December 29, 2025

Informed Consent Form

- Subject Information Page

Protocol Title: A Study to Evaluate the Efficacy of the Dynamic Spatiotemporal Optical Film (S.T.O.P® KIT) in Delaying Ocular Axial Growth in Children with Low HyperopiaPrincipal

Investigator of This Center: Wang Xiaojuan

This Center: Shanghai General Hospital

Sponsor: Zhongjing Weishi (Suzhou) Optical Technology Co., Ltd.

Dear Subject:

You are invited to participate in a study evaluating the use of the Dynamic Spatiotemporal Optical Film (S.T.O.P® KIT) for delaying ocular axial growth in children with low hyperopia. Please read this Informed Consent Form carefully and make a prudent decision on whether to participate in this study. Participation in this study is entirely voluntary, but you may only enter the study after signing this Informed Consent Form. When your study doctor or researcher discusses this form with you, you may ask them to explain any parts you do not understand. We encourage you to fully discuss your decision to participate with your family and friends. You have the right to refuse to participate in this study or withdraw from it at any time without penalty or loss of your entitled rights. If you are currently participating in any other study, please inform your study doctor or researcher. The background, purpose, research process, and other important information about this study are as follows:

I. Research Background

As the focus of myopia management shifts from simply controlling myopia progression to comprehensive long-term risk management, delaying the age of myopia onset has gradually become a key part of clinical myopia prevention and control practices. Timely identification of early signs of myopia and implementation of intervention measures are particularly crucial, especially for children at high risk of early onset and rapid progression once myopia develops.

II. Research Purpose

To compare the efficacy and safety of the Dynamic Spatiotemporal Optical Film (S.T.O.P® KIT) versus conventional single-vision glasses (control group) in preventing myopia onset in children with low hyperopia over a 12-month period.

III. Research Process

1. How Many People Will Participate in This Study?

Approximately 180 individuals will participate in this study conducted across 3 different research/in medical institutions (Shanghai General Hospital, The First Affiliated Hospital of Zhengzhou University, Yantai Yuhuangding Hospital), with 60 participants enrolled at this hospital.

2. Grouping Method

This is a two-arm, randomized controlled trial. The experimental group will consist of 30 participants, who will receive 2 spectacle frames, 4 lenses, and 8 S.T.O.P® KIT optical films for alternating weekly use. The control group will consist of 30 participants with no intervention measures.

3. Research Procedures

If you agree to participate in this study, please sign this Informed Consent Form. The primary and secondary outcome measures include:

1. Changes in ocular axial length from the baseline refraction visit for each experimental and control group at each follow-up visit.
2. Differences in changes in cycloplegic objective refraction (spherical equivalent) from baseline for each experimental and control group at each follow-up visit.
3. Differences in visual function between the experimental and control groups.

Procedures/Data	Baseline	3 Months	6 Months	9 Months	12 Months
Informed Consent Form	√	-	-	-	-
Eligibility Criteria Verification	√	-	-	-	-
Demographic Data	√	-	-	-	-
Medical History/Ocular History/Family History/Living	√	-	-	-	-

Environment					
Compliance Assessment	-	√	√	√	√
Spectacle Fitting	√	*	*	*	*
Visual Acuity	√	√	-	-	-
Slit Lamp Examination (Uncorrected): Ocular Assessment	√	*	*	*	*
Intraocular Pressure	√	*	*	*	*
Ocular Axial Length Measurement	√	√	√	√	√
Cycloplegia	√	√	√	√	√
Automated Refraction (Objective Refraction)	√	√	√	√	√
Subjective Refraction	√	†	†	†	†
Cover Test at 3m and 40cm	√	-	-	-	-
Adverse Event Assessment	√	√	√	√	√

4. Inclusion and Exclusion Criteria

Inclusion Criteria:

1) Age: 6-10 years old.
2) Spherical equivalent ≥ +0.75 D.
3) Anisometropia ≤ 1.50 D.
4) Astigmatism ≤ 1.50 D.
5) No participation in other myopia prevention and control studies or use of other myopia control methods (including low-concentration atropine eye drops, defocus glasses,

orthokeratology lenses, multifocal soft contact lenses, etc.) within 3 months.

6) Best Corrected Visual Acuity (BCVA) of both eyes ≥ 0.8 using a standard logarithmic visual acuity chart.

7) Ability to wear spectacle frames during near work for at least 6 hours per day.

Exclusion Criteria:

1) Patients with strabismus.

2) Patients with abnormal stereopsis.

3) Comorbidity with other ophthalmic diseases, including developmental abnormalities affecting visual function and refractive status.

4) Previous ocular surgery history.

5) Previous receipt of other myopia control treatments (including orthokeratology lenses, multifocal soft contact lenses or spectacle frames, drug therapy [atropine], visual training, etc.).

6) Current use of medications that may affect pupil size and ocular surface function.

7) Comorbidity with other systemic diseases that may affect visual function or refractive status.

8) Family history of hereditary ophthalmic diseases.

9) Other conditions deemed unsuitable for study participation by the researcher.

5. How Long Will the Study Last?

The overall study is planned to last 18 months, and your individual participation will last approximately 12 months. You may withdraw from the study at any time without losing any of your entitled benefits. However, if you decide to withdraw during the study, we encourage you to consult with your doctor first. If you experience a serious adverse event, or if your study doctor determines that continued participation is not in your best interest, he/she may decide to withdraw you from the study. The sponsor or regulatory authorities may also terminate the study during its conduct. Your withdrawal will not affect your normal medical care.

IV. Risks and Benefits

1. What Are the Risks of Participating in This Study?

The potential risks of participating in this study are as follows. You should discuss these risks with your study doctor or, if you wish, with your regular healthcare provider.A small number of children may experience symptoms such as dizziness, glare, or blurred vision during the initial

wearing period. Most children can adapt independently within one week of wearing the device. If adaptation is extremely difficult, please notify your study doctor promptly.No other known risks exist at present.

2. What Are the Benefits of Participating in the Study?

Direct Benefits: If you agree to participate in this study, you may potentially delay your child's ocular axial growth through the S.T.O.P® KIT optical film, but we cannot guarantee this outcome.Potential Benefits: We hope that the information obtained from your participation in this study will benefit you or other patients with similar conditions in the future.For participants in the control group who complete all follow-up visits as required, a pair of dynamic optical films and custom-made glasses matching their diopter will be provided free of charge upon completion of the trial.

3. Insurance Policy

The S.T.O.P KIT Dynamic Optical Film is a medical-grade optical film product specifically designed for optical correction scenarios. Its core application method is to be attached to the front surface of ordinary single-vision glasses, providing users with dynamic visual optimization effects through special optical structures and technical principles, which is widely applicable to daily vision correction and specific visual demand scenarios.From the perspective of product safety, the materials used have undergone multiple tests. Under the premise of correct operation and normal use, it will not interfere with the optical performance of the lenses themselves, nor will it cause serious safety risks such as eye damage or visual abnormalities. There is also no possibility of personal injury or significant property loss to users due to product quality issues.Based on the above safety characteristics and risk assessment results, combined with the conventional service policies of similar low-risk medical optical auxiliary products in the industry, there is currently no separate special insurance policy provided for the S.T.O.P KIT Dynamic Optical Film.

V. Confidentiality of Personal Information

During the study, for research purposes, the research team may need to access your medical history and collect necessary personal information such as your past medical records and test results. By signing this Informed Consent Form, you authorize the research team to contact other healthcare providers who have rendered you medical assistance to obtain necessary medical information related to you during the provision of their healthcare services. Only members of the

research team will have access to your medical information and be able to identify you. Subject to compliance with confidentiality principles and relevant regulations, the Ethics Committee and regulatory authorities may review your original medical records to verify clinical trial data.During the study, we will collect your personal information and research data. To protect your privacy, personally identifiable data such as your name and contact information will be coded to prevent anyone from identifying you. If the study results are published in medical journals or presented at scientific conferences, no personally identifiable information will be disclosed.You may revoke your permission for the use and sharing of your personal information at any time by contacting your study doctor. If you do so, you will no longer be able to remain in the study. Afterward, the researchers will not collect new health data that can identify you. However, the health data already collected may continue to be used and shared with other researchers as described in this Informed Consent Form. To ensure the scientific validity and credibility of the study, you may not be able to access certain study-related records until the study is completed. Upon completion of the study, you may request to view the health data collected during the study from your study doctor and may raise any concerns regarding errors in your personal information.Your information will not be reused for any purposes other than this study.

□ I agree that my research data may be reused for future scientific research.

□ I only agree that my research data will be used for this study and shall not be reused in the future.

(Please handwrite the text of your selected option)

VI. Study-related Costs and Compensation

Costs of Study Drugs/Devices and Related Examinations

All spectacle frames, lenses, and replacement optical films provided in this trial will be free of charge. Routine fees will be charged for ophthalmic diagnostic and treatment items.

VII. Subject Rights and Relevant Notes

1. Your Rights

Your participation in the study is voluntary throughout the entire process. If you decide not to participate in this study, it will not affect your entitlement to other treatments. You have the right to withdraw from the trial at any stage without discrimination or unfair treatment, and your corresponding medical care and rights will not be affected. If there are updates to information that

may affect your rights and safety, you will be required to sign an updated version of the Informed Consent Form to obtain the new information.

2. Relevant Notes

As a subject, you are required to provide truthful information about your medical history and current physical condition; inform the study doctor of any discomfort detected during the study; refrain from taking restricted medications or consuming restricted foods as advised by the doctor; and inform the study doctor of any recent or ongoing participation in other studies.

VIII. Contact Information for Obtaining Information

If any important new information arises during the study that may affect your willingness to continue participating, your doctor will notify you promptly. If you have any questions about your research data, or if you wish to know the findings of the study after its completion, you may raise any questions about the study at any time and receive corresponding answers. Please contact Wang Xiaojuan at phone number 15852260552.The study has been reviewed and approved by the Ethics Committee. If you have any questions related to your rights/benefits, or if you wish to report difficulties, dissatisfaction, or concerns encountered during the study, or provide opinions and suggestions related to the study, please contact the Medical Ethics Committee of Shanghai General Hospital at phone number: 021-36126254.

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Informed Consent Statement:I have been informed of the purpose, background, process, risks, benefits, and other aspects of this study. I have had sufficient time and opportunity to ask questions, and I am satisfied with the answers provided. I agree to participate in this study.I have also been informed of who to contact if I have questions, wish to report difficulties or concerns, provide suggestions for the study, or obtain further information or assistance related to the study.I understand that I may choose not to participate in this study or withdraw from it at any time during its conduct without providing any reason.I have been informed that if my condition worsens, or if I experience a serious adverse event, or if my study doctor determines that continued participation is not in my best interest, he/she may decide to withdraw me from the study. The sponsor or regulatory authorities may also terminate the study during its conduct without my consent. In such cases, the study doctor will notify me promptly and discuss other options with me.I will receive a copy of this Informed Consent Form, which includes the signatures of myself and the researcher.

I understand that my personal information will be used for participation in this study, and I agree to the use and processing of my personal information and/or biological samples for the purposes described in this Informed Consent Form.

□ Agree □ Disagree, unable to participate in this study.

Subject's Signature: _____ Date: _____

Guardian's Signature: _____ Relationship with Subject: （ ） Date: _____

(Required if the subject is incompetent/has limited capacity for conduct; the guardian must sign and date)

Impartial Witness's Signature: _____ Date: _____

(Required if the subject is unable to read this Informed Consent Form; an impartial witness must attest that the researcher has informed the subject of all contents of the Informed Consent Form, and the subject has expressed willingness to participate.The impartial witness must sign and date)

Researcher's Signature: _____ Date: _____

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Simple Explanation of Clinical Trial Informed Consent for Children Aged 8-10

Dear Kiddo,

Hello! We'd like to invite you to join a special study about "magic optical films." The goal is to protect our eyes and keep myopia from coming too soon. This study has been approved by the hospital's special department, so it's totally safe!

I. What Will We Do?

This study is being carried out together by 3 hospitals, including Shanghai General Hospital. About 180 children will take part, and 60 of them will be from our hospital.

We'll split into two groups, just like grouping up for a game:

- One group (30 kids) will get 2 spectacle frames, 4 lenses, and 8 "magic optical films" to wear alternately every week.
- The other group (30 kids) will wear their usual regular glasses, no extra steps needed.
- Your participation will last about 12 months. During this time, you'll visit the hospital a few times for eye checks—specifically at the start, 3 months later, 6 months later, 9 months later, and 12 months later. At each visit, we'll do these things:
- Check how good your eyesight is;
- Measure your eye axis (it's like a little ruler inside the eye that tells us if the eye has grown longer);
- Shine a special light to check if your eyes are healthy;
- Ask if you feel any discomfort while wearing the glasses.

II. How Might Joining the Study Feel?

1. Possible Minor Discomforts

A very small number of kids might feel a bit dizzy, see things a little too bright, or have blurry vision when they first start wearing the glasses with "magic optical films." But most kids will get used to it within a week. If you keep feeling uncomfortable, tell your mom or dad, and they can let the doctor know.

2. Possible Benefits

- Your eyes might not turn nearsighted as quickly;
- Every time you go for an eye check, the doctor will carefully examine your eyes and give

you tips on protecting them;

- You'll also be helping other kids—so more children can keep their eyes healthy!

III. Your Little Rights

- You can choose to join or not join—either way is totally fine;
- If you don't want to continue during the study, just tell your mom or dad anytime. They'll talk to the doctor, and no one will blame you;
- Doctors and nurses will keep your little secrets safe—they won't tell anyone your name or test results;
- If there's any new news about the study, the doctor will tell your mom or dad right away, and they'll pass it on to you.

IV. Who to Ask If You Have Questions?

If you feel any discomfort or have questions during the study, ask your mom or dad to call Dr. Wang Xiaojuan at 15852260552.

If you think this study sounds fun and want to join, tell the doctor together with your mom or dad!

(The space below is for mom and dad to sign—kids don't need to sign!)

Guardian (Mom/Dad) Signature: _____ Date: _____

Researcher (Doctor) Signature: _____ Date: _____