analysis revealed a significant negative association between the BCVA recovery rate and the tetrafoil value before cycloplegia (p = 0.045). Although the post-cycloplegic tetrafoil value also showed a negative trend, the correlation did not reach statistical significance (p = 0.077) (Table 2).

When participants were categorized according to BCVA recovery speed, the fast-recovery group exhibited significantly lower pre-cycloplegic tetrafoil values compared with the slow-recovery group (p = 0.032). Post-cycloplegic tetrafoil values in the fast-recovery group also tended to remain lower (p = 0.057). Additionally, this group demonstrated smaller values of total effective blur power (p = 0.084) and total root mean square (RMS) error (p = 0.061), although these differences did not reach conventional levels of statistical significance (Table 3).

Table 1: Demographic Characteristics and Optical Aberration Parameters of Patients (n = 24)

Parameter	Mean ± SD / Ratio
Age (years)	4.46 ± 0.85
Sex (Male: Female)	06:06
Baseline BCVA (LogMAR)	0.335 ± 0.160
BCVA after 6 months (LogMAR)	0.193 ± 0.156
Follow-up duration (months)	10.25 ± 2.54
Average iDesign sessions per patient	4.6 ± 0.86
Pre-cycloplegia measurements	
Total RMS error (μ)	1.8567 ± 1.2354
High-order RMS error (μ)	0.3729 ± 0.2050
High-order aberration (%)	8.219 ± 5.072
Total effective blur (D)	3.208 ± 2.144
High-order effective blur (D)	0.774 ± 0.511
Coma (μ)	0.0669 ± 0.0421
Trefoil (μ)	0.0577 ± 0.0227
Spherical aberration (μ)	0.0026 ± 0.0248
Tetrafoil (μ)	0.2713 ± 0.0170
Post-cycloplegia measurements	
Total RMS error (μ)	1.6129 ± 0.9975
High-order RMS error (μ)	0.5308 ± 0.2086
High-order aberration (%)	8.409 ± 4.038
Total effective blur (D)	2.925 ± 1.594
High-order effective blur (D)	0.917 ± 0.358
Coma (μ)	0.0674 ± 0.0459
Trefoil (μ)	0.0702 ± 0.0375
Spherical aberration (μ)	−0.0026 ± 0.0246
Tetrafoil (μ)	0.0221 ± 0.0117

BCVA – best-corrected visual acuity; D – diopter; LogMAR – logarithm of the minimum angle of resolution; RMS – root mean square; SD – standard deviation.

Table 2: Relationship between the rate of amblyopic eye recovery and higher-order optical aberrations

Parameter	Mean ± SD	rs	p-value
Before Cycloplegia			
Overall RMS error (µm)	1.86 ± 1.24	–0.13	0.54
Higher-order RMS error (µm)	0.37 ± 0.21	–0.16	0.46
Proportion of higher-order aberrations (%)	8.22 ± 5.07	0.24	0.26
Overall effective blur (D)	3.21 ± 2.14	–0.12	0.58
Higher-order effective blur (D)	0.77 ± 0.51	–0.01	0.97
Coma (µm)	0.067 ± 0.042	–0.11	0.62
Trefoil (µm)	0.058 ± 0.023	0.09	0.69
Spherical aberration (µm)	0.003 ± 0.025	–0.19	0.38
Tetrafoil (µm)	0.271 ± 0.017	–0.41	0.045
After Cycloplegia			
Overall RMS error (µm)	1.61 ± 1.00	–0.22	0.31
Higher-order RMS error (µm)	0.53 ± 0.21	–0.05	0.81
Proportion of higher-order aberrations (%)	8.41 ± 4.04	0.17	0.43
Overall effective blur (D)	2.93 ± 1.59	–0.19	0.39
Higher-order effective blur (D)	0.92 ± 0.36	–0.06	0.77
Coma (µm)	0.067 ± 0.046	–0.09	0.68
Trefoil (µm)	0.070 ± 0.038	–0.12	0.57
Spherical aberration (µm)	–0.003 ± 0.025	0.06	0.77
Tetrafoil (µm)	0.022 ± 0.012	–0.37	0.08

D – diopter; LogMAR – logarithm of the minimum angle of resolution; RMS – root mean square; SD – standard deviation. Spearman's correlation; $p < 0.05$ considered statistically significant.

Table 3: Comparative analysis between rapid and delayed recovery groups

Parameter	Fast recovery (n = 15 eyes)	Slow recovery (n = 9 eyes)	p-value
Demographic & Clinical Data			
Age (years, Mean ± SD)	4.40 ± 0.79	4.56 ± 0.98	0.666
Sex (Male: Female)	07:07	05:04	0.689[a]
Follow-up duration (months, Mean ± SD)	10.6 ± 2.69	9.56 ± 2.24	0.31
iDesign examinations per case (Mean ± SD)	4.6 ± 0.90	4.6 ± 0.86	1
BCVA improvement after 6 months (LogMAR, Mean ± SD)	–0.2266 ± 0.099	–0.0016 ± 0.142	< 0.001
Before Cycloplegia (4 mm zone)			

Overall RMS error (µm, Mean ± SD)	1.54 ± 0.84	2.39 ± 1.63	0.105
Higher-order RMS error (µm, Mean ± SD)	0.36 ± 0.17	0.39 ± 0.26	0.7
Proportion of higher-order aberration (%)	2.65 ± 1.44	4.14 ± 2.83	0.179
Overall effective blur (D, Mean ± SD)	2.65 ± 1.44	4.14 ± 2.83	0.101
Higher-order effective blur (D, Mean ± SD)	0.72 ± 0.45	0.86 ± 0.61	0.543
Coma (µm, Mean ± SD)	0.064 ± 0.041	0.072 ± 0.046	0.673
Trefoil (µm, Mean ± SD)	0.058 ± 0.021	0.058 ± 0.026	0.984
Spherical aberration (µm, Mean ± SD)	–0.004 ± 0.012	0.013 ± 0.036	0.2
Tetrafoil (µm, Mean ± SD)	0.021 ± 0.012	0.037 ± 0.020	0.032
After Cycloplegia (4 mm zone)			
Overall RMS error (µm, Mean ± SD)	1.32 ± 0.61	1.86 ± 1.26	0.061
Higher-order RMS error (µm, Mean ± SD)	0.54 ± 0.22	0.51 ± 0.20	0.758
Proportion of higher-order aberration (%)	9.26 ± 4.29	6.99 ± 3.32	0.189
Overall effective blur (D, Mean ± SD)	2.49 ± 1.11	3.65 ± 2.05	0.084
Higher-order effective blur (D, Mean ± SD)	0.94 ± 0.38	0.89 ± 0.35	0.758
Coma (µm, Mean ± SD)	0.063 ± 0.043	0.074 ± 0.052	0.573
Trefoil (µm, Mean ± SD)	0.055 ± 0.030	0.080 ± 0.048	0.359
Spherical aberration (µm, Mean ± SD)	–0.006 ± 0.011	0.004 ± 0.038	0.469
Tetrafoil (µm, Mean ± SD)	0.018 ± 0.007	0.029 ± 0.015	0.057

BCVA – best-corrected visual acuity; D – diopter; LogMAR – logarithm of the minimum angle of resolution; RMS – root mean square; SD – standard deviation.
$p < 0.05$ indicates statistical significance (independent t-test).
[a] Fisher's exact test.

DISCUSSION

To the best of our knowledge, this is the first study to evaluate the relationship between best-corrected visual acuity (BCVA) recovery speed and high-order aberration (HOA) parameters measured by the iDesign aberrometer in children with refractive amblyopia following 6 months of spectacle correction during the critical visual development period. It also represents the first investigation using iDesign data in preschool-aged children (3–7 years). Our results demonstrated a significant negative correlation between the recovery rate of amblyopic eyes and tetrafoil values measured before cycloplegia, with a similar but non-significant trend observed after cycloplegia.

Furthermore, the fast-recovery group exhibited lower tetrafoil, total RMS error, and total effective blur power than the slow-recovery group. These findings suggest that HOAs, particularly tetrafoil aberrations, may play an important role in determining the recovery rate of refractive amblyopic eyes.

The current study highlights tetrafoil aberration as a potential key factor associated with recovery speed. Previous research has shown that degradation of retinal image quality caused by HOAs may contribute to idiopathic amblyopia[7, 8]. For example, Prakash et al. demonstrated that tetrafoil, coma, and trefoil components accounted for the greatest variance between idiopathic amblyopic eyes and their normal counterparts[8]. However, inconsistencies across earlier studies may be attributed to differences in measurement technologies, including older-generation aberrometers with lower spatial resolution and varying analytical algorithms[1, 9, 10, 12, 13]. Our findings support the concept that HOAs—especially tetrafoil components—may influence neural visual development and recovery potential, emphasizing the need for larger-scale studies to confirm this association.

In our cohort, the baseline BCVA was moderately reduced (mean Snellen equivalent ≈0.4), reflecting clear refractive etiology. All participants received full optical correction with spectacles as the initial treatment and were monitored every 3 months. By averaging repeated HOA measurements across visits, we enhanced measurement reliability. Moreover, participants undergoing occlusion therapy were excluded to isolate the effect of optical correction alone. This ensured that low-order aberrations were fully corrected, allowing the residual impact of HOAs on recovery to be more accurately assessed.

We also observed that total RMS error and total effective blur power tended to correlate with BCVA recovery rate, though not significantly. Interestingly, the percentage of HOAs appeared higher in the fast-recovery group after cycloplegia, suggesting that the proportion of low-order aberrations was smaller in these eyes (Table 3). This implies that the elimination of low-order aberrations through full optical correction may still be a key driver of recovery speed. Future studies with larger sample sizes could further clarify the interplay between low- and high-order aberrations in visual rehabilitation.

Earlier investigations primarily used diagnostic devices such as the Complete Ophthalmic Analysis System (COAS; Wavefront Sciences Inc., Albuquerque, NM, USA), KR-1W (Topcon Co., Tokyo, Japan), or iTrace Visual Function Analyzer (Tracey Technologies, Houston, TX, USA). Some also employed older-generation instruments, including the WaveScan Wavefront System (AMO, Santa Ana, CA, USA) and Zywave II (Bausch & Lomb, Rochester, NY, USA), which are now largely obsolete[1, 7–10, 12, 13]. In contrast, the iDesign aberrometer provides superior measurement resolution, faster acquisition times, and greater tolerance for fixation instability, making it particularly advantageous for pediatric populations. Additionally, iDesign can be integrated with the VISX STAR S4 excimer laser (AMO, Santa Ana, CA, USA) to enable wavefront-guided HOA correction, potentially facilitating the development of customized HOA-corrected contact lenses for the management of refractory or idiopathic amblyopia.

Because accommodation can affect HOA measurements, it is generally recommended to assess children under cycloplegic conditions [(22)]. However, for refractive surgery planning, measurements are often performed without cycloplegia. To account for both conditions, we measured HOAs in both cycloplegic and non-cycloplegic states. A 4-mm pupil analysis zone was selected consistently, as this diameter is most relevant to image quality and visual perception [1, 7, 9, 10, 12, 13, 22–25].

Given the anxiety often experienced by parents when amblyopia is diagnosed, a reliable, noninvasive predictor of recovery rate is highly valuable in clinical practice. The findings from this pilot study suggest that iDesign-based HOA analysis may serve as a useful adjunctive tool for predicting visual improvement speed in children with refractive amblyopia.

This study has several limitations. First, patient cooperation was sometimes suboptimal due to young age, although repeated examinations were performed to improve reliability. Second, the sample size was small, as this was a pilot investigation. Despite these limitations, our findings provide preliminary evidence that HOAs may influence amblyopic eye recovery and offer important groundwork for future large-scale, prospective trials. Ultimately, this line of research may contribute to the design of customizable, HOA-corrected optical devices for amblyopia management.

CONCLUSION

In conclusion, this pilot study demonstrated that refractive amblyopic eyes exhibiting lower tetra foil aberration values, both before and after cycloplegia, tended to show faster visual recovery following spectacle correction. These findings suggest that iDesign-based high-order aberration (HOA) measurements can serve as a useful, noninvasive indicator of the recovery potential in pediatric refractive amblyopia. Moreover, the results indicate that HOA assessment without cycloplegia may provide clinically valuable information for monitoring and predicting visual improvement during amblyopia treatment.

DECLARATIONS

Ethical Approval

Ethical approval was obtained from the Institutional Review Board of the hospital (IRB no.: 103-4554B), and the study adhered to the Declaration of Helsinki. Written informed consent for participation and publication was obtained from the parents or legal guardians of all participants after full explanation of the research protocol.

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