

**A Single-Center Clinical Study to Evaluate the
Efficacy and Safety of a Suture-Free Ophthalmic
Hydrogel for Ocular Surface Tissue Adhesion Therapy**

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Informed Consent Form

Study Title: A Single-Center Clinical Study to Evaluate the Efficacy and Safety of a Suture-Free Ophthalmic Hydrogel for Ocular Surface Tissue Adhesion Therapy

Clinical Protocol Number:

Study Institution: Eye Hospital of Shandong First Medical University
(Shandong Eye Hospital)

Principal Investigator: Shi Weiyun

Subject Initials: _____ Subject Screening Number: _____

Dear Subject,

We sincerely invite you to participate in a clinical study. This study titled " A Single-Center Clinical Study to Evaluate the Efficacy and Safety of a Suture-Free Ophthalmic Hydrogel for Ocular Surface Tissue Adhesion Therapy", is sponsored and initiated by Shi Weiyun. The study will be conducted at Eye Hospital of Shandong First Medical University, and the study protocol has been approved by the institutional ethics committee of this center.

To assist you make an informed decision, this informed consent form aims to provide you with detailed information about the study,

including the purpose, process, potential benefits, and risks of the treatment. This document explains how your medical information will be used and who may have access to it. You will receive a copy of this informed consent form for your reference or to seek advice from others.

The study doctor or research staff will answer all your questions regarding this informed consent form or the clinical study. Please read this document carefully and inquire about any information within it. This document may contain professional terms that you are not familiar with; please ask the study doctor or staff to explain any unfamiliar terms or information. After a thorough understanding, please confirm whether you voluntarily agree to participate in this study. We can only proceed with the treatment if you fully understand the treatment process and risks. Your signature indicates that you voluntarily agree to participate in this study and have a full understanding of all contents. Please sign two copies of the informed consent form. You will receive a signed and dated copy for your records.

Study Background

When severe ocular surface lesions occur (e.g., pterygium, corneal ulcer, ocular surface burn, etc.), the currently clinically common surgical procedures such as conjunctival flap coverage, amniotic membrane transplantation, and keratoplasty are primarily fixed by suturing.

However, suturing has numerous drawbacks. On the one hand, the suturing process causes additional mechanical damage to ocular surface tissues, triggers local inflammatory responses, and increases postoperative discomfort such as pain and foreign body sensation. Moreover, uneven suture tension is prone to cause conjunctival flap shrinkage or displacement, impairing the repair effect [1]. On the other hand, postoperative suture irritation continuously activates fibroblast proliferation, leading to excessive deposition of subconjunctival collagen and the formation of dense scar tissue, which in turn compromises the stability of the ocular surface tear film and visual quality [2,3]. In addition, suturing surgery takes a long time (45-60 minutes on average) and has high requirements for the surgeon's microsurgical skills, limiting its popularization in primary medical institutions.

Based on the successful clinical translation experience of decellularized porcine cornea in the early stage, this project innovatively proposes a new concept of *in-situ repair and functional regeneration* and intends to develop an injectable ophthalmic adhesive. This technology creatively combines natural decellularized porcine corneal matrix with low-energy photocrosslinking technology to achieve a functional breakthrough of the material by constructing a double network crosslinking system. First, transglutaminase (TGase)-mediated biological crosslinking forms an interpenetrating network between decellularized

porcine corneal matrix (CECM) and gelatin methacryloyl (GelMA), which not only retains the pro-regenerative activity of the natural extracellular matrix (ECM) but also provides controllable curing performance. Second, an innovative low-energy curing mode is adopted: compared with traditional ultraviolet (UV) curing, this technology uses low-energy visible light combined with bioenzymatic crosslinking, significantly improving safety. Third, relying on the signal advantages of natural ECM, the material can directly guide the rapid formation of a stratified structure of corneal and conjunctival epithelial cells, completing regeneration within 1 week. In contrast, most international similar studies require additional loading of growth factors to achieve similar effects, giving this technology dual advantages in regeneration efficiency and safety.

Based on the above research foundation, this study intends to develop a suture-free ophthalmic hydrogel for conjunctival flap adhesion. By combining the natural biological activity of decellularized porcine corneal matrix with the photocrosslinking properties of GelMA, and integrating low-energy visible light (465nm) curing technology, the hydrogel enables rapid, firm, and suture-free adhesion of conjunctival flaps. This design not only draws on the efficient fixation experience of photocurable adhesives in amniotic membrane transplantation but also absorbs the biocompatibility advantages of corneal repair hydrogels.

Meanwhile, the material's degradation rate and inflammation regulation ability are optimized for the characteristics of conjunctival tissue. It is expected to reduce surgical damage and complications, improve the effect of ocular surface repair, and provide a new therapeutic option for clinical ocular surface adhesion surgery.

Study Objectives

Primary Objective: To evaluate the safety of the suture-free ophthalmic hydrogel for ocular surface tissue adhesion. Safety will be assessed based on the occurrence, severity, and frequency of all adverse events (including systemic symptoms) using the results of clinical examinations and diagnostic tests as the basis.

Secondary Objective: To evaluate the efficacy (therapeutic effect) of the suture-free ophthalmic hydrogel for ocular surface tissue adhesion, with the detachment rate and conjunctival epithelial healing as the key indicators to assess the hydrogel's efficacy in adhering conjunctival flaps.

Study Methods and Procedures

If you agree to participate in this study, the suture-free ophthalmic hydrogel will be used for ocular surface tissue adhesion during your surgery. Your participation period in this study will be from the time you give informed consent to use the suture-free ophthalmic hydrogel until the end of the observation period (3 months of postoperative follow-up).

Informed Consent Form Signing

If you have fully understood the content of this informed consent form and voluntarily agree to participate in this study, you can sign the informed consent form. After you have signed the informed consent form, you will enter the screening phase.

Inclusion and Exclusion Criteria

Inclusion Criteria

You must meet all the following inclusion criteria to participate in the study:

1. Patients with ocular surface diseases (e.g., pterygium, corneal ulcer, ocular surface burn, etc.) who require conjunctival flap coverage surgery, amniotic membrane transplantation, or keratoplasty;
2. Aged between 18 and 80 years, regardless of gender;
3. Able to provide written informed consent and participate in the study on a voluntary basis;
4. No severe systemic organic diseases (e.g., severe heart, liver, kidney diseases, malignant tumors, etc.).

Exclusion Criteria

You will be excluded from the study if you meet any of the following exclusion criteria:

1. A history of allergy to the components of the suture-free ophthalmic hydrogel (e.g., decellularized porcine corneal matrix, gelatin

methacryloyl, etc.) or the drugs prescribed during the perioperative and postoperative observation periods (e.g., anesthetics, antibiotics, steroid preparations, etc.);

2. Patients with systemic infectious diseases (e.g., bacterial, fungal infections, positive for HBV, HCV and other viruses, etc.).

3. Diabetic patients with poor blood glucose control (glycated hemoglobin [HbA1C] \geq 8.0%).

4. Pregnant women, women who may be pregnant, or women planning to become pregnant during the clinical study.

5. Patients who have participated in other clinical trials or research within 1 month before obtaining informed consent.

6. Other patients deemed unsuitable for the clinical study due to comorbidities or other reasons.

Potential Benefits of Participating in the Study

The intended goal of this treatment is to improve surgical efficiency and reduce conjunctival scar formation by adhering conjunctival flaps with the suture-free ophthalmic hydrogel. During your participation in the study, your symptoms and signs such as ocular foreign body sensation and conjunctival scar formation may be alleviated. However, due to individual differences in treatment effects, we cannot guarantee or promise any definite benefits. If the treatment in this study is effective, the results may benefit other patients with similar diseases in the future.

We hereby express our sincere gratitude for your contribution to the innovation of therapeutic methods.

Potential Risks of Participating in the Study

All clinical studies, study drugs, and study processes may involve unknown risks. If you experience any discomfort after surgery, please promptly inform your study doctor, who will monitor the occurrence of adverse reactions throughout the process.

1. 1. Conjunctival flap graft displacement or detachment: Failure to achieve the expected treatment effect may lead to deterioration of the condition.

2. Infection: Local or systemic infection may occur during the surgery or postoperative follow-up.

3. Ocular complications: Such as poor conjunctival epithelial healing.

4. Other adverse effects: Such as ocular pain, blurred vision, elevated intraocular pressure (IOP), etc.

5. Please immediately inform the medical staff if you experience any discomfort during the treatment.

Storage and Disposal of Cell Materials

You have the right to decide whether to receive conjunctival flap adhesion treatment with the suture-free ophthalmic hydrogel. You may discontinue or terminate the treatment at any stage of the process, and this

will not affect your future medical options.

Right to Choose and Voluntary Principle

You have the right to decide whether to receive anterior chamber cell transplantation. You can stop or discontinue the treatment at any stage of the treatment process without affecting your future medical choices.

Right Protection

You have the right to ask the doctor any questions before treatment and understand the detailed treatment process.

You have the right to know how your personal medical information will be used, and we will strictly keep all your personal and medical data confidential.

If you have any questions or discomfort, you can communicate with the medical team at any time and terminate the treatment at any time.

Privacy Protection Clause

Your personal information and medical data will be strictly confidential and used only for this treatment and related research. If your data needs to be used for academic research or publication, you will be notified in advance and your consent will be obtained.

Study Costs and Compensation

We will provide the suture-free ophthalmic hydrogel to you free of charge. As a subject, if you suffer injury due to receiving the study drug treatment or following the study procedures correctly and in accordance

with the researcher's guidance, the sponsor will compensate you for reasonable medical expenses incurred for the treatment of study-related injuries and reasonable compensation required by relevant Chinese laws and regulations.

Withdrawal from the Study

Your participation in this study is entirely voluntary. You may refuse to participate or request to withdraw from the study at any stage. Your decision will not result in any fines or loss of benefits. Your decision to participate in this study will not affect your future medical treatment at this study center.

The study doctor and/or sponsor may request you to withdraw from the study if:

1. You fail to complete the scheduled study visits;
2. You fail to follow the instructions and explanations of the study doctor;
3. Discontinuing participation in the study is more beneficial to your health and safety.

The study doctor and/or sponsor may request you to continue completing the study visits if:

1. Damage related to the study has occurred;
2. An adverse event has occurred but no consequences have been caused after appropriate treatment.

The sponsor has the right to terminate the study project at any time without giving any reason. If you wish to withdraw from the study before completing all visits, please notify the study doctor or study staff via [contact phone number].

Confidentiality System

Your medical information obtained through participating in this study will be kept confidential. To protect your privacy, you will be identified by a unique number, and your medical records will be linked to your subject number and completely stored at the study institution. The doctor will record the examination results in your medical record. Researchers, monitors, auditors, the ethics committee, and drug regulatory authorities will be allowed to access your medical records; no other unauthorized person may obtain this information. Any public report on the results of this study will not disclose your personal information, and we will make every effort to protect the privacy of your medical data.

Thank you for reading the above information. The decision to participate in this study is entirely yours, and you may consult with your family. If you have any questions or concerns related to this study, you can contact Dr. [name] via [contact phone number] for inquiries.

Informed Consent Form Signature Page

I have read the above introduction to the " A Single-Center Clinical Study to Evaluate the Efficacy and Safety of a Suture-Free Ophthalmic Hydrogel for Ocular Surface Tissue Adhesion Therapy". The study doctor has explained the potential risks and benefits of this study in detail to me and answered all relevant questions. In addition, the purpose, methods, procedures, and duration of the study have been explained to me in detail. After fully understanding all the contents of the informed consent form and the potential advantages and disadvantages of participating in this study, I voluntarily agree to participate in this trial. I am willing to cooperate with my study doctor and carefully complete this trial. I understand that:

1. I have consulted the study doctor about my concerns and voluntarily participate in this trial with full knowledge;

2. As a trial subject, I am willing to comply with the guidelines in this study and the requirements in the subject information to conduct the study;

3. If any adverse event occurs during the trial, I will immediately notify my study doctor;

4. If any adverse event caused by any reason occurs to me during the trial, the study doctor will provide me with active examination and

treatment;

5. I have the right to withdraw from the trial at any stage of the treatment process without affecting the study doctor's treatment of me;

6. Although the trial records will be kept confidential, regulatory authorities, the ethics committee, the investigator, the sponsor, and their designated personnel (monitors, auditors) may have access to them, and the above personnel are responsible for keeping my personal information confidential;

7. I guarantee that I have truthfully informed the researchers of any previous disease conditions and any treatment I have received or will receive;

8. I understand the potential benefits and risks of participating in this study, and I am willing to contribute to the progress of medicine;

9. I will receive a copy of this informed consent form signed by me and the researcher and dated.

Subject's Signature: _____

Date: _____ Year _____ Month _____ Day

Contact Phone Number: _____

If the subject is unable to sign the informed consent form due to lack of capacity, etc., the guardian shall sign on their behalf.

Guardian's Signature: _____

Date: _____ Year _____ Month _____ Day

Relationship with the Subject: _____

Reason the Subject Cannot Sign the Informed Consent Form:

I have given the subject sufficient time to ask questions concerning the subject information, informed consent form, trial protocol, and investigational product, and have answered them to the best of my ability.

Subject's Signature: _____

Date: _____ Year _____ Month _____ Day

Contact Phone Number: _____

----- (To be used only when appropriate) -----

If this consent form is read to the subject because the subject cannot read, an impartial witness, who is independent of the study or research team, must be present to witness the consent process. The impartial witness must also sign the following declaration:

I confirm that the information in the informed consent form and any other written information has been accurately explained to the subject. The subject clearly understood this information. The subject voluntarily agreed to participate in this research.

Impartial Witness Signature: _____

Date: _____ Year _____ Month _____ Day

Contact Phone Number: _____