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Trifecta Outcomes After Use of 3D Digital Models in Robotic Prostatectomy

Secondary Analysis of a Randomized Clinical Trial

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Original Investigation | Urology

Trifecta Outcomes After Use of 3-Dimensional Digital Models for Planning of Robotic Prostatectomy

A Secondary Analysis of a Randomized Clinical Trial

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Abstract

IMPORTANCE Planning complex operations such as robotic-assisted laparoscopic radical prostatectomy (RALP) requires surgeons to review 2-dimensional magnetic resonance imaging (MRI) scans to understand 3-dimensional (3D) patient anatomy. Three-dimensional digital models for planning RALP may allow better understanding of patient anatomy and may lead to better patient outcomes, although data are currently limited.

OBJECTIVE To determine surgical outcomes after RALP when surgeons reviewed 3D digital models during operative planning.

DESIGN, SETTING, AND PARTICIPANTS This study was a planned secondary analysis of a multicenter, single-blind, randomized clinical trial conducted at 6 large teaching hospitals in the US. The study was conducted between January 1, 2019, and December 31, 2022, and included patients undergoing RALP. Patients were assessed and recruited at the time of surgical consultation. Final data analysis was conducted between August and December 2023.

INTERVENTION Patients were randomized to either a control group undergoing usual preoperative planning with prostate biopsy results and multiparametric MRI only or to an intervention group in which imaging and biopsy results were supplemented with a 3D digital model. This model was viewed on the surgeon's mobile phone in 3D format and picture-in-picture on the robotic console screen.

MAIN OUTCOMES AND MEASURES The primary outcome measure for the overall study was oncologic outcomes after RALP, measured as prostate-specific antigen (PSA) detectability. Secondary outcomes were sexual function and urinary function, measured with Sexual Health Inventory for Men (SHIM) scores and rates of urinary incontinence, respectively, as well as use of salvage or adjuvant radiation therapy (RT) or androgen deprivation therapy (ADT). Trifecta outcomes were defined as undetectable PSA without RT or ADT, SHIM score categorically the same or greater than preoperatively, and complete continence. Univariate analysis was performed to compare outcomes between groups.

RESULTS This trial included 92 patients undergoing RALP (51 in the control group and 41 in the intervention group). Their mean (SD) age was 62 (7.4) years; 10 patients (10.9%) were Black and 67 (72.8%) were White. At 18 months postsurgery, the intervention group had lower rates of biochemical recurrence (PSA level >0.1 ng/mL, 0 vs 7 [17.9%]; absolute difference, 17.9% [95% CI, 1.8% to 31.8%]; $P = .01$) and were significantly less likely to undergo adjuvant or salvage RT (1 [3.1%] vs 12 [31.6%]; absolute difference, 28.5% [95% CI, 10.1% to 46.7%]; $P = .002$) compared with the control group. Sexual function at 18 months postsurgery was significantly better in the intervention

(continued)

Key Points

Question Does the use of 3-dimensional (3D) digital models for planning of robotic-assisted laparoscopic radical prostatectomy (RALP) improve trifecta (ie, oncologic, sexual, and urinary) outcomes?

Findings In this secondary analysis of a randomized clinical trial with 92 patients undergoing RALP, the use of 3D digital models was associated with improved oncologic outcomes and sexual function without compromising urinary function.

Meaning In this study, 3D digital models allowed for better cancer control while improving functional outcomes in patients undergoing RALP.

+ Visual Abstract

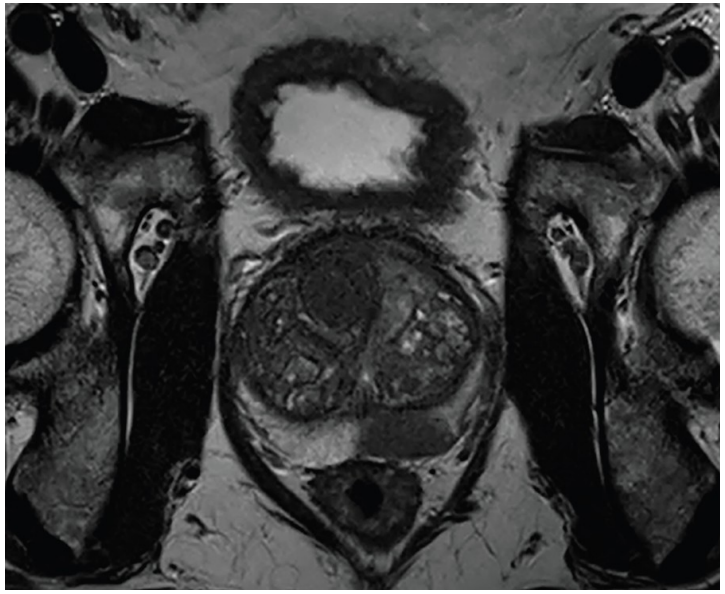
+ Invited Commentary

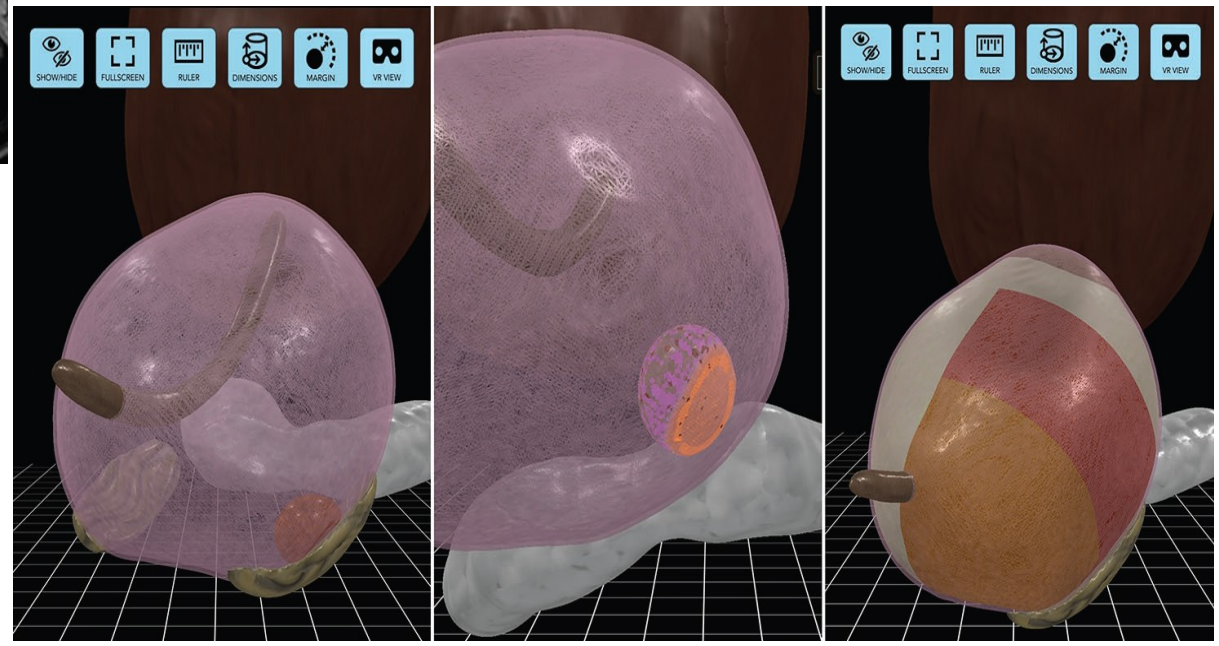
+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Study Overview

- Multicenter, single-blind randomized trial
- 92 patients undergoing robotic prostatectomy (RALP)
- Comparison: standard planning vs. 3D digital model–assisted planning
- Published: JAMA Network Open, Sept 2024





1. Left lateral mid
Prostatic adenocarcinoma
Prostate cancer grading:
Primary Gleason grade: 4
Secondary Gleason grade: 4
Total Gleason score: 8
Grade group: 4
2. Left lateral apex
Prostatic adenocarcinoma
Prostate cancer grading:
Primary Gleason grade: 4
Secondary Gleason grade: 3
Total Gleason score: 7
Grade group: 3
A

C, Threedimensional model of a prostate showing the proximity of the lesion (orange) to the neurovascular bundle (brown). D, Three-dimensional model with the neurovascular bundle hidden, showing wide contact of the lesion (orange) with the capsule (pink). E, Threedimensional model of a prostate showing color-coded biopsy cores (Grade Group 3 is orange, and Grade Group 4 is red).

Study Design

- Randomized 1:1 to intervention or control
- Stratified by surgeon experience
- Intervention: 3D models reviewed pre- and intraoperatively
- 6 large academic US hospitals

Inclusion & Exclusion Criteria

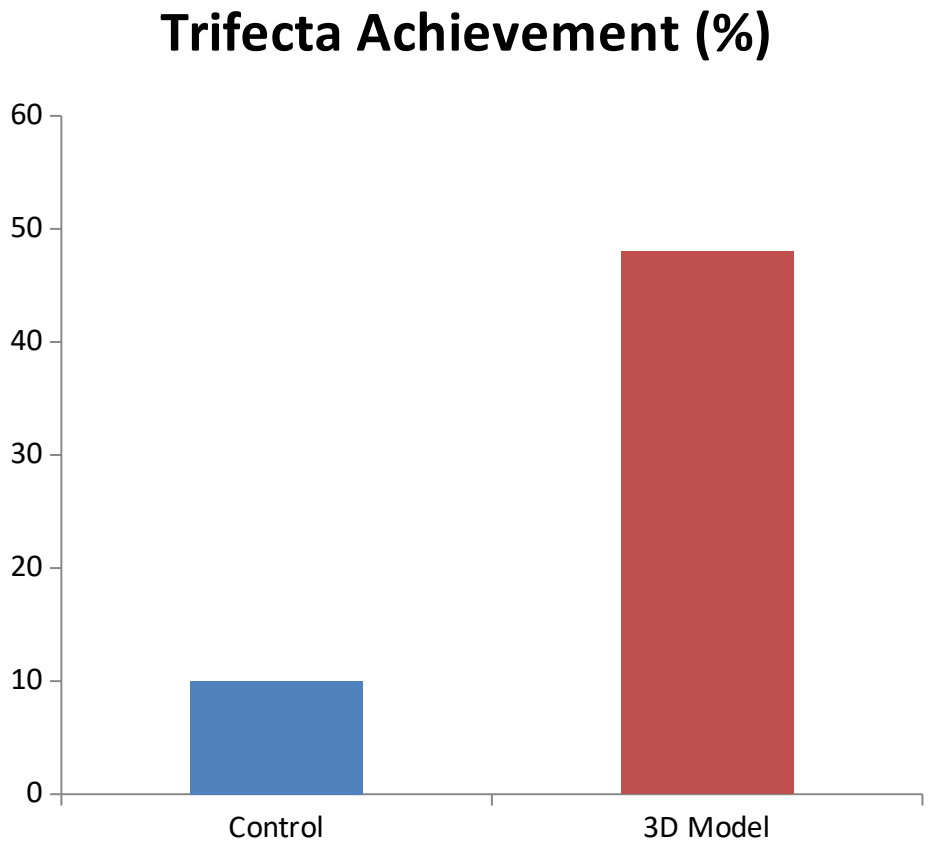
- Inclusion: Localized prostate cancer, suitable for RALP, MRI available
- Exclusion: Prior prostate surgery/RT/ADT, invalid MRI, no consent

Outcomes Measured

- Primary: Oncologic control (PSA detectability)
- Secondary: SHIM score (sexual function), urinary continence
- Trifecta: PSA < 0.1 ng/mL, same/better SHIM, 0 pad use
- All parameters assessed at 18 months for statistical analysis

Trifecta Results at 18 Months

- Intervention group: 48.0% achieved trifecta
- Control group: 10.0% achieved trifecta
- Statistical significance: P = .002

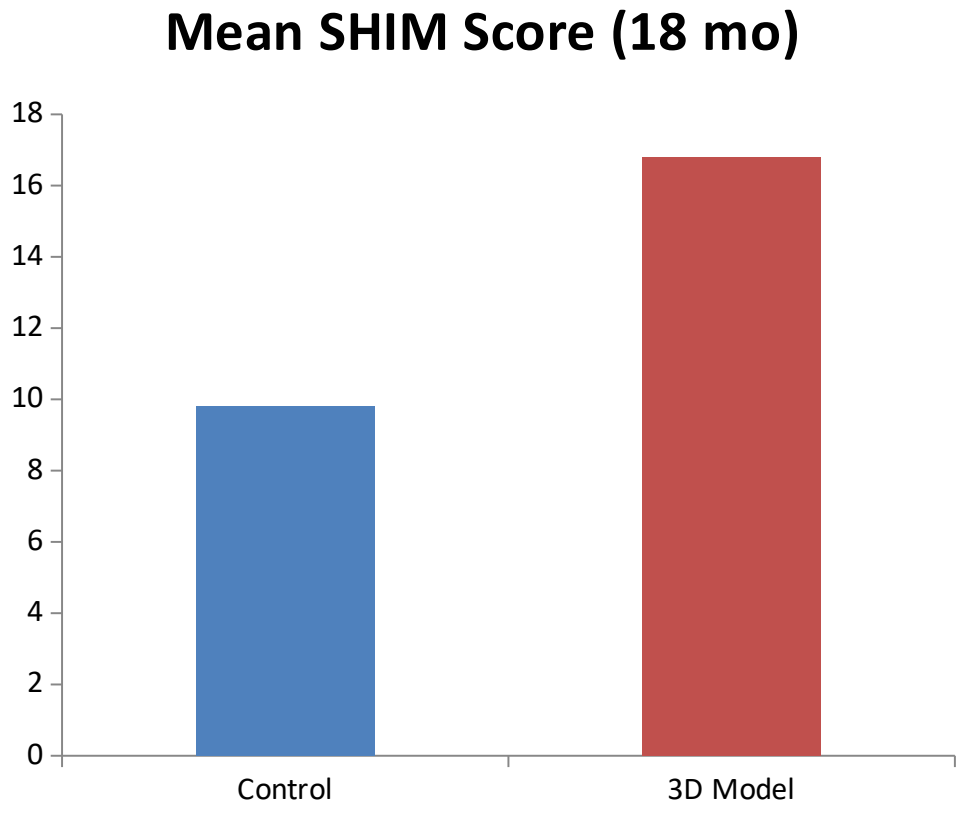


Oncologic Outcomes

- Biochemical recurrence: 0% vs 17.9% (P = .01)
- RT/ADT needed: 3.1% vs 31.6% (P = .002)

Functional Outcomes

- SHIM score higher in 3D group (16.8 vs 9.8, P = .002)
- Urinary continence: No significant difference (78.6% vs 80.6%)



Study Strengths

- Multicenter, randomized design
- Stratification by surgeon experience
- Blinded patients
- Robust long-term outcome data

Study Limitations

- Small sample size
- High positive margin rate (29%)
- No central pathology review
- Homogenous patient/surgeon demographics

Conclusion

- 3D models improved trifecta outcomes
- Better oncologic control and preserved sexual function
- Potential for broad integration in surgical planning

Relevant References

- Porpiglia F et al. Eur Urol 2018 – 3D in nephrectomy
- Wake N et al. Urology 2018 – Augmented reality surgery
- Shirk JD et al. J Urol 2022 – 3D models in prostatectomy

Nerve Monitoring During Radical Prostatectomy

Can it improve functional outcomes?

A Randomised Trial – BJU International, 2024

BJU Int 2024; **133**: 742–751 doi:10.1111/bju.16295

Original Article

BJUI
BJU International

Can nerve monitoring during radical prostatectomy improve functional outcomes? A randomised trial

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Objective

To explore how the use of the ProPep® Nerve Monitoring System (ProPep Surgical, Austin, TX, USA) for intraoperative specific sparing of the pudendal nerve fibres influences postoperative functional outcomes after unilateral nerve-sparing (UNS) or non-nerve-sparing (NNS) robot-assisted radical prostatectomy (RARP).

Patients and methods

We randomised 100 men undergoing UNS or NNS RARP to ProPep nerve monitoring during RARP (intervention) or standard of care RARP (control). Functional outcomes were assessed at 3, 6, and 12 months using the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF), the International Prostate Symptom Score, the Danish Prostate Symptom Score, the International Index of Erectile Function, the Erection Hardness Scale, and 24-h pad tests. The primary outcome was the difference in ICIQ-SF score between the groups at 12 months. Secondary outcomes included differences in the remaining outcome measures and continence rates at all time points. Continence was defined as the use of no pads and the answer 'Never' to the question: 'How often do you experience urinary incontinence?' or a urine loss of <8 g on the 24-h pad test.

Results

A total of 82 patients were included in the per-protocol analysis at 12 months with 41 in each group. At 12 months the mean ICIQ-SF scores were 5.37 (95% confidence interval [CI] 3.71–7.03) and 5.66 (95% CI 4.05–7.27) for the intervention and control groups, respectively ($P = 0.8$). There were no statistically significant differences in any of the remaining outcomes. However, the continence rate was higher in the intervention group at 6 months (63% vs 44%, $P = 0.09$).

Conclusions

Intraoperative nerve monitoring did not result in better functional outcomes following UNS or NNS RARP. Larger studies are needed to explore if ProPep can reduce the time to continence after RARP.

Keywords

prostate cancer, randomised controlled trial, robot-assisted radical prostatectomy, nerve monitoring, urinary continence, erectile function

Introduction

Radical prostatectomy (RP) has shown excellent long-term survival in selected patients with prostate cancer and reduces the risk of cancer progression and metastasis [1,2]. However, there is a substantial risk of functional adverse effects including long-term urinary incontinence (UI), which occurs in 4–31% of patients [3]. Naturally, this can have a detrimental impact on quality of life [4]. The introduction of robot-assisted RP (RARP) in the early 2000s gave hope for better functional results, but high-quality studies have not been able to show superior continence outcomes compared to open surgery [5].

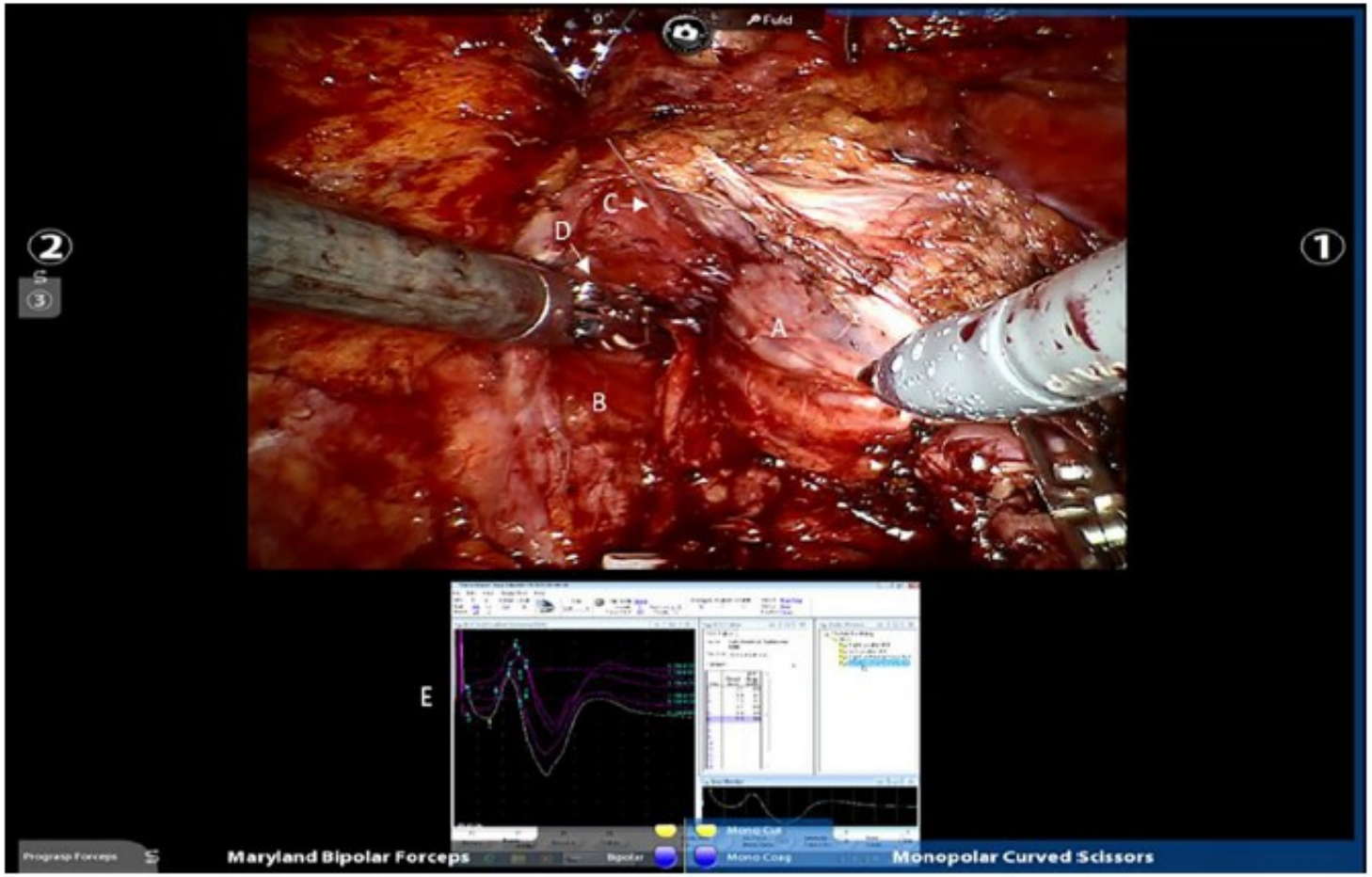
Continence is mainly dependent on the urethral sphincter, which is innervated by branches of the pudendal nerve [6]. Therefore, UI is associated with surgical alterations and damage to the urethral sphincter complex, nerves, and supportive structures [7,8]. Nerve-sparing techniques—developed to improve erectile function—have been associated with both an earlier return of continence and improved long-term continence rates after RARP [9]. This may be due to the

Study Overview

- Objective: Assess if ProPep® nerve monitoring improves continence and erectile function post RARP
- Design: Single-centre, participant-blinded randomized trial
- Population: 100 patients undergoing UNS or Non-NS (NNS) RARP
- Groups: Standard RARP vs RARP with ProPep system

Study Design

- Randomised 1:1 (block size 10)
- Blinded patients, surgeons experienced in RARP (>300 cases)
- Intraoperative ProPep used in intervention group
- All patients underwent pelvic floor training



Intraoperative stimulation of pudendal nerve branches that innervate the external urethral sphincter. Image from the surgeon’s field of view of a RARP showing intraoperative stimulation of somatic branches of the pudendal nerve that innervate the external urethral sphincter. A = Prostate; B = Levator Ani; C = One ProPep electrode inserted in the external urethral sphincter, D = The Maryland forceps; E = The monitor of the ProPep system accessed through the TilePro function.

Inclusion & Exclusion Criteria

- Inclusion: Men undergoing UNS or NNS RARP, continent preoperatively
- Exclusion: Diabetes, neuro disease, prior pelvic RT/surgery, trauma, TURP

Primary and Secondary Outcomes

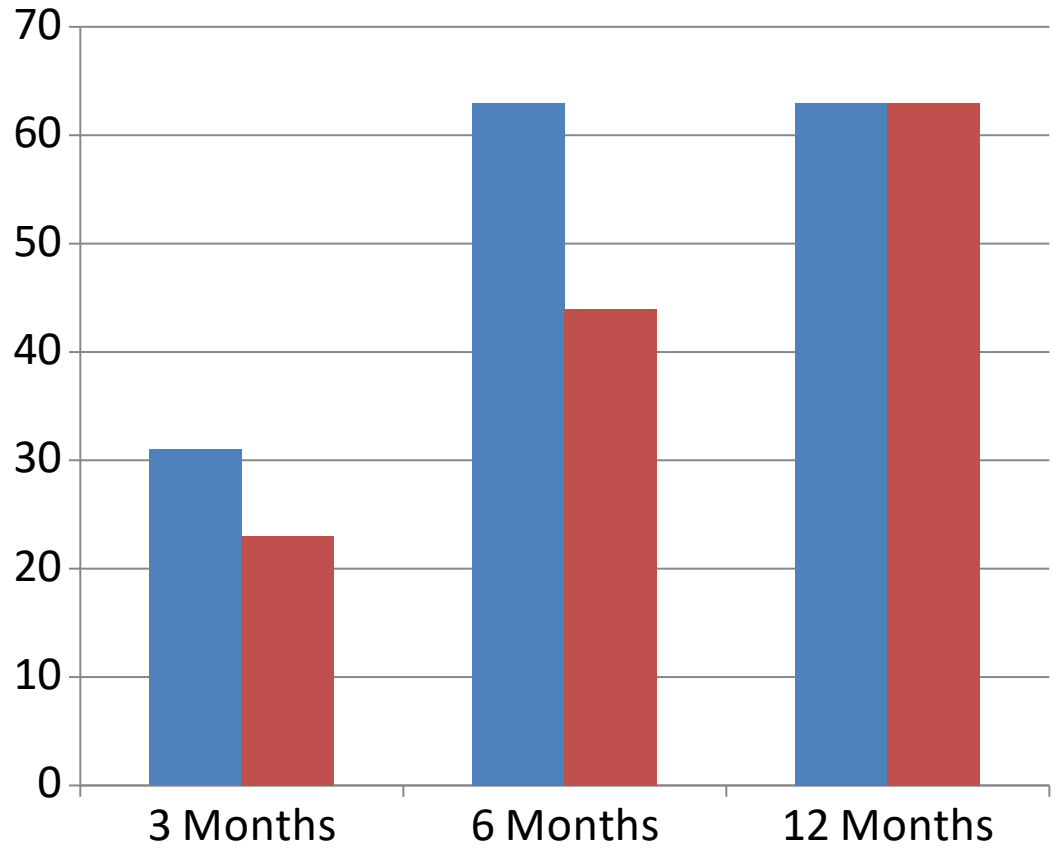
- Primary: ICIQ-SF score at 12 months
- Secondary: Continence rate, pad test, IPSS, IIEF-EF, EHS, sexual activity
- Follow-up at 3, 6, and 12 months

Results Summary

- 82 patients analyzed (41 each group)
- No significant difference in primary or secondary outcomes
- ICIQ-SF at 12 months: 5.37 vs 5.66 (P = 0.8)
- Continence at 6 months: 63% (intervention) vs 44% (P = 0.09)

Continence Rate Comparison

- Numeric difference at 6 months (63% vs 44%) approached significance



Critical Appraisal – Strengths

- First RCT to study intraoperative nerve monitoring impact
- Blinded, controlled design
- Validated tools for outcomes
- Safe and feasible intervention

Critical Appraisal – Limitations

- Single-centre, limited sample (82 per-protocol)
- No statistical significance; underpowered for small differences
- Surgeon learning effect may influence results
- No bilateral nerve-sparing cases

Conclusion

- ProPep® monitoring is safe but did not improve 12-month outcomes
- Trend toward earlier continence; warrants larger trials
- Preservation of urethral structures may be equally critical

Cross References & Context

- Suardi et al. (2013): NS linked to continence
- Walz et al. (2016): anatomy key to continence preservation
- Michl et al. (2016): technique over bundle preservation
- Hoeh et al. (2023): FLUS preservation boosts continence

Thank you