A Single-Center Clinical Study to Evaluate the Efficacy and Safety of Sutureless Ophthalmic Hydrogel for Corneal Wound Repair

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Informed Consent Form for Subjects Undergoing Corneal Repair with Sutureless Hydrogel

Study Title: A Single-Center Clinical Study to Evaluate the Efficacy and Safety of Sutureless Ophthalmic Hydrogel for Corneal Wound Repair

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 Sutureless Ophthalmic Hydrogel for Corneal Wound Repair", 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

Corneal blindness is one of the leading causes of blindness worldwide. For various infectious and non-infectious corneal diseases, current clinical repair strategies include debridement of corneal lesions, conjunctival flap coverage, amniotic membrane transplantation, corneal transplantation, therapeutic contact lens application, and injectable

sealants. Injectable hydrogels, as smart materials that transition from a liquid precursor to a solid gel in response to external stimuli (e.g., light, temperature, or chemical cross-linking), enable precise filling of corneal defects via minimally invasive injection. They offer superior morphological adaptability, conforming tightly to irregular wound surfaces and achieving sutureless closure. Moreover, they promote regenerative repair of the epithelium, stroma, and nerves, significantly reducing patient discomfort, infection risk, recovery time, and healthcare costs, thereby advancing the paradigm of corneal repair from “transplant substitution” to “in situ regeneration.”

Study Objectives

Primary Objective: To evaluate the safety of a sutureless ophthalmic hydrogel for repairing corneal lamellar defects. Safety will be assessed based on diagnostic and clinical examination findings, including the occurrence, severity, and frequency of all adverse events (e.g., systemic symptoms, severe ocular surface inflammatory reaction, poor corneal epithelial healing, infection, displacement or detachment of the hydrogel patch).

Secondary Objective: To evaluate the efficacy (therapeutic effect) of the sutureless ophthalmic hydrogel for repairing corneal lamellar defects, using corneal thickness and corneal clarity as the primary outcome measures.

Study Methods and Procedures

If you agree to participate in this study, we will use a sutureless ophthalmic hydrogel to perform lamellar repair of your corneal stromal defect caused by surgery or trauma. The duration of your participation in this study will be from the time you consent to the use of the sutureless ophthalmic hydrogel for corneal repair until the end of the observation period (8 weeks 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 corneal stromal defects, including those caused by trauma or following lesion excision for infection, with a residual stromal thickness of ⩾300 μm in the defect area.

2. Patients aged 18 to 85 years (inclusive, either sex) at the time of consent.

3. Patients who are capable of providing written informed consent

voluntarily to participate in the study.

Exclusion Criteria

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

1. Patients with unexplained keratoconjunctival diseases.
2. Patients with severe dry eye, symblepharon, corneal neovascularization, or other ocular surface disorders.
3. Patients with systemic infectious diseases (positive for bacteria/fungi/HBV/HCV/HIV/TP, etc.).
4. Patients with autoimmune diseases such as rheumatoid arthritis, Sjögren's syndrome, or graft-versus-host disease.
5. Patients with uncontrolled ocular diseases in the study eye.
6. Patients with major organ failure or other serious systemic conditions, including but not limited to cardiac insufficiency; poorly controlled diabetes mellitus (fasting blood glucose >8 mmol/L despite glucose-lowering therapy); uncontrolled stage II or higher hypertension (blood pressure >160/100 mmHg despite antihypertensive therapy); history of malignancy within the past 5 years; severe immunodeficiency, etc.
7. Patients with psychiatric disorders that may interfere with treatment or evaluation.
8. Pregnant or lactating women, or women planning to become

pregnant during the clinical study.

9. Patients deemed unsuitable for participation in the clinical trial by the investigator.
10. Patients unable to complete follow-up visits.

Potential Benefits of Participating in the Study

The anticipated goal of this treatment is to improve corneal thickness, corneal clarity, and visual acuity by repairing the corneal stromal defect using a sutureless ophthalmic hydrogel. During your participation in this study, symptoms and signs such as blurred vision, abnormal corneal thickness, and ocular pain may improve. However, due to potential individual variability in treatment response, we cannot guarantee or promise a definite benefit. If this study treatment proves effective, the results may help other patients with similar diseases in the future. We sincerely thank you for your contribution to advancing innovative treatment approaches.

Potential Risks of Participating in the Study

All clinical studies, investigational products, and study procedures may involve unknown risks. If you experience any discomfort following the hydrogel implantation, please promptly inform your study doctor, who will monitor the occurrence of adverse events throughout the process.

1. Hydrogel displacement or detachment: The therapeutic effect may not meet expectations, potentially leading to disease progression.

2. Infection: Recurrence of infection may occur during or after the surgical procedure or during postoperative follow-up.

3. Ocular complications: Persistent poor corneal epithelial healing, epithelial implantation cyst of the cornea, etc.

4. Other side effects: Such as ocular pain, blurred vision, etc.

5. If you experience any discomfort during the treatment, please immediately notify the medical staff.

Right to Choose and Voluntary Principle

You have the right to decide whether to undergo corneal wound repair with the sutureless hydrogel. At any stage of the treatment process, you may stop or discontinue the treatment at any time, and this will not affect 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 you with the sutureless hydrogel free of charge. As a subject, if you sustain injury resulting from receiving the investigational drug or from correctly following the study procedures as instructed by the study doctor, the sponsor will compensate you for reasonable medical expenses incurred for the treatment of study-related injuries, as well as 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 Sutureless Ophthalmic Hydrogel for Corneal Wound Repair". 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: _____