Research Square

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Clinical performance of computer-aided fitting of orthokeratology lens in Chinese children

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Abstract

Objective:

To determine the clinical performance, after 1-month lens wear, of fitting of orthokeratology (ortho-k) lenses with the aid of a computer software.

Method:

Chinese myopic children, aged between 8 and 12 years with myopic spherical refractive error between − 4.00 D and − 0.75 D and refractive astigmatism within 1.50 D, were recruited. Lenses were fitted with the aid of a computer software (EyeLite, Procornea, Netherlands). Data analysed included lens performance, myopic reduction, visual acuity, corneal topography, and ocular health. The criteria for successful fit included residual myopia not exceeding − 0.50 D at the 1-month visit, unaided visual acuity (UVA) not worse than 0.1 LogMAR in either eye, lens centration not exceeding 1 mm (all directions), and no significant adverse corneal complications.

Results:

A total of 82 cases were included in the analysis. Initial mean cycloplegic spherical equivalent refraction (SER) was − 1.80 ± 0.69 D. At the 1-month visit, the first fit success rate was 91.5%. UVA was logMAR − 0.03 ± 0.10, with only mild corneal staining observed: central (4.9%), peripheral (25.6%). Lens imprint (mild) was observed in 2.4% of participants.

Conclusion:

A high first-fit success rate was achieved using the EyeLite software to assist lens fitting. Myopia was satisfactorily reduced, resulting in good and stable vision without any significant ocular adverse events.

Clinical trial:

This study was registered on the Chinese Clinical Trial Registry (Registration number ChiCTR2300072008), date of registration 31 May, 2023.

1 Introduction

Myopia has become a significant global public health challenge. It is characterized not only by an increase in refractive error and axial length (AL), but also by an elevated risk of various ocular complications, including myopic macular degeneration, retinal detachment, cataract, and open angle glaucoma [1,2]. Without effective control and intervention during adolescence, the likelihood of developing high myopia in adulthood rises considerably [2,3]. The impact of myopia extends beyond health consequences, imposing substantial economic burdens on society, families, and individuals over their entire life [3–6]. Investigating effective intervention methods is crucial for providing children with timely myopia control strategies to reduce the risk of developing high myopia[7,8]. Previous studies have

shown that orthokeratology (ortho-k), is effective and safe in slowing the progression of myopia in adolescents and is a commonly used method of myopia control [9,10].

In most Chinese hospitals, the fitting of ortho-k lenses primarily relies on the trial lens fitting approach, which is a more intuitive way to show the state of the lens on the surface of the patient's eye and to ensure that the curvature of the lens matches the curvature of the cornea [11]. However, this method presents several drawbacks, such as proper maintenance of the (various brands of) trial lens sets and storage space, which increase overhead and manpower costs. In addition, the success rate of fitting is dependent on the experience of the optometrist, and use of different brands and designs increase the time required for the optometrist to master how to fit each brand/design. Thus, outside of mainland China, many medical institutions have adopted digital fitting software as an alternative [12–15]. This approach collects comprehensive corneal data through corneal topography and the data is analyzed using customized computer software provided by the lens manufacturers. The software recommends optimal lens parameters based on the specific corneal characteristics [12,13]. Although this method is efficient and precise, some patients may still require modifications of parameters to achieve optimal fitting.

An increasing number of medical institutions in mainland China have recently begun to adopt software-based fitting for ortho-k lenses. Previous studies have shown that a computer software-assisted approach can reduce the number of trial lens fittings required [12–15]. Lenses fitted using this method have been shown to perform well in myopia control studies, with minimal adverse ocular problems [14,15]. Success rates reported in previous studies have relied primarily on the percentage of patients achieving satisfactory uncorrected visual acuity (UVA), residual refraction [14,15] or lens centration [16] during daytime. However, in actual clinical practice, clinicians should consider not only UVA, but also the centration and size of the treatment zone as well as corneal health. If only UVA is considered, the fitting success rate may be overestimated. This paper reports the clinical performance of a software-based fitting of ortho-k lenses after 1-month of lens wear. The purpose was to evaluate the success rate of achieving acceptable all efficacy and safety indicators and investigate the potential reasons for sub-normal fitting using software-aided fitting.

2 Materials and methods

2.1. Study design

This prospective, self-controlled study aimed to evaluate the success rate of a computer-assisted fitting of ortho-k lenses. Participants were prescribed ortho-k lenses and lens fitting was evaluated and first fit success rate determined after 1-month of lens wear. Following successful lens fit after 1-month of lens wear, participants proceeded to a 1-year myopia control study in which they were randomly assigned to wear lenses of two different compression factors. The study followed the principles of the Helsinki Declaration and was approved by the Ethics Committee of the West China Hospital of Sichuan University, and was registered with ClinicalTrials.gov. Written informed consent was obtained from all participants

and their guardians prior to enrollment. All participants were diagnosed with binocular myopia, and had no prior history of using myopia control interventions, including myopia control soft contact lenses or spectacles, ortho-k lenses, and atropine eye drops. Participants and their guardians were instructed to refrain from using any other myopia control methods during the study period.

All participants were fitted with ortho-k lenses and wore the lenses for at least 30 days. Baseline parameters were recorded prior to lens fitting and reexamined at 1 day, 1 week, 2 weeks, and 1 month after initiation of lens wear.

2.2. Participants

A total of 85 participants were recruited. Inclusion criteria included (1) myopic children of Chinese ethnicity, aged between 8 and 12 years; (2) best corrected visual acuity (BCVA) measured with ETDRS chart ≥ 20/25 in each eye; (3) spherical refractive error (SER) between − 4.00 D and − 0.75 D, with astigmatism ≤ 1.50 D (4) anisometropia ≤ 1.00 D; (5) average nightly sleep duration ≥ 8 hours and ortho-k lens wear ≥ 6 nights per week; (6) absence of ocular diseases or contraindications for contact lens fitting. Exclusion criteria included (1) abnormal visual function; (2) persistent or intermittent strabismus; (3) history of ocular trauma or surgery.

2.3. Lens fitting

The corneal topography data, refraction data, and horizontal visible iris diameter were inputted into computer software (EyeLite, Procornea, CooperVision company, San Ramon, CA, USA) to generate parameters of lens to order for each eye.

All participants were provided with a set of contact lens solutions, including a multi-purpose solution for daily cleaning and disinfection, a weekly enzymatic cleaner, saline, and lubricating eye drops.

Lens parameters, design and solutions prescribed are shown in Table 1.

Table 1
Specifications of orthokeratology lens and solutions used

Orthokeratology lens	**DreamLite (Procornea, Eerbeek, The Netherlands B.V.)**
Material	Boston XO (Bausch + Lomb, Bridgewater, NJ, USA)
Jessen factor	0.75 D
Dk	105×10^{-11} (cm2/s)[mLO2/(mL × hPa)]
Design	Spherical or toric lens
Back optic zone radius (mm)	7.50–9.93 (0.01 mm step)
Back optic zone diameter (mm)	6.0
Lens diameter (mm)	10.10 to 10.90
Central thickness (mm)	0.22
Solutions	
Daily care solutions	MeniCare Plus (Menicon Co., Ltd., Nagoya, Japan)
Weekly enzymatic cleaning	Menicon Progent (Menicon Co., Ltd., Nagoya, Japan)
Eye drops	Clear Contact Lens Eye Drops (Taiwan Biotech Co., Ltd. Taoyuan City, Taiwan)
Saline	Buffer Saline (Taiwan Biotech Co., Ltd., Taoyuan City, Taiwan)

All participants underwent a comprehensive ocular examination at enrollment,, which included the following assessments: ocular health examination, measurement of uncorrected and best-corrected visual acuity (UVA and BCVA), objective refraction (Topcon KR-1, Topcon Corporation, Tokyo, Japan) and subjective refraction (Topcon CV-3000, Topcon Corporation), cycloplegic refraction (Mydrin-P, Santen Pharmaceutical Co., Ltd., Osaka, Japan), corneal topography (Medmont E300, Medmont Pty Ltd., Nunawading, Victoria, Australia), corneal endothelial cell density (Topcon SP3000P, Topcon Corporation), intraocular pressure measurement (Canon TX-20, Canon Medical System, Tustin, CA, USA), axial length(ZEISS IOLMaster 700, Carl Zeiss Meditec, Oberkochen, Germany) and ocular higher-order aberration (COAS; Wavefront Sciences Ltd., Albuquerque, NM, USA).

2.4. Examination visits

All participants were required to wear their ortho-k lenses for at least 8 h (but not exceeding 9 h) for 6–7 days per week. During the lens dispensing visit, the examiner instructed both the participants and their parents on proper lens handling, including insertion, removal, and cleaning procedures. The fluorescein pattern of each lens in situ was assessed. Lenses would not be dispensed if the fluorescein pattern indicated a loose or tight fit, or if lens decentration exceeded 1 mm. All lenses ordered were delivered.

Follow-up visits were performed for all participants at 1 day, 1 week, and 1 month after lens wear, with all examinations conducted in the morning. After 1-month lens wear, the following information/data were collected for analysis: lens performance, myopic reduction, visual acuity, corneal topography, and ocular health. A lens fit was classified as unsuccessful if any of the following criteria was met during the 1-month visit: residual myopia more than − 0.50 D, UVA worse than 0.1 LogMAR, lens decentration exceeding 1 mm in any direction, or presence of a significant corneal complication. Corneal staining was graded according to the Efron scale [17], with separate statistical analyses performed for peripheral and central staining. If any serious adverse reactions were observed during the 1-month lens wear, lens wear was discontinued immediately. Participants were permitted to resume wear only after the adverse reactions had completely resolved and ocular health was restored to allow them to proceed to the myopia control study. Data from both eyes were recorded in this study, but only data from the right eye were used for statistical analysis.

2.5. Statistical analysis

Statistical analyses were performed using SPSS software (version 22.0, IBM Corp., Armonk, NY, USA). Descriptive statistics were presented as mean ± standard deviation (SD) (or median (range) for non-normally distributed data) for continuous variables and as numbers (percentages) for categorical variables. The normality of data distribution was assessed using the Shapiro-Wilk test. For comparing spherical equivalent refraction (SER) and other continuous parameters across different time points (baseline, 1 day, 1 week, 1 month), a one-way repeated-measures analysis of variance (ANOVA) or Friedman test was used, depending on data normality. Paired t-tests or Wilcoxon signed-rank tests were applied for post-hoc comparisons between specific time points if overall significance was found. The success rate of software fitting was calculated as the proportion of participants meeting all success criteria at the 1-month visit relative to the total number of participants who completed the 1-month follow-up. A p-value of < 0.05 was considered statistically significant.

3 Results

A total of 85 children who met the eligibility criteria were enrolled. Three participants subsequently withdrew due to non-compliance with lens handling. Eighty-two participants completed the 1-month follow-up. The flowchart of the study is shown in Fig. 1. At the 1-month follow-up visit, the first fit success rate was 91.5% (75/82).

SER significantly decreased from − 1.87 ± 0.71 D at baseline to 0.04 ± 0.38 D at the 1-month visit ($p < 0.001$). UVA improved from 0.20 ± 0.20 after first overnight lens wear to 0.03 ± 0.10 at the 1-month visit ($p < 0.001$). At the 1-month follow-up visit, 77 out of 82 participants (93.9%) achieved UVA of 0.1 logMAR or better. Among the five participants with UVA worse than 0.1 logMAR, four had residual refraction less than − 0.50 D. (The back optic zone radius (BOZR) was adjusted for these four participants to accommodate the residual refraction to allow them to proceed to the main myopia control study.)

At the 1-month follow-up visit, 80 out of 82 participants (97.6%) exhibited a treatment zone decentration distance of less than 1 mm. As shown in Fig. 2, two participants demonstrated decentration exceeding 1 mm, although their UVA was good at 1 week and 1 month, both achieving 0.1 logMAR or better. Notably, despite ideal initial fluorescein patterns, temporal decentration was observed after the first overnight wear. The practitioner adjusted the parameters for these two cases, resulting in effective improvements. No persistent corneal staining or indentation was observed in these participants with decentration.

According to the Efron scale, seven participants (8.5%) had mild peripheral corneal staining and one participant (1.2%) had central corneal staining at the baseline visit. At the 1-night, 1-week and 1-month follow-up visits, the incidence of peripheral corneal staining was 25.6%, 29.3%, and 25.6%, respectively, while the incidences of central corneal staining were 3.7%, 2.4%, and 4.9%, respectively (Table 2). The severity of all observed staining was not greater than Grade 1, which was not considered clinically significant. Consequently, none of the participants discontinued lens wear. Staining was not persistent, with no participant exhibiting staining at two consecutive follow-up visits. No corneal imprints were detected on the first day of follow-up. However, during the 1-week and 1-month follow-up visits, the incidence of corneal imprints was 2.4% (Table 2).

Table 2
Incidence of corneal staining and lens imprint at each visit during the first month of lens wear

	Staining (%)		**Central staining (%)**		**Imprint (%)**	
	Grade 1	**Grade 2**	**Grade 1**	**Grade 2**	**Grade 1**	**Grade 2**
Baseline	7 (8.5)	0	1 (1.2)	0		
First overnight	21 (25.6)	0	3 (3.7)	0	0	0
First week	24 (29.3)	0	2 (2.4)	0	2 (2.4)	0
First month	21 (25.6)	0	4 (4.9)	0	2 (2.4)	0

4 Discussion

With the increasing prevalence of myopia worldwide, the current mainstream approaches for myopia prevention and control include: sufficient daytime outdoor exposure, optical interventions, and low-concentration atropine eye drops. For children already diagnosed with myopia, optical correction is necessary, and combination therapies may be considered based on the progression of myopia [17]. Among optical treatments, ortho-k lens has been established as an effective method for myopia control. Cho et al. [16] reported that over a two-year period, the average AL elongation in the ortho-k group was 0.36 ± 0.24 mm, which was significantly less than the 0.63 ± 0.26 mm observed in a single-vision spectacle group ($p < 0.01$). Whether software-assisted fitting yields superior axial length (AL) control outcomes remains to be determined. A study by Wei et al. showed that the two methods of ortho-k fitting for myopic children aged 8–13 had the same effect on the control of AL elongation over one year, with

results of 0.20 ± 0.20 mm and 0.28 ± 0.20 mm respectively (p = 0.07) [15]. However, some studies have indicated that software fitting may yield superior AL control outcomes [14]. Based on existing evidence and clinical experience, both fitting methods can achieve satisfactory AL control in practical clinical settings.

In China, most ortho-k lens fitting primarily relies on the practitioners' experience. The process involves selecting trial lens parameters based on this experience, followed by evaluating the fluorescein pattern and post-wear corneal topography to finalize the lens prescription for ordering. For complex cases, multiple lens trials may be required to determine the optimal lens parameters, which is time-consuming and may cause eye discomfort, potentially leading to resistance against ortho-k lens use in myopic children. In addition, the management of trial lenses poses significant challenges for hospitals, encompassing procedures for lens disinfection, parameter verification, and regular replacement, thereby increasing operational complexity.

Several ortho-k lens manufacturers in China now offer computer-assisted fitting software that provides simulated fluorescein patterns and recommends lens ordering parameters. In previous studies, most definitions of fitting success rate were inconsistent, mainly using the percentage of UVA during daytime [15,18]. Other studies have considered lens centration as the primary criterion for successful fitting [19–21]. However, in actual clinical practice, practitioners must evaluate multiple factors beyond UVA, including lens positioning, corneal health, residual myopia, and other safety-efficacy indicators. Any abnormality or failure to meet expectations can easily cause dissatisfaction or even complaints from patients, particularly after approximately one month of lens wear—a period when ocular conditions tend to stabilize. Relying solely on UVA or centration criteria overestimates the success rate of fitting. Therefore, this study defined the fitting success rate based on real-world clinical requirements as the proportion of participants demonstrating acceptable outcomes in all of the following domains: visual acuity, residual myopia, corneal health, and lens positioning.

Previous studies have shown that corneal curvature and vision typically stabilize approximately 30 days after initiating ortho-k lens wear [18,22,23]. In this study, however, five participants exhibited unaided visual acuity (UVA) worse than 0.1 logMAR at the 30-day follow-up, which did not meet the expected outcome. Of these five participants, four had a residual refractive error greater than − 0.50D. The overall rate of good visual acuity (UVA ≤ 0.1 logMAR) was 93.9% (77/82), consistent with findings from earlier software-fitting studies [15,24].

For the four participants with an inadequate response, practitioners adjusted the base curve of the lens. Following this intervention, two participants achieved the target UVA (≤ 0.1 logMAR) by the two-month follow-up, while two participants still failed to meet the criterion. Notably, upon clinical assessment, four of these cases were attributed to an insufficient corneal response with the initial software-generated parameters, necessitating lens adjustment. The fifth case, despite an optimal fluorescein pattern, experienced delayed visual correction, suggesting that factors beyond lens fit, such as individual corneal biomechanics, may occasionally influence the initial response time. In clinical practice, a small

proportion of patients may not achieve satisfactory visual outcomes despite an optimal lens fit and a sufficient treatment zone. Some studies have reported that a flat-K and the corneal biomechanics may influence visual acuity and AL control after ortho-k treatment [25–27].

Previous studies have frequently used lens centration as a key criterion for defining the success of ortho-k lens fitting [19–21]. This assessment primarily evaluates whether the fluorescein pattern and corneal topography align with the ideal "bull's eye" pattern. In the present study, the rate of acceptable lens centration (decentration < 1 mm) at the 30-day follow-up was 97.6%, which is consistent with rates reported in most previous studies [19–21]. Some studies found that patients with lens decentration exceeding 1mm may continue lens wear without adverse effects on corneal health. Some studies have reported that a certain degree of decentration may provide better control of AL elongation and myopia [28–31]. Despite these observations, lens centration remains a fundamental and clinically recommended criterion for judging fitting success in actual ortho-k practice. Considering that the database of the EyeLite system was based on corneal shapes of children in Europe and the United States, it may be affected by different eyelid shapes and corneal parameters when used by Asian children. The first lens parameters in this study were directly generated using software without manual adjustment. However, in routine clinical practice, practitioners often make individualized adjustments, including incorporating a toric design or modifying the lens diameter, based on the patient's specific eyelid characteristics and corneal toricity to optimize treatment zone centration [32,33].

The health status of the cornea and conjunctiva requires close monitoring throughout the entire period of ortho-K lens wear. The most common eye adverse event associated with ortho-k was corneal staining [34–37]. In the present study, corneal staining occurred intermittently, with the majority of cases being peripheral staining and only a minority showing central staining. The incidence of the peripheral staining ratio was less than 30%, the central staining ratio was less than 5%, with Efron grade 1 severity, which was close to the ratio in previous trial lens fitting studies. Occasional, mild staining typically does not necessitate clinical intervention, and no participants in this study exhibited persistent central or peripheral staining. Previous research has indicated that peripheral punctate staining may be associated with pre-existing conditions such as misdirected lashes, lid margin disorders, lagophthalmos, sensitivity to contact lens solutions or care products, as well as suboptimal Ortho-K lens fitting [36].

This study also had certain limitations. The generalizability of the findings is constrained by the specific demographic and refractive characteristics of the enrolled participants. This study evaluated the performance of the EyeLite ortho-k lens fitting system in children aged 8–12 years with low-and-moderate myopia. Future investigations should aim to validate these results in populations beyond the current study's scope, including individuals over 12 years of age, those with moderate to high myopia, or astigmatism exceeding 1.50 D.

As noted in previous studies utilizing software for ortho-k lens fitting, the success rate was primarily defined based on either lens centration or UVA. No matter which fitting method was used, the fitting result that meets the expectations of patients and practitioners should encompass a combination of

acceptable visual acuity, optimal lens centration, and good corneal health. Although some studies have reported that patients with lens decentration of more than 1 mm may continue lens wear without issues provided their vision is satisfactory and the cornea remains healthy [30,38], such cases do not meet the comprehensive criteria for a successful fit as defined in this study. However, it is important to recognize that with any fitting approach, whether using conventional trial or software-assisted fitting, a proportion of patients may not achieve an ideal outcome. The reasons for suboptimal results may include lens decentration, inadequate visual correction, corneal compromise, or a combination of these factors.

5 Conclusions

In this study, the first-lens success rate achieved through software-assisted fitting was 91.5%, indicating that all key outcome measures, including uncorrected visual acuity, residual myopia, lens centration, and corneal health, met the predefined clinical criteria. In China, many experienced practitioners prefer conventional trial fitting, often expressing limited confidence in software-generated lens parameters. The EyeLite ortho-k lens fitting system used in this study had a high success rate without manual parameter adjustment. It is plausible that further customization accounting for individual anatomical variations, such as eyelid morphology and corneal topography, could enhance the lens-eye compatibility and potentially improve outcomes.

Declarations

Competing Interests

The authors declare that they have no conflicts of interest or personal relationships to disclose.

Consent to Participate

Informed consent to participate was provided by all participants.

Consent to publish

The authors affirm that patients signed informed consent regarding publishing their data.

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Author Contribution

WM: Conceptualization (lead) ; data curation (lead); formal analysis(lead) ; methodology(lead) ; writing – original draft (lead).CCX: Data curation (supporting); formal analysis (supporting); investigation (equal).BY: Formal analysis (supporting); investigation (equal).LQL: Conceptualization (supporting); funding acquisition (lead); project administration (lead).PC: Conceptualization (equal); supervision (lead); review and editing (lead); resources (lead).

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Figures

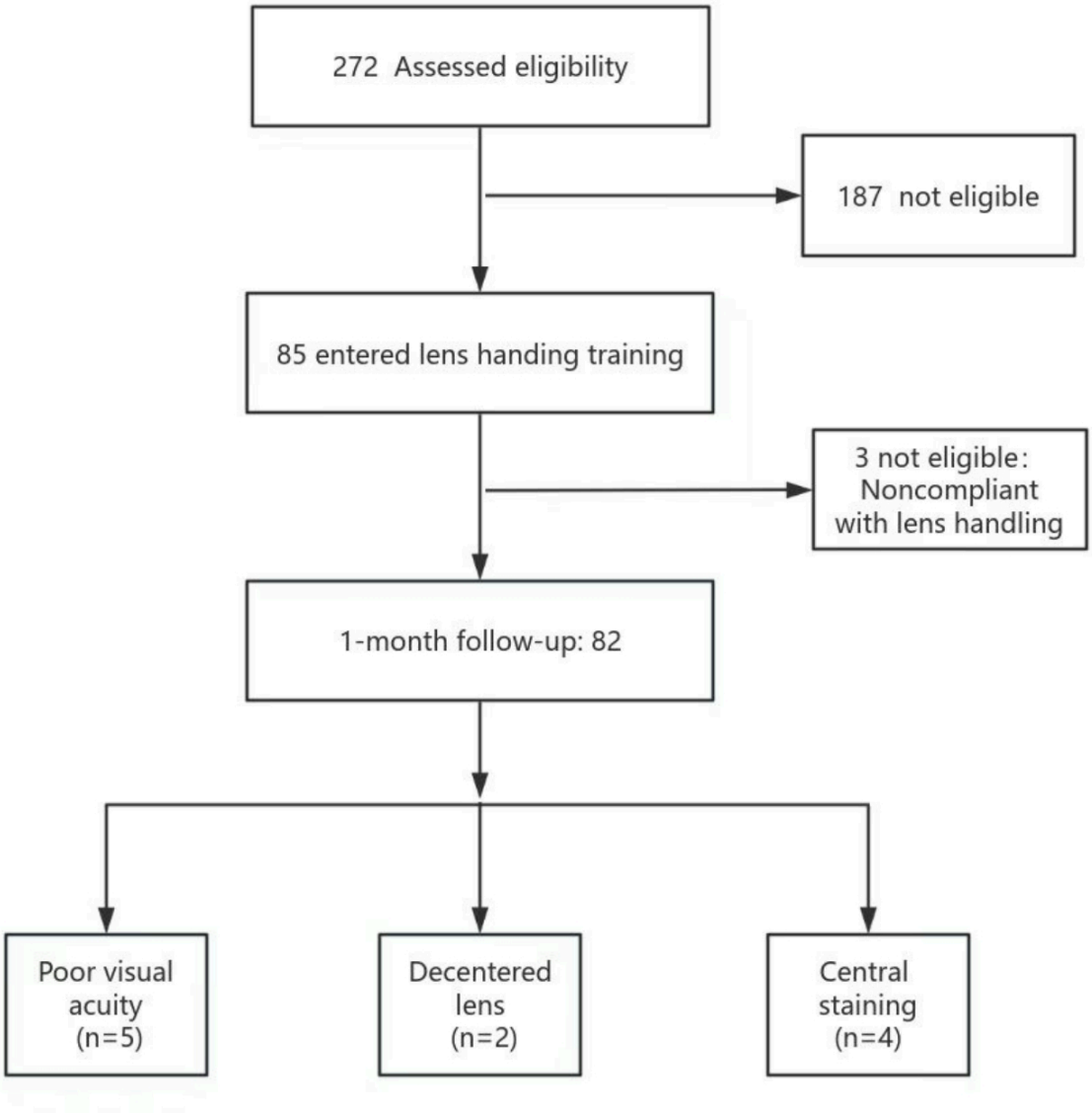


Figure 1

Flow diagram of the 1-month study.

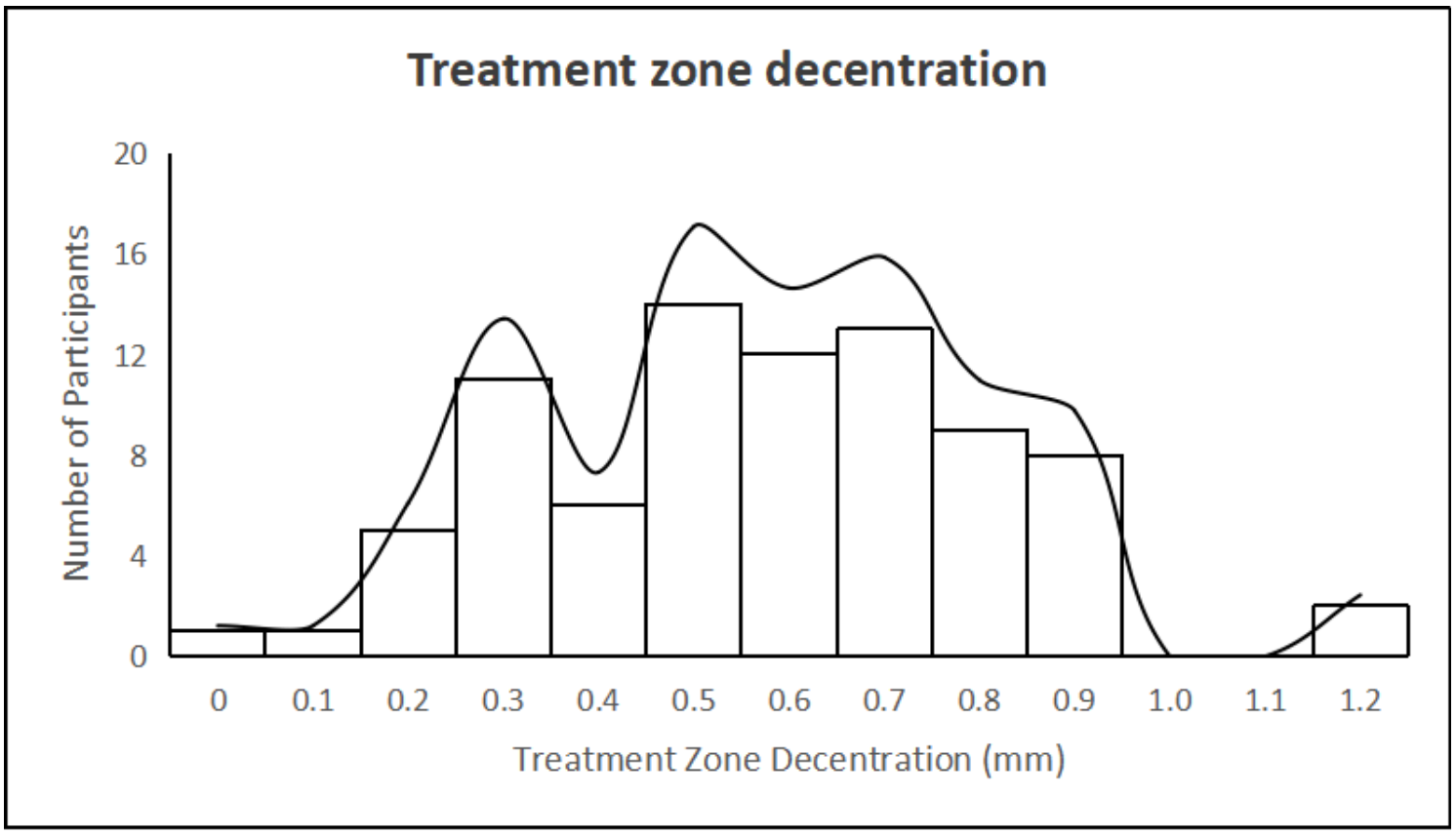


Figure 2

Lens decentration observed in 82 participants after 1-month lens wear