Research Project Protocol

Project Title:Diagnostic Performance Evaluation and Clinical Translation Research of a New Intelligent Flexible Penile Monitoring System for Erectile Dysfunction
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I.Rationale

Erectile dysfunction(ED)refers to the inability of the penis to achieve and/or maintain sufficient erectile rigidity and duration for satisfactory sexual intercourse.ED is the most prevalent physiological functional disorder in urology and andrology.It not only seriously affects the quality of life and mental health of patients but also serves as an early local manifestation of systemic vascular endothelial function impairment and metabolic disorders in men.Epidemiological data show that approximately 50%of men over the age of 40 worldwide are troubled by varying degrees of ED.In China,with the acceleration of the pace of life,increasing work pressure,and the surge in the incidence of metabolic diseases(such as diabetes and hypertension),the prevalence of ED shows a significant upward trend,and the age of onset tends to be younger.According to estimates,the scale of the potential ED audience in China has reached 140 to 150 million people.ED is often regarded as a"wind vane"indicator of systemic diseases,and its appearance often precedes clinically visible cardiovascular events by 2 to 5 years.From a psychological perspective,the loss of self-confidence,depression,and maladjustment of partner relationships caused by it often trap patients in a vicious cycle of"stress-erectile dysfunction-psychological anxiety-aggravation of dysfunction"[1,2].

In the process of precise clinical diagnosis and treatment,distinguishing psychogenic factors from substantial organic damage is the core prerequisite for formulating personalized plans.Nocturnal Penile Tumescence(NPT)monitoring,as the currently internationally recognized gold standard for differential diagnosis,has its scientific basis in the fact that healthy men experience uncontrolled physiological erections during the Rapid Eye Movement(REM)stage of sleep.This phenomenon can truly reflect the basic physiological functions of peripheral nerves,blood vessels,and cavernous tissues without being interfered with by daytime emotional anxiety[3,4].Currently,the clinically recognized NPT monitoring tool is the RigiScan Plus system,which mainly captures indicators of circumference variation and peak rigidity throughout the entire erection process by wearing rigid mechanical hoops at the base and the head of the penis,respectively[5].

However,RigiScan Plus has exposed significant technical limitations and a lack of humanization in nearly thirty years of clinical application.First,the device relies on physical rigid hoops to collect data through frequent active mechanical constriction,bringing a strong sense of foreign body sensation and restraint to patients.This rigid structure often induces unintended arousal in subjects and forcibly interrupts the REM sleep stage,creating a technical paradox of"interfering with monitoring for the sake of monitoring,"which often leads to a large number of diagnostic false negatives and"first-night effect"biases,aggravating the psychological burden on patients[6,7].Second,RigiScan can only provide limited data from two discrete points at the base and the head,failing to reflect the three-dimensional morphological evolution of the entire penile segment.Clinically,even if organic ED is confirmed,it is difficult for doctors to precisely identify the subtyping of vascular(such as arterial insufficiency or venous leak),neurogenic,or mixed ED based solely on two points of data,resulting in a lack of intuitive morphological evidence for the selection of subsequent precise treatment paths[8].

Flexible sensing technology,as a cutting-edge direction in bioelectronics,has its core advantage in utilizing functional materials with high extensibility,ultra-thin thickness,and excellent biocompatibility to achieve high compliance between monitoring equipment and human anatomical structures.In clinical erectile function assessment,the core significance of introducing flexible sensing materials lies in their extremely low physical load,which allows them to extend synchronously with the subject's body surface deformation,thereby capturing high-quality electrical signals without interfering with natural physiological activities.This provides a solution to the long-standing problem of"monitoring interference with physiological feedback"in the field of Nocturnal Penile Tumescence(NPT)monitoring.By achieving"unfelt"monitoring,the physical interference of traditional rigid equipment on the subject's Rapid Eye Movement(REM)sleep stage can be minimized,and unintended

arousal can be reduced,thereby obtaining diagnostic data close to the subject's natural physiological state,which is of significant value for improving diagnostic accuracy and subject compliance[9].

This clinical study intends to systematically evaluate the performance of a new flexible monitoring system in complex clinical scenarios through a prospective randomized crossover controlled design.First,the study aims to quantitatively evaluate the superiority of the flexible device in reducing the destruction of the subject's sleep structure and alleviating the"first-night effect"through different-night crossover NPT monitoring while simultaneously connecting to a medical-engineering grade sleep recorder.The significance of this experimental design is that,through objective sleep parameter comparison,it confirms that while the new equipment protects the subject's privacy and sleep quality,it can provide rigidity and circumference change indicators that highly consistent with the clinical gold standard,thereby verifying its credibility as a new clinical diagnostic tool.

Secondly,aimed at the requirements for precise clinical subtyping,the research will be carried out under Audiovisual Sexual Stimulation(AVSS)induction and drug-induced states.By capturing the dynamic deformation characteristics in the initiation stage of erection and performing a correlation analysis between the extracted spatial-temporal parameters of the"deformation heatmap"and the hemodynamic gold standard of Penile Color Doppler Ultrasound(CDDU).The clinical significance of this part lies in exploring a non-invasive and flexible sensing method to identify the uniformity of congestion and differences in local compliance throughout the entire penile segment,thereby evaluating the application value of this technology in assisting the clinical differentiation of fine pathogenic subtyping such as vascular and neurogenic types[10].

In summary,the clinical evaluation scheme proposed in this study represents a leap in precise andrology diagnosis from"mechanical sampling"to"flexible natural-state field sensing."This project not only aims to assess the monitoring capability of the new system for objective physical indicators of erection and its efficacy in clinical diagnosis but also strives to alleviate the psychological negative pressure and physiological discomfort of subjects during the diagnosis and treatment process through technological innovation,providing scientific evidence-based grounds for building a precise andrology diagnosis and treatment system with more humanistic care.

Reference：

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Entry Point and Significance of This Study

This study focuses on evaluating the monitoring capability for objective physical indicators of erection and the efficacy in clinical diagnosis of a new intelligent flexible monitoring system.Current clinical monitoring equipment,RigiScan,has actual pain points such as heavy physical load and the tendency of its rigid hoops to induce arousal in subjects.By introducing an ultra-thin flexible sensing layer with good biocompatibility,this study aims to reduce the physical interference of the examination method itself on the Rapid Eye Movement(REM)sleep stage of the subjects.If the verification results show that this scheme has good consistency with the existing gold standard in terms of rigidity and circumference monitoring indicators,it will provide the clinic with an auxiliary diagnostic tool that is more ergonomic and has a lower compliance threshold,which will help improve the patient's examination experience and reduce the risk of false-negative diagnosis caused by impaired sleep structure.

Our team plans to conduct a prospective randomized crossover controlled study in the Urology Department of Zhongda Hospital Affiliated to Southeast University.Subject information will be obtained through the hospital's electronic medical record system and outpatient screening,and a randomized grouping sequence will be strictly followed to compare the data differences of the same subject wearing the new flexible device and the RigiScan device on different monitoring nights,respectively.The study will simultaneously quantify objective sleep parameters(such as the number of arousals and the proportion of REM stage)and subjective comfort scores to systematically evaluate the reliability of the new system on core diagnostic indicators.If this scheme is confirmed,it will provide objective clinical evaluation data for the domestic localization and transformation of precise andrology diagnosis and treatment technology.

II.Research Content

1.Research Objectives

This project aims to systematically evaluate the monitoring capability for objective physical indicators of erection and the efficacy in clinical diagnosis of a new intelligent flexible penile monitoring system through a prospective clinical trial.The core objective of the research is to establish the consistency and non-inferiority of the flexible system relative to the clinical gold-standard equipment(RigiScan Plus);meanwhile,by quantitatively evaluating the superiority of the new unfelt monitoring scheme in reducing unintended arousal and protecting the natural sleep structure of subjects,its clinical compliance value will be verified.Ultimately,by constructing a correlation model between deformation heatmaps and hemodynamic indicators,the application potential of this technology in the refined subtyping of vascular ED will be explored.

2.Research Content

(1)Selection of the Research Site:

This research will be conducted in the Urology Department of Zhongda Hospital Affiliated to Southeast University.

(2)Selection of Research Subjects:

The research subjects are planned to recruit patients with a main complaint of erectile dysfunction and healthy volunteers.Subject information will be initially screened through the electronic medical record system of Zhongda Hospital,and enrollment will take place after the medical history is verified by two senior physicians.Enrollees must sign an informed consent form,and then be allocated to Sequence A or Sequence B in a 1:1 ratio through the random number table method.This study adopts a

randomized,crossover,and single-blind design,utilizing a washout period to achieve self-control of the subjects,so as to maximize the elimination of the consistency interference of individual physiological differences on the diagnostic conclusions.

Number of Enrolled Subjects:

60 cases in the Urology Department of Zhongda Hospital Affiliated to Southeast University.

Sample Size:

This study is a prospective,single-center,randomized,crossover controlled clinical validation trial,aiming to evaluate the efficacy and clinical consistency of a new intelligent flexible penile monitoring system in the diagnosis of erectile dysfunction(ED).

1.Statistical Estimation Basis and Parameter Setting=

The determination of the sample size in this study comprehensively considers two dimensions:the precision evaluation of clinical measurement values(quantitative indicators)and the consistency evaluation of diagnostic conclusions(qualitative indicators).According to the principles of clinical validation for medical devices,the primary endpoint of this study is set as the numerical consistency of physical parameter measurements between the two systems during erectile events,namely,the measurement deviation of the peak rigidity indicator(%)and the maximum circumference expansion(cm).Aimed at the consistency evaluation of quantitative values,this study adopts the non-inferiority test logic under a paired design for sample size estimation.Parameters are set as follows:the significance level is set atα=0.05(0.025 is taken for a one-sided test,corresponding to Z1−α/2=1.96);to obtain higher data credibility,the statistical power(test efficacy 1−β)is set at 0.90(corresponding to Z1−β=1.28).According to the fluctuation characteristics of the previous equipment calibration model,the standard deviation of the measurement difference between the two devices,σd,is set at 0.10;the maximum clinically allowable non-inferiority margin(allowable error)Δis set at 0.05(i.e.,the rigidity error is controlled within 5%).In addition,to confirm the reliability of the new system in clinical classification diagnosis,this study takes diagnostic subtyping consistency(Cohen's Kappa coefficient)as the core secondary endpoint for verification.The expected Kappa valueκ1 is set at 0.85,and the null hypothesis marginκ0 is set at 0.60.

2.Sample Size Calculation Process

The sample size calculation formula based on the non-inferiority test for paired design is as follows:

$$N=\frac{(Z_{1-\alpha}+Z_{1-\beta})^2\cdot\sigma_d^2}{\Delta^2}$$

It is calculated that to achieve a statistical power of 90%,at least 42 subjects are required to complete the entire monitoring process.

3.Determination of the Final Recruitment Scale

Although the statistical bottom line is 42 valid samples,considering the following factors,the final total recruitment scale for this project is determined to be 60 cases:

1.Hedging against data loss:Nocturnal monitoring is susceptible to interference from the"first-night effect"leading to sleep failure,or the displacement of flexible sensors due to violent postural turning.Based on an expected data dropout rate of 30%,the initial sample pool needs to be expanded.

2.Subgroup analysis power:This study involves the extraction of feature vectors from heatmaps for different subgroups such as vascular and psychogenic types.A certain scale is necessary to support more robust subgroup statistical analysis.

3.Credibility of domestic translation:Sufficient clinical sample size is a necessary condition for the application for marketing of innovative medical devices and the establishment of industry benchmarking standards.

The final total recruitment scale for this study is determined to be 60 cases.To ensure the acquisition of sufficient data covering the full range(EHS grades 1-4),the subjects are divided into the following two groups in a 1:1 ratio:

Healthy Volunteer Group(n=30):30 cases are planned for enrollment.

Grouping Rationale:Subjects in this group are intended to provide high signal-to-noise ratio(SNR)and high-frequency samples of"effective erectile events"for the flexible sensor.Healthy volunteers usually possess regular and high-quality physiological erections during the REM sleep stage,which can produce significant girth expansion and pressure changes.This plays a decisive role in verifying the measurement precision of the flexible sensing array in the high-rigidity range(EHS grades 3-4).

ED Patient Group(n=30):30 cases are planned for enrollment.

Grouping Rationale:Subjects in this group are intended to verify the diagnostic sensitivity of the system under complex pathological states.By including patients with different degrees of severity and different subtypes,the system's performance in capturing weak signals and pathological deformations will be evaluated.

(3)Research Period

August 1,2026—February 1,2028

Extraction and Allocation Methods for Research Subjects

To ensure the scientific nature of the experiment,a randomized sequence for subject allocation will be used in this study.After enrollment,subjects will be randomly assigned to Sequence A(wearing the new flexible device first,then wearing RigiScan after the washout period)or Sequence B(wearing RigiScan first,then wearing the new flexible device after the washout period)through a central randomization system in a 1:1 ratio.The random sequence will be pre-generated by an independent statistician who does not participate in clinical operations.To achieve allocation concealment,on-site clinical researchers can only obtain the corresponding monitoring sequence from the system after the subjects are officially enrolled and the baseline information collection is completed,thereby eliminating selection bias.In the data evaluation stage,to reduce subjective bias,this project adopts an evaluator-blind method:the raw electrical signals collected by the flexible sensing array will be converted into standardized rigidity and girth reports by the engineering team.After hiding the device source information,these will be submitted to two independent senior urologists for diagnosis.This is to ensure that at any stage of the study,the number of enrollees in Sequence A and Sequence B can maintain a tight dynamic balance.Through this rigorous randomization path,this study strives to maximize the elimination of the impact of individual physiological differences and monitoring sequence effects on the diagnostic consistency evaluation.

Informed Consent of Research Subjects

Signing of the Informed Consent Form

(4)Evaluation Indicators(Endpoints)

1.Primary Endpoint:The peak rigidity(%)and maximum girth expansion rate(cm)of the two devices during erectile events.By calculating the Mean Bias and 95%Limits of Agreement(LoA)of both,the accuracy of the new system in underlying physical data collection will be evaluated.

2.Secondary Endpoints:

①Clinical Diagnosis Agreement Rate:Evaluate the degree of agreement between the two systems in determining the diagnostic conclusions of the subjects'erectile function status(normal,psychogenic,organic).

②Superiority Evaluation:Use medical-engineering grade sleep recorders to collect sleep efficiency(SE),REM sleep proportion,and unintended arousal frequency of subjects on different monitoring nights to evaluate the superiority of the flexible system.

③Subjective Evaluation and Compliance:Use the Visual Analogue Scale(VAS)to evaluate the comfort scores of the subjects during the wearing process of the two devices;use the Pittsburgh Sleep Quality Index(PSQI)to evaluate the subjects'subjective sleep perception on the morning after monitoring and record the subjects'final preference for the monitoring scheme.

④Dynamic Response Agility:In the Audiovisual Sexual Stimulation(AVSS)experiment,record the response latency from the start of stimulation to a rigidity increase of more than 10%,as well as the congestion initiation slope reflected by the deformation heatmap.

⑤Vascular Subtyping Characteristic Correlation:Extract morphological feature vectors from the deformation heatmaps and perform correlation analysis with the hemodynamic indicators measured by Color Doppler Duplex Ultrasound(CDDU)to evaluate the clinical value of heatmaps in assisting the refined subtyping of vascular ED.

3.Research Methods

(1)Research Design

This experiment will adopt the design scheme of a randomized controlled prospective study.

(2)Inclusion and Exclusion Criteria

The inclusion criteria for subjects are as follows:

Common Criteria:

·Male aged 18-70 years with good communication skills and compliance;

·Able to follow clinical Standard Operating Procedures(SOP)and complete the two-stage whole-night monitoring of the randomized crossover design;

·Fully informed about this study and signed the informed consent form.

Criteria for ED Patient Group:

·Clinically diagnosed with erectile dysfunction;

·IIEF-5 scale score<21 points.

Criteria for Healthy Volunteer Group:

·Normal sexual function,no history of psychosexual disorders or related physiological diseases;

·IIEF-5 scale score≥21 points.

The exclusion criteria for subjects are as follows:

1.Systemic disease limitations:Suffering from severe cardiovascular disease(such as recent myocardial infarction,unstable angina),uncontrolled severe diabetes,or severe obstructive sleep apnea syndrome.

2.Local anatomical factors:Organic structural damage caused by severe anatomical malformation,spinal cord injury,or pelvic fracture,or a history of related surgery within the past six months.

3.Skin and allergy factors:Presence of active infection,eczema,or other skin diseases in the local penile area,or known allergy to flexible materials(medical-grade silicone/adhesives).

4.Mental and psychological factors:Suffering from untreated or unstable severe depression,anxiety,or other mental illnesses.

5.Medication interference factors:Previous use of PDE5 inhibitors,androgens,anti-androgen drugs,or neurological drugs that significantly interfere with the REM sleep structure.

6.Other factors:Currently participating in other interventional clinical trials,or judged by the researcher to have poor compliance or be unable to complete the different-night crossover controlled experiment.

(3)Enrollment and Experimental Protocol:

Subject recruitment for this study will rely on the preliminary screening of the electronic medical record system of Zhongda Hospital Affiliated to Southeast University and on-site recruitment at the urology outpatient clinic.Subjects(including ED patients and healthy volunteers)who meet the inclusion criteria and exclude related contraindications will be officially enrolled after fully understanding the research content and signing the informed consent form.

1.Randomization and Grouping Process

The study adopts a prospective,randomized,crossover controlled design scheme.After enrollment,subjects are assigned to Sequence A or Sequence B in a 1:1 ratio through a central randomization system.Subjects in Sequence A wear the new intelligent flexible monitoring system on the first stage monitoring night,and after a

washout period,wear the clinical gold-standard RigiScan Plus device on the second stage monitoring night;subjects in Sequence B follow the reverse wearing order.To ensure experimental efficacy,a washout period of 3 to 7 days is established between the two monitorings,aiming to eliminate local mechanical residual interference and psychological suggestion that may be generated by the previous monitoring,and to alleviate the"first-night effect"common in clinical monitoring.

2.Nocturnal Monitoring(NPT)Standardized Procedure

The experimental protocol covers two stages of whole-night Nocturnal Penile Tumescence(NPT)monitoring.On the night of monitoring,subjects undergo data collection lasting no less than 6 hours.When wearing the flexible monitoring system,a sleep recorder is connected simultaneously to quantitatively evaluate the subjects'arousal frequency and sleep quality during the REM phase by capturing heart rate variability and body movement signals.

3.Dynamic Response and Advanced Subtyping Exploration Protocol

Audiovisual Sexual Stimulation(AVSS)response tests and vascular subtyping correlation research will be conducted.Subjects receive induction with standardized audiovisual materials in a private consulting room,and the dynamic evolution characteristics of the"deformation heatmap"during the initiation stage of erection are captured in real-time using the new flexible system.For subjects suspected of vascular ED,simultaneous monitoring with the new device and Penile Color Doppler Duplex Ultrasound(CDDU)examination will be conducted under the state of Intracavernous Injection(ICI).The Peak Systolic Velocity(PSV)and End-Diastolic Velocity(EDV)of the cavernous artery will be measured by an ultrasound physician,aiming to perform spatial-temporal alignment analysis of hemodynamic indicators and the spatial compliance parameters extracted by the flexible sensing array.

Therapeutic Evaluation(Efficacy Evaluation:

1.Primary Endpoint:

Peak rigidity(%)and maximum girth expansion rate(cm)of the two sets of devices during erectile events.By calculating the mean bias(Bias)and 95%limits of agreement(LoA)of both,the accuracy of the novel system in underlying physical data collection will be evaluated.

2.Secondary Endpoints:

①Clinical diagnosis agreement rate:Evaluate the degree of agreement between the two systems in determining the subjects'erectile function status conclusion(normal,psychogenic,or organic).

②Sleep parameters:Sleep efficiency(SE),Rapid Eye Movement(REM)period proportion,and unexpected arousal(Arousal)frequency collected by medical-engineering grade sleep recorders on different monitoring nights to evaluate the superiority of the flexible system.

③Patient subjective evaluation and compliance:Adopt the Visual Analogue Scale(VAS)to evaluate the subjects'comfort score during wearing the two sets of devices;utilize the Pittsburgh Sleep Quality Index(PSQI)to evaluate the subjects'subjective sleep perception on the morning after monitoring,and record the subjects'final preference choice for the monitoring scheme.

④Dynamic response agility:In the Audiovisual Sexual Stimulation(AVSS)experiment,record the response delay time from stimulus onset to a rigidity increase of>10%,as well as the congestion initiation slope reflected by the deformation heatmap.

⑤Vascular subtyping feature correlation:Extract morphological feature vectors from the deformation heatmaps,perform correlation analysis with hemodynamic indicators measured by Color Doppler Duplex Ultrasound(CDDU),and evaluate the clinical value of heatmaps in assisting the refined subtyping of vascular ED.

(4)Statistical Analysis

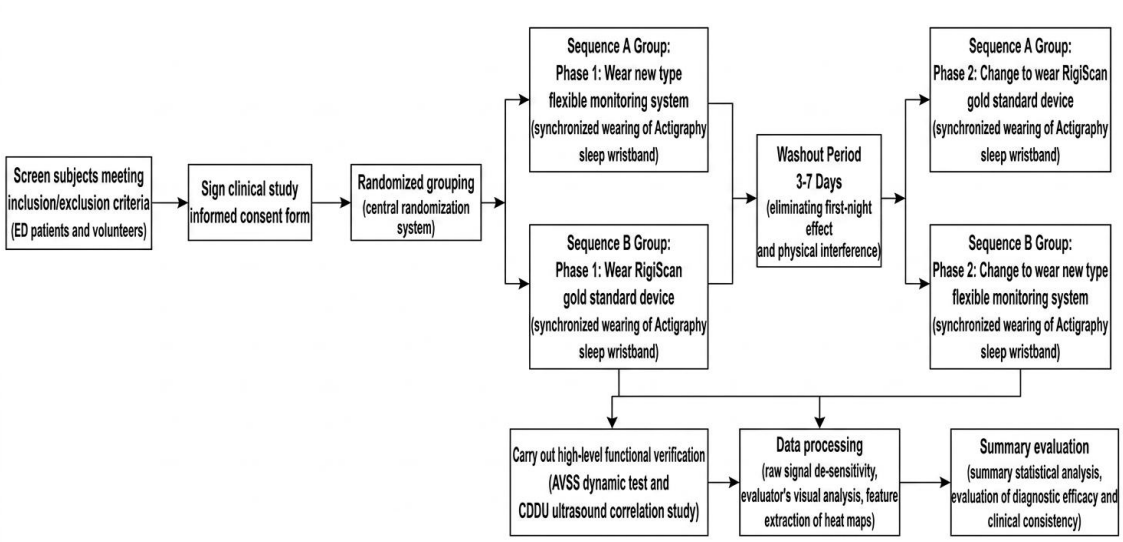
Statistical work will be executed by professional statisticians at the Clinical Evaluation and Analysis Center of Zhongda Hospital Affiliated to Southeast University,using SPSS 26.0 or R language.This study follows the Intention-to-

Treat(ITT)principle,analyzing all enrolled subjects who generate at least one set of monitoring data.

Specific methods are as follows:First,the Shapiro-Wilk test is used to evaluate the normality of continuous variables.For the primary endpoint,the Bland-Altman scatter plot is used to analyze the difference distribution of measurements between the two devices,and the 95%limits of agreement are calculated.For qualitative diagnostic data,Cohen's Kappa test is used to evaluate the level of diagnostic agreement.

Differences in baseline data and sleep structure on monitoring nights with different devices are expressed as(x±s)using paired t-tests for normally distributed data,and as median(interquartile range)using Wilcoxon signed-rank tests for non-normally distributed data.For missing data in the primary endpoint,Multiple Imputation will be used for imputation processing.All statistical tests are set as two-tailed tests,with $P<0.05$ considered statistically significant.

4.technology roadmap



5.Feasibility Analysis

Theoretical Feasibility of the Research

The theoretical feasibility of this study is established on the basis of the deep integration of flexible electronic materials science and clinical diagnostics.The core value of Nocturnal Penile Tumescence(NPT)monitoring lies in capturing the physiological feedback of the subject in a natural sleep state,whereas the limitation of the current gold standard,RigiScan,lies in the micro-arousal intervention of its rigid physical structure on the REM sleep structure.The flexible sensing scheme proposed in this project is not a simple hardware replacement,but a diagnostic and therapeutic paradigm evolution based on the concept of"conformal fit."Flexible sensing materials possess extremely low mechanical impedance and can extend synchronously with tissue deformation,thereby resolving the technical paradox of"monitoring interfering with physiology"at the physical level and ensuring the primitivity and authenticity of the collected data.

Furthermore,the research group has previously completed the publication of related articles on the andrology artificial intelligence diagnosis and treatment system(published in Sexual Medicine),demonstrating from the perspective of evidence-based medicine the decisive role of high-quality,standardized underlying data for the precise subtyping of ED,providing a theoretical anchor for the clinical path design of this scheme.Preliminary in vitro performance calibration already completed shows that the flexible sensing array possesses excellent linear response and high signal-to-noise ratio within the simulated physiological pressure range,and the sensing materials comply with medical-grade biocompatibility specifications.This progressive logic from"underlying theoretical discovery"to"physical benchmark calibration"and then to"clinical efficacy verification"constitutes the solid theoretical credibility of this study.

Clinical Operational Feasibility

This research is designed as a prospective,randomized crossover controlled trial,carried out relying on the mature clinical evaluation platform of the Urology Department of Zhongda Hospital Affiliated to Southeast University,and possesses a high degree of operability:

1.Subject Recruitment and Compliance Guarantee:The annual outpatient volume of the hospital's urology department is sufficient,and it possesses a complete ED patient database and a standardized electronic medical record system,making it easy to quickly lock in the target population through outpatient screening and intra-hospital recruitment.The study intends to recruit 60 subjects,and since the flexible system possesses the wearing advantage of being"near-unfelt,"the subjects'cooperation and compliance for completing the two-stage crossover monitoring are expected to be good.

2.Standard Operating Procedures(SOP):The research group has formulated a detailed clinical operation manual.The monitoring process is carried out in wards where the environment is constant temperature(24-26° C)and soundproof,which can eliminate environmental confounding factors.The wearing process of the flexible device is simple,non-invasive,and does not generate electrical stimulation,meeting ethical safety requirements.Evaluation indicators(such as Kappa consistency and Bland-Altman bias analysis)all adopt internationally recognized medical statistical models,and the measurement of results is objective and traceable.

3.Interdisciplinary Team and Hardware Support:Zhongda Hospital is equipped with advanced Color Doppler Duplex Ultrasound(CDDU)and NPT monitoring auxiliary equipment,ensuring the accurate collection of gold-standard control data.The research team is composed of senior urology clinical doctors,flexible electronic technology experts,and medical statisticians;all members have received standardized training,which can ensure the concealment of the randomized sequence,the implementation of the evaluator-blind method,and the synchronous analysis of multi-modal data.In summary,at the level of clinical operation,this study has a mature scheme and sufficient resources,and can effectively advance and obtain reliable clinical evidence-based evidence.

6.Innovations of the Project

At present,the objective evaluation of erectile dysfunction mainly relies on RigiScan equipment,but its rigid hoops tend to produce a squeezing sensation during the monitoring process,interfering with the natural sleep structure of the subject.The innovation of this study lies in the adoption of ultra-thin flexible sensing technology to carry out nocturnal monitoring,aiming to reduce the interference of examination methods on physiological responses.Through a randomized crossover controlled trial,we will systematically evaluate the accuracy of the new flexible device in obtaining erectile data under natural states.If the results confirm the expectations,this scheme will provide the clinic with an auxiliary diagnostic tool with low physical load and high compliance,significantly improving the subject's examination experience.In addition,the deformation heatmap generated by this technology in this study can obtain morphological details that cannot be captured by traditional point measurements,which is expected to provide intuitive evidence-based grounds for the refined subtyping of vascular ED and promote the digital evaluation process of andrology diagnosis and treatment technology.

7.Research Plan and Predicted Progress

Work Progress	Main Tasks
August 2026 to August 2027	Enroll relevant clinical research patients and conduct clinical trials while simultaneously collecting data
August 2027 to February 2028	Complete data collection and analysis

8.Expected Research Results

It is expected to confirm the high consistency of the new flexible system with the gold-standard equipment in core diagnostic indicators,and to demonstrate significant superiority in reducing sleep interference and minimizing unintended arousal.The project will yield 1-2 high-quality SCI clinical research papers and provide highly

credible evidence-based medical grounds for the medical device registration and industrialization of this monitoring system.

II.Working Basis and Conditions

1.Accumulation of Research Work Related to This Project

The Urology Department of Zhongda Hospital Affiliated to Southeast University has a sufficient patient source in andrology,providing the objective conditions to conduct large-scale clinical trials.Regarding theoretical accumulation,the research group has systematically completed the publication of related articles on andrology artificial intelligence diagnosis and treatment and flexible sensing technology.Regarding hardware R&D and calibration,this project relies on deep medical-engineering cross-collaboration with the team of Dean Wu Jun from the School of Electronic Science and Engineering,Southeast University.Currently,the development of a finalized prototype for the flexible monitoring system and preliminary laboratory debugging have been completed.Regarding personnel allocation,the Principal Investigator,Associate Chief Physician Chao Sun,serving as a senior expert in the field of andrology,is responsible for the authoritative control of clinical direction and patient screening;Chief Physician Bin Xu provides guidance on the overall clinical evaluation scheme;Professor Wu Jun's team is responsible for the technical support of the underlying sensing algorithms.The team encompasses professional talents in clinical medicine,electronic engineering,and statistics,possessing a solid foundation for cross-disciplinary collaboration to complete the clinical translation research of this innovative medical device.

2.List of Research Team Members

Name	Gender	Age	Position/Title	Institution and Department	Professional Specialty	Role in Project
Chao Sun	Male	43	Associate Chief Physician of Urology	Zhongda Hospital Affiliated to Southeast University	Urology	Project Design,Quality Control
Bin Xu	Male	43	Vice President;Chief Physician of Urology	Zhongda Hospital Affiliated to Southeast University	Urology	Project Design,Quality Control
Jun Wu	Male	42	Professor;Vice President	School of Electronic Science and Engineering,Southeast University	Flexible sensing materials,wearable device R&D	Development and upgrade of new erectile detection equipment
Chunhui Liu	Male	39	Attending Physician	Zhongda Hospital Affiliated to Southeast University	Urology	Project Implementation
Bo Zhang	Male	25	Master's Student	Southeast University	Urology	Project Implementation

III. Budget Estimate

The funds for this research project are planned to be self-raised. For the 60 clinical subjects and in vitro calibration experiments, the project budget is preliminarily estimated as follows:

Flexible sensing units and patches: Plan to customize one set of the new erectile monitoring equipment and related consumables, subtotal 5,000 Yuan.

Medical-engineering grade sleep bracelet wear and tear: Replacement of bracelet wristbands and maintenance of charging bases during the trial period, subtotal 3,500 Yuan.

Data printing and management fees: Approximately 1,500 Yuan.

Document printing: Printing fees for 60 detailed informed consent forms (multi-page version), IIEF-5 scales, PSQI questionnaires, and clinical Standard Operating Procedures (SOP) manuals, subtotal 500 Yuan.

Ethics review fee: Initial review fee for the project by the hospital ethics committee, subtotal 500 Yuan.

Related patent application fees: Estimated at 10,000 Yuan.