Informed Consent Form

Diagnostic Performance Evaluation and Clinical Translation Research of a New Intelligent Flexible Penile Monitoring System for Erectile Dysfunction

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Dear Sir:

We will invite you to participate in a study titled"Diagnostic Performance Evaluation and Clinical Translation Research of a New Intelligent Flexible Penile Monitoring System for Erectile Dysfunction"responsible by the Department of Urology of Zhongda Hospital Affiliated to Southeast University.This study has been reviewed and approved by the Ethics Committee for Clinical Research of Zhongda Hospital Affiliated to Southeast University(Approval Number:2026ZDSYLL244-P01).

Before you decide whether to participate in this study,please read the following content as carefully as possible.It can help you understand this study as well as why this study is being conducted,the procedures and duration of the study,and the potential benefits,risks,and discomforts that may be brought to you after participating in the study.If you are willing,you may also discuss it with your relatives and friends,or ask a doctor to provide an explanation to help you make a decision.

I.Research Background,Research Objectives,and Research Methods

1.Research Background

Erectile dysfunction(ED)refers to the inability of the penis to reach or maintain sufficient rigidity when attempting to engage in sexual life.Erectile dysfunction is not only a common physiological functional disorder in urology and andrology,but also an early local manifestation of systemic vascular endothelial function impairment and metabolic disorders in men;physiological functional limitations are often accompanied by significant psychological negative pressure and a decline in the quality of life.In the process of precise clinical diagnosis and treatment,distinguishing psychogenic factors from substantial organic damage is the key prerequisite for formulating personalized treatment plans.Nocturnal Penile Tumescence(NPT)monitoring,as a currently internationally recognized basis for differential diagnosis,has its core principle in effectively excluding the interference of daytime emotions and psychological pressure by recording the uncontrolled spontaneous erection phenomenon occurring during the Rapid Eye Movement(REM)sleep stage of research participants,thereby quantitatively reflecting the true physiological functions of the body's nervous,vascular,and cavernous tissues.

However,the monitoring device RigiScan Plus,which has been used in clinical practice for a long time,has significant technical limitations in practical applications.Because this device relies on rigid mechanical hoops to collect circumference and rigidity data through frequent active tightening,such constriction pressure often interferes with the natural sleep structure of research participants,inducing unexpected arousal,which in turn leads to diagnostic false negatives or"first-night effect"biases resulting from poor sleep quality.This paradox of"the monitoring method itself interfering with physiological feedback"has become a problem that urgently needs to be overcome in the field of precise diagnosis in andrology.

Aiming at the aforementioned clinical pain points,the Department of Urology of our hospital,through medical-engineering cross-collaboration,has introduced a new intelligent monitoring system developed based on flexible electronics technology.This system utilizes an ultra-thin sensing layer with a thickness of less than 0.8mm,achieving a technological leap from traditional"mechanical restraint sampling"to"unfelt biological conformal sensing."The purpose of this study is,through a rigorous prospective randomized crossover controlled trial,to confirm that this flexible system can reach an accuracy consistent with traditional equipment in measuring basic physical indicators such as rigidity and circumference.After confirming the accuracy of the collected data,we will further quantitatively evaluate the consistency of this system with existing gold-standard equipment in clinical diagnosis,and quantitatively assess its clinical advantages in terms of reducing sleep interference and protecting the privacy of research participants.Through the implementation of this study,we strive,on the basis of confirming the reliability of physical measurements,to utilize its unique deformation heatmap technology to excavate deeper morphological indicators,providing scientific evidence-based grounds for promoting the clinical translation and application popularization of domestic precise diagnostic and therapeutic instruments for andrology,ultimately enabling patients to benefit from a more precise digital evaluation system.

2. Research Objectives

This study aims to evaluate the accuracy of the new flexible monitoring system in diagnosing ED and its consistency with existing gold-standard equipment through a clinical comparison trial.Meanwhile,we will evaluate the advantages of the system in improving wearing comfort and reducing sleep interference,and explore its diagnostic value in the fine-grained subtyping of vascular ED.

3. Research Design

3.1 Methodology

This study adopts a prospective,randomized crossover controlled design scheme.Research participants will be assigned through randomized grouping to wear the new flexible device and the RigiScan device respectively on different monitoring nights.

3.2 Participating Institution and Estimated Number of Research Participants

Participating Institution:Zhongda Hospital Affiliated to Southeast University

Number of Research Participants:60 cases(30 patients and 30 healthy volunteers are planned to be included)

3.3 Expected Research Duration and Project Start Time

This study is expected to last for 1.5 years and will officially start in August 2026.

3.4 Main Inclusion Criteria for Research Participants

The subjects to be recruited in this study are divided into an ED patient group and a healthy volunteer group.The specific criteria are as follows:

1)Common Criteria:

• Aged between 18 and 70 years,with the capacity for independent civil conduct;

• Able to understand and cooperate to complete two consecutive stages of nocturnal monitoring and outpatient provocation tests;

• Voluntarily participate in this study and sign the informed consent form.

2)Specific Criteria for ED Patient Group:

• Main complaint of erectile dysfunction with a disease duration of more than 6 months;

• International Index of Erectile Function-5(IIEF-5)score<21 points.

3)Specific Criteria for Healthy Volunteer Group:

• No prior history of erectile dysfunction and normal sexual function performance;

• International Index of Erectile Function-5(IIEF-5)score≥21 points.

3.5 Main Exclusion Criteria for Research Participants

• Presence of severe penile anatomical malformation(such as severe curvature caused by Peyronie's disease)resulting in the inability to wear the device normally;

• Clinically diagnosed with severe sleep apnea(AHI>30)or severe insomnia;

• History of penile prosthesis implantation,urethral surgery,or severe pelvic trauma within the last half year;

• Currently taking medications that significantly affect REM sleep structure or erectile function,such as sedatives,hypnotics,antidepressants,hormones,etc.;

• Known history of allergy to medical-grade silicone or related adhesive materials.

II.Participant Responsibilities

1.Clinical Monitoring Procedures

If you decide to participate in this study,you will cooperate to complete the evaluation in the following four parts:

(1)Crossover Comparison Monitoring:You will undergo two nights of nocturnal monitoring on different nights.On the first night,you will wear one of the monitoring devices according to the randomized sequence.After a washout period of 3-7 days,you will wear the other device on the second night.

(2)Sleep Structure Recording:During the monitoring period,you will simultaneously wear a medical-engineering grade sleep bracelet.This bracelet only records your body movement and heart rate variability to evaluate the impact of wearing the device on your natural sleep.

(3)Audiovisual Stimulation Response:In the outpatient clinic,you may need to watch a segment of standardized audiovisual materials to record the device's sensitivity in capturing acute erectile responses.

(4)Ultrasound Correlation Examination:For some patients suspected of vascular ED,while being monitored by the new device,an ultrasound physician will perform a non-invasive penile color Doppler ultrasound examination for you to verify the accuracy of the data.

2.Participant Duties

Within 24 hours before monitoring,please avoid drinking excitatory beverages such as coffee and alcohol,and avoid strenuous exercise.On the monitoring night,please cooperate with the research personnel to complete the wearing of the device and truthfully fill out the comfort scale and sleep quality questionnaire.

Before you are selected for the study,the investigator will inquire about your past medical history.

You are a qualified enrollee.Research personnel will communicate with you face-to-face in the urology clinic or ward.After you fully understand the research content and risks,you will sign the paper version of the informed consent form on-site.If you are unwilling to participate in the study,we will follow your wishes.

If you voluntarily participate in the study,it will proceed according to the following steps:

All testing procedures of this study are completed in the Urology Department of Zhongda Hospital Affiliated to Southeast University.The specific steps are as follows:

• Step 1:Baseline Screening.A urology research physician will conduct an interview with the subject,collect the IIEF-5 score and medical history,and confirm them as either the ED patient group(score<21)or the healthy volunteer group(score≥21).

• Step 2:Crossover Monitoring.Subjects will complete two stages of monitoring in a standardized ward.In the first stage,the subject wears the new flexible device or RigiScan according to the randomized sequence;after the washout period,devices are swapped for the second stage of monitoring.

• Step 3:Objective Data Extraction.On the night of monitoring,a medical-engineering grade sleep recorder will be used simultaneously to monitor the subject's REM phase.

• Step 4:Synchronous Verification(limited to some subjects).For subjects requiring further subtyping,a urology ultrasound physician will simultaneously perform a Penile Color Doppler Duplex Ultrasound(CDDU)examination to measure PSV/EDV indicators,which will be used for spatial alignment analysis with the deformation heatmaps generated by the flexible system.

III.Rights of Research Participants

Your participation in the study is voluntary.Information regarding your participation in the study is confidential.You may refuse to participate in the study or withdraw from the study at any time without facing discrimination or retaliation,and your medical treatment and rights will not be affected.

You may choose not to participate in this study or withdraw from the study midway;you may ask the researcher about potential alternative treatment methods.You do not have to choose to participate in this study in order to treat your disease.

If you need other diagnosis/treatment,or if you do not comply with the research plan,or for any other reasonable reasons,your doctor or researcher,out of consideration for your best interest,may terminate your participation in this study at any time.

If you withdraw from the study for any reason,you may be asked about your use of the test drug.If the doctor deems it necessary,you may also be requested to undergo laboratory tests and physical examinations.This is very beneficial for protecting your health.

If there is any important new information during the study process that may affect your willingness to continue participating in the study,your doctor will notify you or your guardian in a timely manner.

You may stay informed about information materials and research progress related to this study at any time.If you have questions related to this study,or if you experience any discomfort or injury during the trial process,or if you have questions regarding your rights involved in this study,you may consult with the researcher at any time.

Researcher name:Chao Sun.Contact:13813966939.

If you have any complaints about participating in this study,please contact the Clinical Research Ethics Committee of Zhongda Hospital Affiliated to Southeast University,contact:025-83272015.

IV.Potential Benefits of Participating in the Study

All related tests and evaluations in this study are provided free of charge.Although your participation may not produce immediate therapeutic effects,the data you provide possesses important scientific value for promoting the progress of clinical evaluation technology and optimizing the diagnosis and treatment processes for related diseases in the future.Your contribution will help develop clinical evaluation systems that are more ergonomic and precise,thereby benefiting future patient populations.

V.Potential Adverse Reactions,Risks,Discomforts,and Inconvenience of Participating in the Study

Be informed that phone consultations and subsequent follow-up work after participating in the study will occupy the time of research participants and may bring inconvenience.

If you experience any discomfort,or new changes in your condition,or any unexpected situation during the study period,regardless of whether it is related to the study,you should notify your doctor in a timely manner;he/she will make a judgment and provide appropriate medical treatment.

VI.Related Expenses

All monitoring items,scale assessments,and related clinical examinations involved in this study(including nocturnal penile tumescence monitoring,sleep structure recording,outpatient provocation

tests,and ultrasound examinations)are provided free of charge,and subjects are not required to bear any expenses related to this study.

VII.Related Compensation

The researcher will do their best to prevent and treat injuries that may be caused by this study.If study-related damage occurs during the research period,you will receive timely and free treatment,and meanwhile,the researcher will provide corresponding compensation or indemnity in accordance with laws and regulations.

VIII.Confidentiality of Personal Information

Your medical records and materials will be kept in full at the hospital.Researchers,the ethics committee,drug regulatory authorities,and health commission management departments will be allowed to review your medical records.Any public report regarding the results of this study will not disclose your personal identity.We will protect the privacy of your personal medical information within the scope permitted by law.

According to the principles of medical research ethics,except for personal privacy information,trial data will be available for public inquiry and sharing.Inquiry and sharing will be limited to web-based electronic databases,guaranteeing that no personal privacy information will be leaked.

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Statement of Consent

I have read the aforementioned introduction regarding this study,and I have had the opportunity to discuss and raise questions about this study with the researcher.All questions I raised related to the research have been answered,and meanwhile,my family and I have had sufficient time to consider this.

I am aware of the potential risks and benefits of participating in this study.I am aware that participation in the research is voluntary,and I understand that:

- The study has been approved by the Clinical Research Ethics Committee of Zhongda Hospital Affiliated to Southeast University.
- All my information is confidential.
- My rights to privacy,medical treatment,and compensation are guaranteed.
- I can consult the researcher for more information at any time.
- I can choose not to participate in this study,or I can withdraw from this study at any time,without facing discrimination or retaliation,and my medical treatment and rights will not be affected.
- If I withdraw from the study midway,especially if the withdrawal is due to drug-related reasons,I should inform the researcher of changes in my condition and complete corresponding physical examinations and laboratory/physical-chemical tests,which will be highly beneficial to the entire study.
- If I need to adopt any other treatment due to changes in my condition,or if I do not comply with the research plan,I will seek the researcher's opinion in advance or truthfully inform the researcher afterwards;the researcher may terminate my continued participation in this study for these reasons or other reasonable grounds.

I agree that the drug regulatory authorities,health commission management departments,the ethics committee,or representatives of the sponsor may review my research data.

I will receive a signed and dated copy of the informed consent form.

Finally,I have decided to agree to participate in this study and guarantee to follow the research procedures as much as possible.

I agree□refuse□to allow research other than this study to utilize my medical records and pathological examination specimens.

Participant Signature:_____Date:___Year___Month___Day___Hour___Minute
Contact Number:_____

Guardian Signature(if applicable):_____Date:___Year___Month___Day___Hour___Minute
Participant Name(Block Letters):_____Relationship between the Guardian and the Participant:_____
Guardian Contact Number:_____

Impartial Witness Signature(if applicable):_____Date:___Year___Month___Day___Hour___Minute
Impartial Witness Contact Number:_____Impartial Witness ID Number:_____

I confirm that I have explained the details of this study to the research participant,including their rights as well as potential benefits and risks,and have answered their questions.The research participant voluntarily participates in this study,and a signed copy of the informed consent form has been provided to them.

Investigator Signature:_____Date:____Year____Month____Day____Hour____Minute
Investigator Contact Number:_____