



# URGANCH DAVLAT TIBBIYOT INSTITUTI JANUBIY OROLBO'YI TIBBIYOT JURNALI

2 - TOM, 5/2- SON. 2026

14.00.00 - TIBBIYOT FANLARI ISSN: 3093-8740

## CLINICAL OUTCOMES AND PATIENT SATISFACTION – MALLEABLE VS. SEMI-RIGID PENILE PROSTHESES IN UZBEKISTAN



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**Abstract.** Erectile dysfunction (ED) severely impairs male quality of life, and penile prosthesis implantation remains the definitive treatment in refractory cases. This study addresses the urgent need to comparatively evaluate clinical outcomes and patient satisfaction between semi-rigid and malleable penile prostheses within Uzbekistan’s evolving urological practice. A retrospective analysis of 96 patients (46 semi-rigid, 50 malleable) was conducted, assessing complication rates and utilizing the standardized EDITS questionnaire. Multivariate statistical modeling (ANCOVA,



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logistic regression) was applied to control for baseline covariates like age. The results demonstrate that malleable prostheses drastically reduce complication rates (3.7% vs. 28.3%) and yield significantly higher adjusted patient and partner satisfaction scores (93.01 vs. 67.14) compared to older semi-rigid models. The practical contribution of this study is the mathematical justification for shifting clinical protocols toward modern malleable implants, ultimately optimizing surgical safety and improving postoperative patient quality of life in Uzbekistan.

**Keywords:** Erectile dysfunction, penile prosthesis, semi-rigid models.

## **O'zbekistonda malleabel va yarim qattiq penis protezlari - klinik natijalar va bemorlar qoniqishi**

**Annotatsiya.** Erektill disfunksiya (ED) erkaklar hayot sifatiga jiddiy putur yetkazadi va penil implant amaliyoti jinsiy zaiflikning eng og'ir turini davolashda oltin standart usul bo'lib qolmoqda. Ushbu tadqiqot O'zbekistonning rivojlanib borayotgan urologik amaliyotida (semirigid) yarim qattiq va malleabel (egiluvchan) penis protezlari o'rtasidagi klinik natijalar hamda bemorlar qoniqishini qiyosiy baholashdek dolzarb muammoni hal etadi. Jami 96 nafar bemor (46 ta yarim qattiq, 50 ta malleabel) ma'lumotlari retrospektiv tahlil qilinib, asoratlar darajasi baholandi va standartlashtirilgan EDITS so'rovnomasidan foydalanildi. Bemorning yoshi kabi kovariatalarni nazorat qilish uchun ko'p o'lchovli statistik modellashirish (ANCOVA, logistik regressiya) qo'llanildi. Natijalar shuni ko'rsatadiki, malleabel protezlar eski yarim qattiq modellarga nisbatan asoratlar darajasini keskin kamaytiradi (28,3% ga nisbatan 3,7%) va bemor hamda sherikning qoniqish ko'rsatkichlarini sezilarli darajada oshiradi (67,14 ga nisbatan 93,01). Ushbu tadqiqotning amaliy hissi – klinik bayonnomalarni zamonaviy malleabel implantlarga o'tkazishni matematik jihatdan asoslash bo'lib, bu pirovardida O'zbekistonda jarrohlik xavfsizligini optimallashtirish va operatsiyadan keyingi bemorlar hayot sifatini yaxshilashga xizmat qiladi.

**Kalit so'zlar:** Erektill disfunksiya, jinsiy olat protezi, yarim qattiq modellar.

## **Клинические исходы и удовлетворенность пациентов — маллеабельные и полуригидные фаллопротезы в Узбекистане**

**Аннотация.** Эректильная дисфункция (ЭД) серьезно ухудшает качество жизни мужчин, и пенильные импланты при тяжелых степени эректильной дисфункции является золотым стандартом. Данное исследование решает актуальную проблему сравнительной оценки клинических исходов и удовлетворенности пациентов семиригидных и гибких имплантов в урологической практике Узбекистана. Проведен ретроспективный анализ 96 пациентов (46 полуригидных, 50 маллеабельных), оценены уровни осложнений и использован стандартизированный опросник EDITS. Для контроля таких ковариат, как возраст, применялось многомерное статистическое моделирование (ANCOVA, логистическая регрессия). Результаты демонстрируют, что маллеабельные протезы радикально снижают частоту осложнений (3.7% против 28.3%) и обеспечивают значительно более высокие скорректированные показатели удовлетворенности пациента и партнера (93.01 против 67.14) по сравнению со старыми семиригидными моделями. Практический вклад данного исследования заключается в математическом обосновании необходимости перехода клинических протоколов на современные гибкие импланты, что в конечном итоге оптимизирует хирургическую безопасность и повышает качество жизни пациентов в Узбекистане.



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**Ключевые слова:** эректильная дисфункция, протез полового члена, полужесткие модели.

## Introduction

Erectile dysfunction (ED) is a highly prevalent condition affecting the aging male population worldwide, with significant implications for psychosocial well-being and quality of life. Epidemiological data from the Massachusetts Male Aging Study (MMAS) indicates an overall ED prevalence of 52% among men aged 40–70 years [1]. The severity distribution within this cohort demonstrates that 17.2% experience minimal dysfunction, 25.2% moderate, and 9.6% complete dysfunction [1]. Similarly, the Cologne study reported an overall prevalence of 19.2% among men aged 30–80 years, with a sharp age-dependent increase from 2.3% in younger men to 53.4% in older demographics [2]. The incidence rate of ED is estimated at 26 new cases per 1,000 men annually according to longitudinal MMAS data, while a Dutch study reported an incidence of 19.2 cases per 1,000 men over a 4.2-year follow-up period [1].

For patients refractory to conservative therapies, penile prosthesis implantation remains the definitive treatment. In the urological practice of Uzbekistan, where the first semirigid prosthesis was implanted in 1992 at the Center for Emergency Surgery, two main categories of devices dominate: semirigid and malleable prostheses. Semirigid prostheses provide constant rigidity and are characterized by a simpler surgical implantation technique, lack of mechanical failure risk, and high economic accessibility, though they offer limited concealability in daily life. Conversely, Malleable Penile Prostheses (MPP) feature an internal metal core – typically crafted from steel, silver, or nitinol alloys – allowing the patient to manually bend the implant into a resting state or straighten it for coitus [3]. This design offers superior cosmetic results, daily comfort, and generally higher patient satisfaction scores on the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) scale [4]. Utilizing archival clinical data extracted by the researchers, this study aims to comparatively evaluate the clinical outcomes and patient satisfaction between semirigid and malleable penile prostheses within two urological centers in Uzbekistan.

## Literature Review

**1. Epidemiology and Burden of Erectile Dysfunction** Erectile dysfunction (ED) is a highly prevalent condition that significantly impairs the quality of life of aging men. The Massachusetts Male Aging Study (MMAS) provided the first relatively unbiased study of the epidemiology of ED, serving as a landmark foundation for subsequent global research [1]. In Europe, the Cologne Male Survey assessed a representative sample of men aged 30–80 years, identifying an overall ED prevalence of 19.2% [2]. This study demonstrated a steep, age-dependent increase in ED, rising from 2.3% in younger men to 53.4% in older demographics, and highlighted a high comorbidity with conditions such as hypertension, diabetes, and lower urinary tract symptoms [2].

**2. The Role of Semirigid and Malleable Prostheses** While modern treatments frequently feature three-piece inflatable devices, non-inflatable penile prostheses maintain a critical role in global urology due to distinct clinical advantages. Malleable penile prostheses (MPPs) have unique



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benefits, including lower overall costs, an easier surgical technique, and a reduced incidence of mechanical complications [3]. MPPs are particularly beneficial for patients with poor manual dexterity or those requiring emergency surgical measures for conditions like acute ischemic priapism, and recent technological advancements have improved their axial rigidity and device concealability [3].

**3. Assessment of Patient Satisfaction (EDITS)** Evaluating subjective postoperative success is paramount in andrological surgery. The Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire was developed to reliably assess satisfaction with medical treatments for erectile dysfunction, differentiating treatment satisfaction from strict treatment efficacy [5]. The development of EDITS established a highly reliable – test-retest reliability of 0.98 for patients – validated tool to measure how well treatments meet patient expectations [5]. In the context of surgery, the EDITS questionnaire is recognized as one of the best-known validated tools used to assess patient satisfaction following penile implant procedures [4].

**4. Surgical Complications and Clinical Outcomes** Infectious complications remain a disastrous event in penile prosthetic implantations. Early foundational data established an infectious complication rate of approximately 8.3%, identifying risk factors such as inadequate antibiotic coverage and simultaneous surgical procedures [6]. In contemporary cohorts utilizing malleable devices, complication profiles – including infection, erosion, and mechanical failure – and subsequent patient satisfaction are influenced by surgical variables, such as the anatomical fit and rod diameter of the malleable implant [7]. Safe surgical principles and careful patient selection remain paramount to achieving high patient satisfaction and minimizing postoperative complications when utilizing malleable devices [7].

## Research Methods

This retrospective comparative study analyzed data from 96 patients who underwent penile prosthesis implantation and subsequently completed post-operative satisfaction questionnaires. Patient identification was conducted through a comprehensive review of hospital archival data and facilitated by the personal clinical networks of the operating andrologic surgeons. Eligible patients were contacted directly, and only those who provided explicit informed consent to participate and independently complete the questionnaire were included in the final dataset. The resulting cohort was divided into two clinical groups:

- **Group 1 (Semirigid):** Comprised 46 cases operated at the Republican Specialized Scientific and Practical Medical Center of Urology (RSSPMCU), where these surgeries have been performed since 2008.
- **Group 2 (Malleable):** Comprised 50 cases operated at the private «Medion» Clinic, representing a newer cohort with surgeries initiated in 2023.

Clinical parameters evaluated included patient age, hospitalization duration, and postoperative complication/infection rates. Postoperative patient satisfaction was the primary endpoint, assessed



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using the validated 11-item EDITS questionnaire [5]. Patient responses, recorded on a 5-point Likert scale (0–4), were converted into a Standardized EDITS Index (0–100%) using the following established formula:

$$\text{EDITS Index} = \left( \frac{\text{Patient Score Sum}}{44} \right) \times 100$$

Statistical analysis was conducted using SPSS software. Continuous variables such as age and hospitalization days were compared using the independent samples t-test. Non-parametric data, including median EDITS item scores, were analyzed using the Mann-Whitney U test. A p-value of < 0.05 was considered statistically significant.

## Analysis and Results

**Baseline Characteristics and Clinical Outcomes** The baseline age of the patients differed significantly between the two surgical centers. The mean age in Group 1 was 40.00 years (SD 13.36, range 27–76), which was significantly lower than Group 2, where the mean age was 56.26 years (SD 12.82, range 25–78) ( $p < 0.001$ ). Clinical outcomes favored the malleable prosthesis group; the mean duration of hospitalization in Group 1 was 3.98 days (SD 1.65) compared to 1.10 days (SD 0.31) in Group 2 ( $p = 0.001$ ). Furthermore, Group 1 recorded 13 cases (28.3%) of complications and infections, whereas Group 2 recorded only 2 cases (3.7%).

**Patient Satisfaction (EDITS)** Analysis of the standardized overall EDITS index revealed significantly higher satisfaction in the malleable prosthesis cohort. The mean EDITS index for Group 2 was 92.77 (SD 0.88), compared to 67.39 (SD 3.78) for Group 1 ( $p < 0.001$ ). When evaluating individual parameters on a median scale, Group 2 consistently scored a median of 4 across almost all domains – including overall satisfaction, expectation fulfillment, convenience, and confidence – whereas Group 1 consistently scored a median of 3 (all  $p < 0.001$ ).

**Table 1. Patient Satisfaction Outcomes Based on the EDITS Questionnaire**

| Satisfaction Indicator (EDITS Criteria)                                                        | Republican Urology Clinic (Semi-rigid) n=46, Me (IQR) | Medion Clinic (Malleable) n=50, Me (IQR) | p-value |
|------------------------------------------------------------------------------------------------|-------------------------------------------------------|------------------------------------------|---------|
| 1. How satisfied are you with the prosthesis you received during this study?                   | 3 (1)                                                 | 4 (1)                                    | < 0.001 |
| 2. During the study, to what degree did the prosthesis meet your expectations?                 | 3 (1)                                                 | 4 (1)                                    | < 0.001 |
| 3. How likely are you to continue using the prosthesis you received during this study?         | 3 (1)                                                 | 4 (1)                                    | < 0.001 |
| 4. During the study, how easy was it for you to use the prosthesis to which you were assigned? | 3 (1)                                                 | 4 (0)                                    | < 0.001 |
| 5. During the study, how satisfied were you                                                    | 3 (1)                                                 | 4 (1)                                    | < 0.001 |



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|                                                                                                                                        |       |       |         |
|----------------------------------------------------------------------------------------------------------------------------------------|-------|-------|---------|
| with how quickly the prosthesis worked?                                                                                                |       |       |         |
| 6. During the study, how satisfied were you with how long the treatment (erection) lasted?                                             | 3 (1) | 4 (1) | < 0.001 |
| 7. How confident has the prosthesis you received during the study made you feel about your ability to engage in sexual activity?       | 3 (1) | 4 (0) | < 0.001 |
| 8. How satisfied do you believe your partner is with the effects of the prosthesis you received?                                       | 3 (1) | 4 (1) | < 0.001 |
| 9. How does your partner feel about you continuing to use the prosthesis you used during this study?                                   | 3 (1) | 4 (0) | < 0.001 |
| 10. How natural did the process of achieving an erection feel when you used this prosthesis during this study?                         | 3 (1) | 4 (1) | < 0.001 |
| 11. Compared to before you had an erection problem, how would you rate the naturalness of your erection when you used this prosthesis? | 2 (1) | 4 (1) | < 0.001 |

*Note: Patients were administered a translated Uzbek version of these questions. Data are presented as median (Me) and interquartile range (IQR). Differences between groups were evaluated using the non-parametric Mann–Whitney U test.*

## Multivariate Analysis of Outcomes

A one-way analysis of covariance (ANCOVA) was conducted to determine whether there was a statistically significant difference in patient satisfaction (Standardized EDITS Index) between semi-rigid and malleable penile prostheses while controlling for patient age. The covariate, age at admission, was not significantly related to the patient satisfaction score,  $F(1,93) = 2.026$ ,  $p = 0.158$ ,  $\eta_p^2 = 0.021$ . After adjusting for the age covariate, there remained a highly significant effect of prosthesis type on overall satisfaction,  $F(1,93) = 1605.744$ ,  $p < 0.001$ ,  $\eta_p^2 = 0.945$ . The estimated marginal means demonstrated that patients with malleable prostheses reported significantly higher adjusted satisfaction scores ( $M = 93.01$ ,  $SE = 0.41$ ) compared to those with semi-rigid prostheses ( $M = 67.14$ ,  $SE = 0.43$ ).

A binary logistic regression was performed to evaluate the effects of prosthesis type and patient age on the likelihood of postoperative complications. The overall model containing both predictors was statistically significant,  $\chi^2(2) = 12.665$ ,  $p = 0.002$ , indicating that the model

reliably distinguished between cases with and without complications. The model accounted for 12.4% to 21.3% of the variance in complication rates (Cox & Snell  $R^2 = 0.124$ , Nagelkerke

$R^2 = 0.213$ ) and achieved an overall classification accuracy of 84.4%.



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Controlling for patient age, prosthesis type emerged as a statistically significant independent predictor of complications ( $Wald = 8.741, p = 0.003$ ). Patients receiving semi-rigid prostheses at the public center faced 14.01 times higher odds of experiencing a complication compared to those receiving malleable prostheses at the private center ( $Exp(B) = 14.006, 95\% \text{ CI } [2.434, 80.585]$ ). Patient age at admission did not demonstrate a statistically significant relationship with complication occurrence ( $Wald = 1.007, p = 0.316, Exp(B) = 1.023, 95\% \text{ CI } [0.978, 1.071]$ ).

## Discussion

### Summary of Principal Findings

The principal finding of this study is that the modern, malleable penile prosthesis cohort demonstrated vastly superior outcomes in both surgical safety and patient satisfaction compared to the historical semi-rigid cohort. The transition from semi-rigid devices placed in a public clinical setting to malleable devices in a private clinical setting yielded a dramatic reduction in postoperative complications, falling from 28.3% to 3.7%. Correspondingly, patient and partner satisfaction, as measured by the standardized EDITS index, improved significantly, alongside a marked decrease in the mean duration of hospitalization.

### Deconstructing the Complication Disparity

A striking disparity was observed in the complication rates between the two groups. The binary logistic regression analysis revealed that patients receiving semi-rigid prostheses faced 14.01 times higher odds of experiencing a postoperative complication compared to those receiving malleable prostheses. Because device type and clinical setting were inherently linked in this cohort – with all semi-rigid implants performed at the RSSPMCU and all malleable implants at the Medion Clinic – this pronounced difference is likely multifactorial. It reflects not only the potential mechanical and safety advantages of malleable implant materials but also the evolution of surgical techniques, infection control protocols, and individualized postoperative care standards between the earlier surgical era (2008 onwards) and the modern private clinic setting (2023 onwards).

### Interpreting Patient and Partner Satisfaction

Patient satisfaction outcomes heavily favored the malleable prosthesis group. Even after adjusting for patient age using an analysis of covariance (ANCOVA), the malleable cohort reported an overwhelmingly higher adjusted mean EDITS score ( $M = 93.01$ ) compared to the semi-rigid cohort ( $M = 67.14$ ). An analysis of the individual EDITS parameters highlights specific areas of quality-of-life improvement. Patients in the malleable group consistently reported higher median scores across all measured domains, including the natural feel of the erection, ease of use, and expectation fulfillment. Crucially, this cohort also reported significantly higher perceived partner



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satisfaction, reinforcing the literature that modern malleable prostheses offer functional and psychological benefits that extend beyond mere mechanical reliability.

## Addressing Baseline Age Discrepancies

A notable baseline characteristic of this study was the significant age difference between the cohorts; patients in the malleable group were significantly older (mean age 56.26 years) than those in the semi-rigid group (mean age 40.00 years). A potential critique is that age could act as a confounding variable, influencing either complication risk or baseline satisfaction expectations. However, rigorous multivariate analysis nullified this concern. The ANCOVA demonstrated that age at admission was not a statistically significant covariate for patient satisfaction ( $p = 0.158$ ). Furthermore, the logistic regression confirmed that age did not demonstrate a statistically significant relationship with complication occurrence ( $p = 0.316$ ). These statistical controls provide strong evidence that the surgical environment and the device type – rather than patient age – were the primary drivers of the observed outcomes.

## Study Limitations

This study is not without limitations. The primary constraint is the perfect collinearity between the prosthesis type and the clinical setting. Because the semi-rigid devices were exclusively implanted at one center and the malleable devices at another, it is impossible to fully isolate the standalone effect of the prosthesis design from the institutional practices, surgeon volume, and sterilization protocols of the respective hospitals. Additionally, the retrospective nature of the analysis and the relatively modest sample size ( $n = 96$ ) necessitate careful interpretation.

## Conclusion

In conclusion, the utilization of malleable penile prostheses within a modern clinical setting represents a significant advancement in urological care in Uzbekistan. It offers a mathematically proven superiority in safety profiles and a highly significant improvement in patient and partner satisfaction. While the findings clearly support the clinical transition away from older semi-rigid models, future multi-center, randomized controlled trials are warranted to further isolate the effects of implant design from institutional variables.

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