Study Protocol

Randomized Controlled Clinical Study on the Effectiveness and Wearing Safety and Comfort of Photolithographic Microstructure Myopia Management Lenses in Myopia Prevention and Control among Children and Adolescents

Research Institution	Shanghai Eye Diseases Prevention &Treatment Center
Project Leader	Wei Xu, Xiaofeng Zhu
Sponsoring Institution	Nantong Nuotong Yimu Medical Technology Co., Ltd
Project No.	QX-2025-A-020
Ethics Number	IIT2025-029-RE-01
Date	December 10, 2025

Indications:

Ages 6-14; after cycloplegia, both eyes with spherical equivalent between -0.50D and -4.00D; cylindrical lens ≤1.50D in both eyes; anisometropia ≤1.50D; best corrected visual acuity ≥5.0; subjects willing to undergo treatment.

Study Product:

Photolithographic microstructure myopia management lenses

Study Objectives:

Primary objective: To evaluate the effectiveness of different photolithographic microstructure myopia management lenses in controlling myopia progression in children and adolescents, as well as the safety and comfort of wearing them; to explore effective defocus microlens designs for myopia control and the feasibility of applying photolithographic microstructure myopia management lenses in myopia prevention and control.

Secondary objective: To understand and analyze the diagnosis and treatment status of myopia prevention and control in children and adolescents and related influencing factors such as age at onset, gender, wearing duration, and visual habits.

Study Design:

1. Prospective, single-center, randomized, double-blind controlled clinical trial.

2. Initial and follow-up visits conducted by designated optometrists/physicians who will record patients' basic information, visual acuity, objective and subjective refraction results before and after cycloplegia, axial length, and other biometric and special examination data.

3. Subjects aged 6 years and older, diagnosed by investigators as suitable for photolithographic microstructure myopia management lenses.

4. Observation period of 1 year with daily wear of at least 12 hours. Baseline at enrollment and follow-ups every 3 months thereafter. The right eye will be the study eye. Observations include visual acuity, spherical equivalent refraction, axial length, corneal curvature, pupil diameter, multispectral refraction topography (defocus measurement), amplitude of accommodation, contrast sensitivity, etc.

Study Duration:

18 months total, including a 6-month recruitment and screening period and a 12-month trial period.

Sample Size:

This is a non-inferiority study comparing three experimental groups with a control group at a 1:1:1:1 ratio. The Dunnett method will be used to control the overall type I error, with a significance level $\alpha=0.0094$ (one-sided) for the primary efficacy endpoint hypothesis test.

Reference is made to the study by Professor Zhou Xingtao and Professor Chen Zhi's team at Fudan University Eye and ENT Hospital on the Starfun Control Plano Defocus Lens (American Journal of Ophthalmology, AJO, 2024). The 12-month difference in spherical equivalent (SE) progression between the Starfun Control Plano Defocus Lens (highly aspherical lenslets, HAL group) and ordinary single-vision plano lenses (SV group) was 0.21D (SV group -0.25D vs. HAL group -0.04D), representing the core efficacy difference of Starfun Control technology compared to no myopia control treatment. Based on clinical statistical principles for non-inferiority margins and expert recommendations, the non-inferiority margin δ is set at -0.12D.

Accordingly, this study sets the non-inferiority margin δ = -0.12D, with a nominal α of 0.0094 (one-sided) for any paired test, standard deviation SD = 0.18D, and power of 85%. Randomization is at a 1:1:1:1 ratio. Using PASS software, the minimum sample size per group is 53 subjects. Considering an approximate 15% loss to follow-up, each treatment group requires 63 subjects, totaling 252 subjects.

Non-inferiority is established if the lower bound of the two-sided 98.12% confidence interval for the change from baseline in cycloplegic refraction spherical equivalent (SE) in any experimental group compared to the control group is greater than δ.

Inclusion Criteria:

1. Age 6-14 years;

2. After cycloplegia with 1% cyclopentolate hydrochloride eye drops (Saifeijie), both eyes with spherical equivalent between -0.50D and -4.00D; cylindrical lens ≤1.50D; anisometropia ≤1.50D; best corrected visual acuity better than 5.0;

3. No use of multifocal glasses, orthokeratology lenses, defocus soft lenses, progressive lenses, atropine eye drops, red light therapy, acupuncture, or other myopia control methods within the past 3 months;

4. Subject willing to undergo treatment and legal guardian has signed informed consent.

Exclusion Criteria:

1. Diagnosed constant strabismus;

2. Diagnosed pathological myopia;

3. Other congenital eye diseases;

4. Other reasons deemed unsuitable for inclusion by the study physician.

Study Endpoints:

Non-inferiority

Primary Endpoint:

Change from baseline in cycloplegic refraction spherical equivalent (SE, diopters)

Secondary Endpoints:

Change from baseline in axial length (AL, millimeters)

Change from baseline in choroidal thickness (ChT, micrometers)

Exploratory Endpoints:

Other biological parameters including anterior chamber depth (ACD), horizontal and vertical corneal curvature (CC), corneal diameter (white-to-white distance, WTW), central corneal thickness (CCT), pupil size, multispectral refraction topography (MRT), amplitude of accommodation, contrast sensitivity, etc.

Best corrected visual acuity (BCVA)

Daily lens wearing time and other data collected via questionnaire

Safety:

Safety, comfort, and acceptability of lens wear as reported by subjects through questionnaires