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STUDY PROTOCOL: CROSS-CULTURAL VALIDATION, DIAGNOSTIC ACCURACY, AND SURGICAL RESPONSIVENESS OF THE UZBEK IIEF-5 A MULTICENTER NATIONAL COHORT INCLUDING SINGLE-COMPONENT PENILE PROSTHESIS RECIPIENTS

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ABSTRACT

Erectile dysfunction (ED) is a common male sexual health disorder associated with cardiometabolic disease, psychological distress, and impaired quality of life. Standardized patient-reported outcome measures (PROMs) are essential for ED detection, severity grading, and monitoring treatment response, yet measurement equivalence requires rigorous cross-cultural adaptation and psychometric validation.

Methods:

This multicenter protocol includes (i) a validation cohort of 300 adult men for psychometric analyses (internal consistency, test–retest reliability, structural and construct validity, floor/ceiling effects) and (ii) a prospective surgical cohort of approximately 80–90 men undergoing single-component penile prosthesis implantation to evaluate responsiveness (pre–post change, effect size indices). Diagnostic accuracy will be assessed using receiver operating characteristic (ROC) analysis against a predefined clinical reference standard.

Discussion/Expected impact:

The study will deliver the first nationally validated Uzbek-language ED instrument, enabling standardized screening, epidemiological surveillance, and comparable surgical outcomes reporting. The protocol aligns with ISPOR translation principles and COSMIN measurement property standards and is designed to support publication in international sexual medicine journals.

1. Introduction

Erectile dysfunction (ED), commonly defined as a persistent inability to achieve and/or maintain an erection sufficient for satisfactory sexual performance, remains a major public health concern. Beyond sexual function, ED is associated with reduced health-related quality of life, relationship distress, and reduced work productivity, and it frequently coexists with conditions such as diabetes mellitus, hypertension, dyslipidemia, obesity, lower urinary tract symptoms, and depressive symptoms. Contemporary evidence supports ED as a potential early marker of systemic vascular disease; thus, standardized ED assessment can facilitate timely risk stratification and integrated cardiometabolic management.

Recent literature continues to document substantial ED prevalence across diverse populations, with particularly high rates in men with metabolic disorders and in older age groups. For example, pooled estimates suggest a very high prevalence of ED among men with diabetes, emphasizing the importance of routine screening and structured assessment in urological and primary care settings. Likewise, population analyses show marked increases in ED prevalence with age and comorbidity burden. In parallel, health-economic evaluations demonstrate that ED can impose meaningful direct and indirect costs, reinforcing its relevance for health system planning.

International guidelines provide evidence-based recommendations for ED diagnosis and management, including clinical evaluation, identification of reversible causes, shared decision-making, and stepwise therapy selection. The European Association of Urology (EAU) Sexual and Reproductive Health guidelines are updated regularly and summarize best practices for ED management—from lifestyle optimization and pharmacotherapy to endovascular or surgical interventions. For men with severe, refractory ED who do not respond to or cannot tolerate conservative therapy, penile prosthesis implantation remains the definitive surgical option with consistently high satisfaction rates when appropriately selected and counseled.

PROMs are central to ED assessment because they capture the patient's perception of sexual function and treatment benefit. The International Index of Erectile Function (IIEF) is one of the most widely used multidimensional PROMs in sexual medicine, and the abridged five-item version (IIEF-5, also known as SHIM) is widely used for ED screening and severity grading in both clinical practice and research. However, PROMs are not universally transferable across settings: translation alone is insufficient without rigorous cross-cultural adaptation to ensure conceptual equivalence, comprehensibility, and cultural acceptability.

To address these issues, ISPOR principles of good practice outline a transparent and reproducible process for translation and cultural adaptation of PRO measures, including forward–backward translation, expert committee review, cognitive debriefing, and documentation of all decisions. Complementing this, the COSMIN initiative provides internationally recognized standards to evaluate PROM measurement properties (reliability, validity, and responsiveness), supporting consistent methods and interpretation across validation studies. In 2024, COSMIN released updated resources (version 2.0 guidance) that further emphasize structured evaluation and transparent reporting.

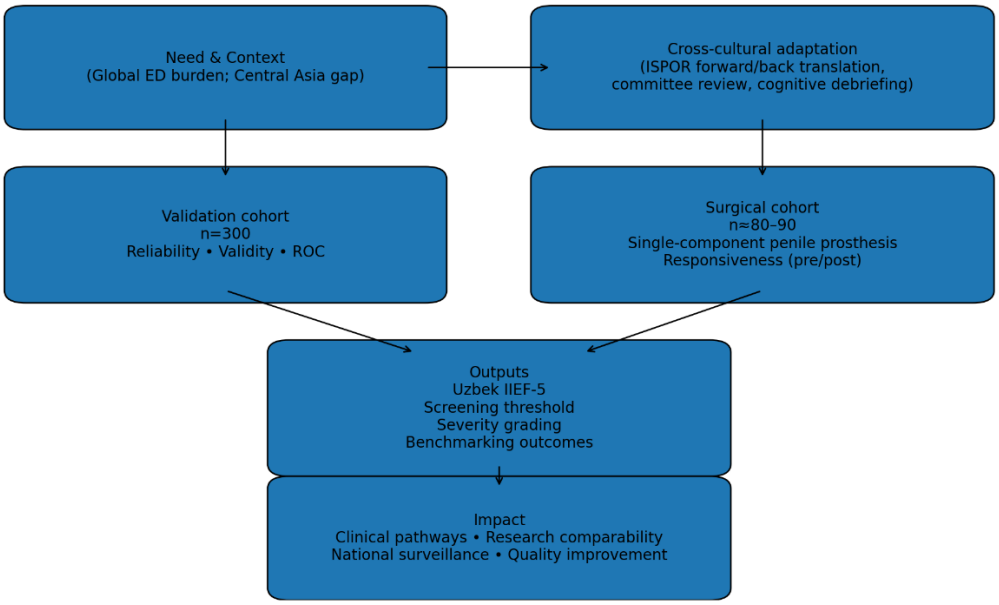
In Uzbekistan, the lack of a psychometrically validated Uzbek-language IIEF-5 has limited standardized ED research, the comparability of epidemiological findings, and the implementation of unified clinical pathways. Moreover, the ability of the Uzbek IIEF-5 to detect clinically meaningful change after definitive surgical treatment has not been evaluated. Demonstrating responsiveness is crucial for

postoperative monitoring and benchmarking outcomes in penile prosthesis surgery, where patient-centered metrics are essential.

Accordingly, this protocol describes a national multicenter study designed to validate the Uzbek IIEF-5 using contemporary PROM standards, to establish its diagnostic accuracy (including ROC-derived screening thresholds), and to evaluate responsiveness in a surgical cohort undergoing single-component penile prosthesis implantation. The protocol is structured to meet reporting expectations of international journals in sexual medicine and to support future results-based publications.

Figure 1. Conceptual framework

Conceptual model linking cross-cultural adaptation, psychometric validation, diagnostic accuracy, and surgical responsiveness components.



2. Objectives

Primary objectives:

1) To establish linguistic and conceptual equivalence of the Uzbek IIEF-5 using ISPOR translation principles.

2) To evaluate measurement properties of the Uzbek IIEF-5 (reliability, structural validity, construct validity, floor/ceiling effects) in a national cohort (n=300).

3) To quantify diagnostic accuracy and derive an optimal screening threshold using ROC analysis against a predefined clinical reference standard.

4) To evaluate responsiveness to clinically meaningful change in men undergoing single-component penile prosthesis implantation (n≈80–90).

Secondary objectives:

To explore associations between ED severity and cardiometabolic risk factors and to assess feasibility for national epidemiological deployment.

3. Methods

3.1 Study design and setting

This is a multicenter observational study with two linked components: (i) a psychometric validation component (cross-sectional with a test–retest subset) and (ii) a prospective pre–post

surgical component assessing responsiveness after single-component penile prosthesis implantation. Recruitment will occur in urology/andrology outpatient clinics and affiliated screening sites representing different regions of Uzbekistan.

3.2 Participants

Validation cohort (n=300):

Adult men (≥18 years) with Uzbek language proficiency sufficient for self-completion. Exclusion criteria include cognitive impairment preventing valid completion, acute severe illness, and inability to provide informed consent.

Surgical cohort (n≈80–90):

Consecutive men with severe, refractory ED who are scheduled for single-component penile prosthesis implantation. Exclusion criteria include active infection, uncontrolled comorbidities precluding surgery, and inability to complete follow-up. The postoperative assessment window will be standardized (e.g., 3–6 months) once sexual activity is feasible.

3.3 Instrument: IIEF-5

The IIEF-5 assesses erectile function and intercourse satisfaction over the preceding 4 weeks. Items are scored 1–5 (total 5–25), with higher scores indicating better erectile function. Standard severity categories commonly used internationally will be retained for comparability, while local performance will be examined via ROC analysis.

3.4 Translation and cross-cultural adaptation

Translation will follow ISPOR good practice: (1) forward translation by two independent bilingual translators; (2) reconciliation; (3) backward translation by two independent translators blinded to the original; (4) expert committee review (urologists/andrologists, linguists, methodology experts) to ensure conceptual equivalence; (5) cognitive debriefing interviews with target users to confirm clarity and cultural acceptability; (6) final proofreading and formatting. All changes will be documented.

3.5 Surgical methodology (single-component penile prosthesis)

Indications: Penile prosthesis implantation will be offered as definitive surgical therapy for men with severe ED refractory to first- and second-line treatments (e.g., PDE5 inhibitors, intracavernosal injections, vacuum devices) or in whom these therapies are contraindicated or unacceptable. Etiological categories may include vasculogenic ED, diabetes-related ED, post-pelvic surgery ED, neurogenic ED, and mixed etiologies. Candidate selection will follow guideline-consistent assessment, including medical history, focused examination, evaluation of comorbidities, and counseling regarding expectations and device characteristics.

Preoperative pathway: Patients will undergo standardized preoperative evaluation including infection screening, glycemic control assessment in diabetics, and optimization of modifiable risk factors (smoking cessation, weight management, blood pressure control). Antimicrobial prophylaxis and skin preparation will follow institutional protocols, with documentation to enable quality monitoring.

Operative technique: The surgical approach (e.g., penoscrotal or infrapubic) and device type (single-component malleable prosthesis) will be

standardized as far as feasible across centers. Key steps include corporal exposure, corporotomy, sequential dilation, measurement, device insertion, meticulous hemostasis, and layered closure. Strict aseptic technique is emphasized to minimize infection risk. Operative details (approach, operative time, intraoperative complications) will be recorded using a predefined case report form.

Postoperative care and follow-up: Postoperative protocols will include wound care, pain control, infection surveillance, and counseling on device handling and timing of resumption of sexual activity. Follow-up visits will assess complications (infection, hematoma, erosion, discomfort), functional outcomes, and PROM completion. The primary PROM time point will be standardized (e.g., 3–6 months), with additional visits per routine care.

Complication definitions: Prosthesis infection will be defined by clinical criteria (e.g., erythema, pain, discharge, systemic symptoms) and/or need for explantation or antibiotics as per treating surgeon. Revision procedures and device-related adverse events will be captured to support benchmarking.

4. Statistical Analysis Plan (SAP)

Analyses will follow COSMIN recommendations for PROM studies. A detailed analysis script will be prespecified to minimize selective reporting. Statistical software: SPSS/Stata/R (version recorded). Two-sided α=0.05 will be used unless otherwise specified.

4.1 Data management and descriptive statistics

Continuous variables will be summarized as mean ± standard deviation (SD) when approximately normally distributed or median (interquartile range, IQR) otherwise. Categorical variables will be summarized as counts and percentages. Missing data patterns will be described; if missingness exceeds 5% for key variables, multiple imputation may be considered depending on mechanism.

4.2 Reliability

Internal consistency (Cronbach's alpha):

Cronbach's alpha will be computed as: $\alpha = (k/(k-1)) \times (1 - (\Sigma\sigma_i^2 / \sigma_t^2))$, where k is the number of items (k=5), σ_i^2 is the variance of item i, and σ_t^2 is the variance of the total score. Item–total correlations and alpha-if-item-deleted will be reported.

Test–retest reliability (ICC):

For a stable subset completing the instrument twice within 7–14 days (no treatment change), ICC will be calculated using a two-way mixed-effects model, absolute agreement (ICC(3,1)). Interpretation: ICC≥0.75 good; ≥0.90 excellent.

4.3 Measurement error

Standard error of measurement (SEM) will be estimated as $SEM = SD \times \sqrt{(1 - ICC)}$. The minimal detectable change at 95% confidence will be computed as $MDC_{95} = 1.96 \times \sqrt{2} \times SEM$.

4.4 Structural validity

Exploratory factor analysis (EFA) will examine dimensionality (eigenvalues, scree plot). Confirmatory factor analysis (CFA) will test a one-factor model. Model fit will be evaluated

using standard indices (CFI, TLI, RMSEA, SRMR).

4.5 Construct validity (hypothesis testing)

A priori hypotheses will assess expected relationships between IIEF-5 and clinical variables. For example, lower scores are expected in older age strata, in men with diabetes, and in men with cardiovascular risk factors. Correlations (Pearson/Spearman) and known-groups comparisons (t-test/Mann–Whitney; ANOVA/Kruskal–Wallis) will be applied as appropriate.

4.6 Diagnostic accuracy (ROC)

Diagnostic accuracy will be evaluated via ROC analysis against a predefined reference standard (clinician diagnosis or structured interview). AUC will be estimated with 95% confidence intervals. The optimal threshold will be selected using the Youden index: J = Sensitivity + Specificity − 1. At the chosen cut-off, sensitivity, specificity, positive/negative likelihood ratios (LR+ = Sens/(1−Spec); LR− = (1−Sens)/Spec), and predictive values will be reported.

4.7 Responsiveness (surgical cohort)

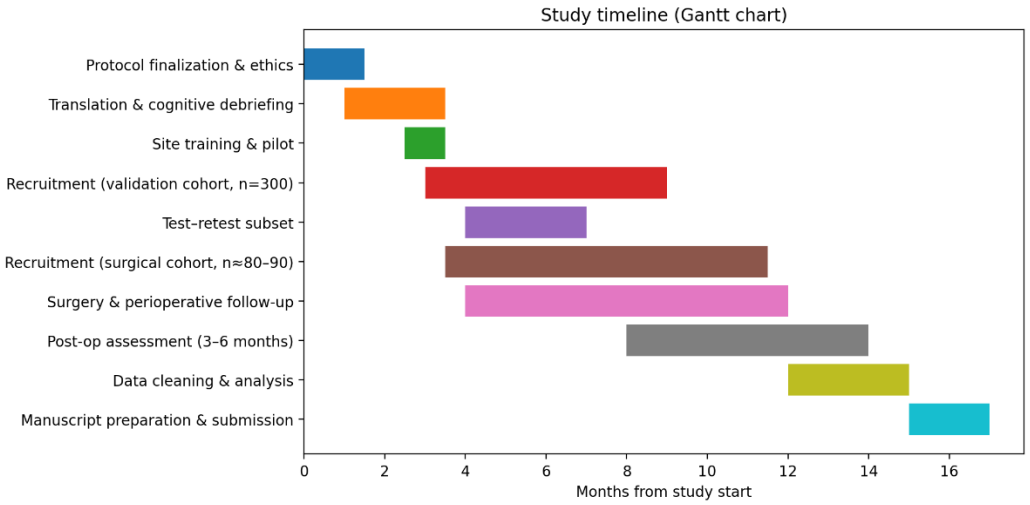
Change score: Δ = Postoperative IIEF-5 − Preoperative IIEF-5. Paired tests (paired t-test or Wilcoxon signed-rank) will test change. Effect size (Cohen's d) will be computed as d = (Mean_post − Mean_pre) / SD_pre. Standardized response mean (SRM) will be computed as SRM = Mean(Δ) / SD(Δ). Where an anchor is available (e.g., patient global impression of improvement), anchor-based MCID will be estimated; otherwise, distribution-based estimates (e.g., 0.5 SD) will be reported for interpretability.

4.8 Sensitivity analyses

Sensitivity analyses will test robustness by age strata, diabetes status, and recruitment site. If evidence supports, measurement invariance may be explored in future work.

Figure 2. Study timeline

Planned study phases and timing (months from study start).



5. Ethics, trial registration, and dissemination

The protocol will be reviewed and approved by the institutional ethics committee(s). All participants will provide written informed consent. If required by the target journal, the study will be registered in an appropriate registry (e.g., ClinicalTrials.gov or local registry) prior to analysis. Results will be

disseminated through peer-reviewed journals and conference presentations.

6. Target journal formatting notes (IJIR)

Manuscript preparation will align with International Journal of Impotence Research (Nature) guidance: numbered in-text citations and Vancouver-style reference list, structured sections, and concise referencing (avoid exhaustive lists).

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