

Clinical Outcomes and Safety of Modified Prostatic Urethral Lift Using a Zero-Angle Firing and Needle-Guided Puncture Technique for BPH

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Abstract

Purpose

To evaluate the clinical efficacy and safety of prostatic urethral lift (PUL) using a modified zero-angle firing and needle-guided puncture technique in men with symptomatic benign prostatic hyperplasia (BPH).

Methods

This prospective, single-arm, single-center study enrolled 12 patients who underwent modified PUL between December 2023 and August 2024. Perioperative outcomes were recorded, and IPSS, QoL, Qmax, PVR, and SHIM were assessed preoperatively and at 14, 30, 90 days, and 1 year postoperatively. Pre- and postoperative outcomes were compared using paired analyses. This prospective, single-center, single-arm exploratory study was prospectively registered at ClinicalTrials.gov (NCT07776158; registered on August 18, 2026).

Results

All procedures were completed successfully without conversion. Mean operative time was 27.1 ± 11.2 minutes, with a mean of 4.4 ± 1.8 implants placed. At 90 days, IPSS decreased from 21.67 ± 6.47 to 5.17 ± 4.75 ($P < 0.001$), QoL improved from 4.08 ± 0.29 to 1.33 ± 1.07 ($P < 0.001$), and Qmax increased from 8.43 ± 3.84 to 14.95 ± 5.38 mL/s ($P = 0.002$). PVR decreased from 78.65 ± 98.42 to 39.60 ± 46.44 mL without statistical significance ($P = 0.260$). SHIM remained stable ($P = 0.841$). Early hematuria and urgency/dysuria were transient and managed conservatively. No severe complication, urinary tract infection, urethral stricture, or secondary surgery occurred. Symptom improvement was maintained at 1 year.

Conclusion

Modified PUL using zero-angle firing and needle-guided puncture appears feasible and safe, with durable symptom relief and preserved erectile function. Comparative studies are needed to confirm its clinical value.

1. Introduction

Benign prostatic hyperplasia (BPH) is one of the most common urological disorders in middle-aged and elderly men and is a major cause of lower urinary tract symptoms (LUTS), which substantially impairs quality of life and may progress despite medical therapy¹. Current treatment strategies for BPH are generally stepwise, with pharmacological treatment as the first-line approach. However, long-term

medication may be limited by insufficient efficacy, poor adherence, adverse effects, or progression of bladder outlet obstruction^{1–3}.

For patients requiring surgical intervention, conventional procedures such as transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP) are effective in relieving obstruction, but they are associated with risks including bleeding, retrograde ejaculation, irritative urinary symptoms, and possible impairment of sexual function. In this setting, prostatic urethral lift (PUL, UroLift system) has emerged as a minimally invasive alternative that relieves obstruction by mechanically retracting the lateral prostatic lobes without resection, ablation, or thermal injury^{4–6}.

Nevertheless, conventional PUL requires appropriate positioning and angulation of the delivery device to achieve adequate capsular penetration and effective tissue retraction. In patients with limited working space or challenging prostatic anatomy, these technical requirements may reduce procedural flexibility and consistency. And A key technical challenge in conventional PUL is implant deployment near the prostatic apex, where limited space and proximity to the pubic bone can cause bony impingement, leading to needle misfire, failed implant deployment, suboptimal positioning, or prolonged operative time⁷. Therefore, technical refinements that simplify device positioning and improve the reliability of needle placement may help broaden the applicability of PUL in selected patients. In this context, we introduced a modified PUL technique using zero-angle firing and needle-guided puncture. By positioning the delivery device at the midline in a neutral orientation and using manual compression to facilitate needle-guided capsular penetration, this technique was designed to reduce dependence on lateral device angulation and improve implant deployment. The present study evaluated the feasibility, efficacy, and perioperative safety of this modified technique in selected patients with BPH-related LUTS.

2. Materials and Methods

2.1 Study population

This prospective, single-arm, single-center study was conducted at the Department of Urology, Chinese People's Liberation Army General Hospital (PLAGH), Beijing, China.

Eligible participants were men aged 50–80 years who met all of the following inclusion criteria: (1) prostate volume 30–80 mL (measured by transabdominal or transrectal ultrasonography); (2) International Prostate Symptom Score (IPSS) > 12; (3) peak urinary flow rate (Qmax) ≤ 15 mL/s with a voided volume ≥ 125 mL (verified by uroflowmetry); (4) post-void residual volume (PVR) < 350 mL (measured by ultrasonography); (5) sexual activity within the preceding 6 months and Sexual Health Inventory for Men (SHIM) score > 6; (6) preserved antegrade ejaculation confirmed by preoperative clinical assessment; (7) provision of written informed consent. Exclusion criteria included: prior prostate surgery (e.g., TURP, laser enucleation, or open prostatectomy), prostate cancer (confirmed or suspected), neurogenic bladder, urethral stricture, severe coagulopathy, or concurrent use of anticoagulants contraindicated for the procedure.

Between December 2023 and August 2024, 12 consecutive eligible patients underwent modified prostatic urethral lift (PUL) using the “zero-angle firing and needle-guided puncture” technique and were included in the final analysis.

The study protocol adhered to the principles of the Declaration of Helsinki and its later amendments. Ethical approval was granted by the Institutional Review Board of PLAGH (approval no. S2023-493-01). Written informed consent was obtained from all participants prior to enrollment.

2.2 Surgical technique

All procedures were performed by a single urologist (with > 10 years of PUL experience) under general intravenous anesthesia with the patient in the dorsal lithotomy position. Endoscopic access was established using a 2.9-mm 0° cystoscope (NeoTract UL-SCOPE™, now part of Boston Scientific) and a 20F sheath.

For the proximal and mid-prostatic segments, implant deployment followed the standard UroLift® protocol as per the manufacturer’s instructions for use (NeoTract Inc., 2021). At the prostatic apex—where conventional lateral angulation of the delivery device is constrained by the pubic symphysis—the modified technique was employed: (1) The delivery device was aligned in the midline neutral orientation (0° angle relative to the urethral axis); (2) The hollow needle was deployed in this neutral position to minimize risk of pubic arch impingement; (3) Incremental manual compression was applied to ensure adequate tissue capture and capsular penetration; (4) The capsular tab and monofilament were tensioned, followed by deployment of the urethral end piece and trimming of excess monofilament;

The system was withdrawn, and a 22F three-way Foley catheter was placed when clinically indicated (e.g., gross hematuria, urinary retention, or need for irrigation). Catheter removal was guided by postoperative urinary flow and residual volume assessment. A schematic illustration of the modified technique is provided in Fig. 1.

2.3 Follow-up Assessment

Baseline demographic and clinical data included age, body weight, height, prostate volume, Qmax, PVR, total serum prostate-specific antigen (PSA), IPSS, quality-of-life (QoL) score, SHIM, and comorbidities (e.g., hypertension, diabetes mellitus, cardiovascular disease). All validated questionnaires were administered by trained research coordinators in a standardized manner. Patients were evaluated preoperatively and at scheduled postoperative intervals: 14 days, 30 days, 90 days, and 12 months. Primary efficacy endpoints were changes in IPSS, QoL, and Qmax; secondary endpoints included PVR, SHIM, and safety outcomes. Adverse events (AEs) were recorded perioperatively and throughout follow-up, classified per the Common Terminology Criteria for Adverse Events (CTCAE v5.0), and included: gross hematuria, urgency, dysuria, urinary retention requiring re-catheterization, urinary tract infection (UTI), hospital readmission, and need for secondary intervention (e.g., TURP, laser resection, or repeat PUL).

2.4 Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics v27.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as mean $\pm$ standard deviation (SD) if normally distributed (assessed by Shapiro–Wilk test), or as median (interquartile range [IQR]) if non-normally distributed. Categorical variables were presented as frequencies (percentages). Paired comparisons between baseline and follow-up time points were conducted using the paired t-test (for normally distributed differences) or Wilcoxon signed-rank test (for non-normal differences). The significance level was set at two-sided $P < 0.05$.

3. Results

3.1 Baseline characteristics

A total of 12 men were included in the study. Baseline characteristics are summarized in Table 1. The mean age was 65.1 ± 6.7 years. Mean body weight and height were 71.6 ± 11.4 kg and 169.2 ± 2.7 cm, respectively. The mean prostate volume was 53.0 ± 14.7 mL. At baseline, the mean IPSS was 21.67 ± 6.47 , and the mean QoL score was 4.08 ± 0.29 , indicating a substantial symptom burden.

Table 1
Baseline characteristics of the study population

Characteristic	Value
Age, years	65.1 ± 6.7
Body weight, kg	71.6 ± 11.4
Height, cm	169.2 ± 2.7
Prostate volume, mL	53.0 ± 14.7
IPSS	21.67 ± 6.47
Qmax, mL/s	8.43 ± 3.84
PVR, mL	78.65 ± 98.42
QoL	4.08 ± 0.29
SHIM	17.92 ± 4.54
Abbreviations: IPSS, International Prostate Symptom Score; Qmax, maximum urinary flow rate; PVR, post-void residual volume; QoL, quality of life; SHIM, Sexual Health Inventory for Men.	

3.2 Operative and perioperative outcomes

All 12 procedures were completed successfully, with no conversion to alternative surgical treatment. The mean operative time was 27.1 ± 11.2 min, and the mean number of implants deployed was 4.4 ± 1.8 .

Intraoperative blood loss was < 10 mL in all patients, with only minimal bleeding observed in one case. Individual perioperative data are provided in Table 2.

Table 2
Perioperative and early postoperative outcomes

Variable	Result
Operative time, min	10–50 (27.1 ± 11.2)
Number of implants	2–8 (4.4 ± 1.8)
Intraoperative blood loss	< 10 mL
Catheterization duration, days	0–4 (2.4 ± 1.3)
Hospital stay, days	2–6 (3.6 ± 1.1)
Gross hematuria	11/12 (91.7%)
Duration of hematuria, days	1–8 (4.1 ± 2.5)
Urgency/dysuria	6/12 (50.0%)
Severe urgency requiring medication	1/12 (8.3%)
Re-catheterization during follow-up	1/12 (8.3%)
Urinary tract infection	0
Urethral stricture	0
Secondary surgery/reoperation	0
Major perioperative complications	0

Intraoperative release difficulty involving individual implants occurred in two patients. Both events were managed successfully during the same procedure, and no case required procedure abandonment or conversion. No major intraoperative complications occurred.

The postoperative catheterization duration ranged from 0 to 4 days, with a mean of 2.4 ± 1.3 days. The mean length of hospital stay was 3.6 ± 1.1 days. Gross hematuria occurred in 11 patients (91.7%) and generally resolved within 1 week. Urgency and/or dysuria occurred in 6 patients (50.0%), including one severe case that improved after medication adjustment. One patient required re-catheterization during follow-up. No urinary tract infection, urethral stricture, severe bleeding event, or reoperation was observed. The main perioperative outcomes are summarized in Table 3.

Table 3
Summary of perioperative outcomes

Variable	Result
Operative time, min	10–50 (27.1 ± 11.2)
Number of implants	2–8 (4.4 ± 1.8)
Intraoperative blood loss	< 10 mL in all cases; minimal bleeding in 1 case
Catheterization duration, days	0–4 (2.4 ± 1.3)
Postoperative hospital stay, days	2–6 (3.6 ± 1.1)
Gross hematuria	11/12 (91.7%)
Duration of gross hematuria, days	1–8 (4.1 ± 2.5) [†]
Urgency/dysuria	6/12 (50.0%)
Severe urgency requiring medication adjustment	1/12 (8.3%)
Intraoperative implant release difficulty (individual implants)	2/12 (16.7%)
Re-catheterization during follow-up	1/12 (8.3%)
Urinary tract infection	0
Urinary retention	0
Urethral stricture	0
Secondary surgery/reoperation	0
Major perioperative complications	0
Values are presented as range (mean ± standard deviation) or n/N (%).	

3.3 Functional and Longitudinal Outcomes

Significant improvements in urinary symptoms were observed after surgery and were sustained through 1 year. Compared with baseline, IPSS and QoL scores decreased significantly at 14 days, 30 days, 90 days, and 1 year. Improvement was evident as early as 14 days and remained generally stable during follow-up.

At 90 days, mean IPSS decreased from 21.67 ± 6.47 to 5.17 ± 4.75 ($P < 0.001$), and mean QoL score decreased from 4.08 ± 0.29 to 1.33 ± 1.07 ($P < 0.001$). Mean Qmax increased from 8.43 ± 3.84 mL/s to 14.95 ± 5.38 mL/s ($P = 0.002$). Mean PVR decreased from 78.65 ± 98.42 mL to 39.60 ± 46.44 mL, although the change was not statistically significant ($P = 0.260$).

Longitudinal follow-up showed sustained symptom relief. Mean IPSS values were 9.50 at 14 days, 7.25 at 30 days, 5.17 at 90 days, and 6.92 at 1 year. Mean QoL scores were 1.67 at 14 days, 1.83 at 30 days, 1.33 at 90 days, and 1.83 at 1 year. Longitudinal changes in IPSS and QoL from baseline to 1 year are shown in Fig. 2.

SHIM scores showed no significant postoperative change. Mean SHIM scores were 17.92 at baseline, 18.58 at 90 days, and 18.25 at 1 year. Comparative functional outcomes before surgery and at 90 days are shown in Table 4. Longitudinal changes in SHIM scores are illustrated in Fig. 3.

Table 4
Comparison of functional outcomes before and 90 days after surgery

Outcome	Preoperative	90 days postoperative	Change	P value
IPSS	21.67 ± 6.47	5.17 ± 4.75	-16.50	< 0.001
Qmax, mL/s	8.43 ± 3.84	14.95 ± 5.38	+ 6.52	0.002
PVR, mL	78.65 ± 98.42	39.60 ± 46.44	-39.05	0.260
QoL	4.08 ± 0.29	1.33 ± 1.07	-2.75	< 0.001
SHIM	17.92 ± 4.54	18.58 ± 9.04	+ 0.67	0.841
Data are presented as mean ± standard deviation. IPSS, QoL, and SHIM data were available for all 12 patients. Qmax and PVR measurements at postoperative 90 days were unavailable in 2 patie				

4. Discussion

In this prospective, single-arm study, the modified PUL technique incorporating zero-angle firing and needle-guided puncture was feasible and associated with rapid, sustained improvement in urinary symptoms and quality of life in men with symptomatic BPH. The technique also improved urinary flow while preserving sexual function, with no severe perioperative complications, conversions, or reoperations observed during follow-up. These findings suggest that this modification may represent a practical refinement of standard PUL for selected patients, particularly when apical implant deployment is technically constrained.

Conventional PUL is validated by randomized trials⁸, however, implant deployment at the prostatic apex remains technically challenging because the confined space and pubic arch proximity restrict lateral angulation of the delivery device⁷. This limitation is substantiated by PUL learning curve analyses⁹, MAUDE database reports of device-related deployment failures¹⁰, and case reports of pelvic hematoma after apical deployment¹¹. The modified technique addresses this by maintaining midline neutral orientation during needle advancement—eliminating lateral rotation and pubic arch impingement—while incremental manual compression ensures capsular penetration. All 12 procedures were completed without conversion; two intraoperative release difficulties were managed successfully.

The IPSS reduction of approximately 16 points at 90 days compares favorably with the 10–14 point reductions reported in landmark PUL trials^{1,12}. Contributing factors may include the high baseline IPSS (21.67) providing greater dynamic range and reliable apical deployment enabling more effective lateral lobe retraction; however, the small sample (n = 12) and single-arm design preclude any claim of superiority. Qmax improved significantly (P = 0.002), consistent with effective bladder outlet obstruction relief demonstrated across PUL series and a recent network meta-analysis¹³. Post-void residual volume decreased from 78.65 ± 98.42 to 39.60 ± 46.44 mL but was not statistically significant (P = 0.260), likely reflecting high inter-individual variability (SD exceeding the mean) and insufficient power—a pattern observed across PUL studies. At 1 year, IPSS (6.92) and QoL (1.83) remained substantially improved versus baseline, consistent with the established PUL durability profile; however, longer follow-up is needed given evidence that reintervention rates approach 13–16% at 4 years¹⁴.

Preservation of sexual function is a defining advantage of PUL over tissue-ablative procedures¹⁵. In this cohort, SHIM scores remained stable (17.92 to 18.58 at 90 days, P = 0.841; 18.25 at 1 year), indicating no adverse impact on erectile function. These findings align with a landmark 2026 meta-analysis of 77 studies (11,477 patients), which confirmed that Urolift significantly improves erectile function (IIEF + 1.86 points) and ejaculatory function (MSHQ-EjD + 1.06 points) with 0% retrograde ejaculation, contrasting sharply with TURP (34–90%) and HoLEP (88–94%)¹⁶; Urolift was similarly identified as a top-performing MIST for sexual function preservation in a recent narrative review¹⁷. However, SHIM captures only erectile function; ejaculation was not systematically evaluated with the MSHQ-EjD, and the single-arm design cannot disentangle the inherent sexual-sparing property of the PUL platform from any effect of the technical modification.

The perioperative safety profile—gross hematuria in 91.7% (resolving within one week), urgency/dysuria in 50.0%, and one re-catheterization, with no urinary tract infection, urethral stricture, severe bleeding, or reoperation—is consistent with the known post-PUL course¹⁶. Regarding durability, Eure et al. demonstrated that implant number and density independently predict PUL longevity: ≤4 implants was associated with increased 1-year retreatment risk, while each additional implant reduced retreatment odds by 41.2%¹⁷. By facilitating reliable apical deployment, the zero-angle technique may contribute to more complete implant distribution; however, this remains hypothesis-generating without a comparator group. Clinically, this modification may be suited to patients with moderate prostate volumes (30–80 mL) who prioritize sexual function preservation and in whom apical constraints challenge conventional deployment. It represents an incremental refinement of the PUL platform, not a replacement. Future studies should include a randomized comparison against conventional PUL, multicenter validation, extended 3–5 year follow-up, systematic MSHQ-EjD assessment, and imaging-based implant position evaluation.

This study has several limitations: the single-arm design precludes direct comparison with conventional PUL; the small sample (n = 12) limits statistical power and generalizability; the single-center, single-surgeon design introduces operator-related confounding; patient-reported outcomes are subject to

reporting bias in an unblinded study; Qmax and PVR data at 90 days were incomplete; ejaculatory function was not systematically assessed; 1-year follow-up is insufficient for durability evaluation; and the absence of blinded assessment introduces potential bias. Despite these limitations, this prospective study provides preliminary evidence that the modified PUL technique using zero-angle firing and needle-guided puncture is technically feasible, safe in the short-to-medium term, and associated with clinically meaningful improvements in selected BPH patients, establishing a foundation for larger comparative investigations.

5. Conclusion

Modified PUL using zero-angle firing and needle-guided puncture was feasible and safe in this preliminary prospective study, providing rapid and sustained improvement in urinary symptoms and quality of life while preserving erectile function. No major complications, conversions, or reoperations were observed. These findings support further evaluation of this technical modification in larger, comparative studies to clarify its clinical value relative to conventional PUL.

Declarations

Ethics Approval

This study was performed in accordance with the Declaration of Helsinki and its later amendments. Ethical approval was obtained from the Ethics Committee of the Chinese People's Liberation Army General Hospital (approval number: S2023-493-01). Written informed consent was obtained from all participants before enrollment.

Conflict of Interest

The authors declare no conflicts of interest.

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Author Contribution

R.L. contributed to Conceptualization, Data curation, Investigation, Methodology, and Writing – original draft; G.Y. contributed to Conceptualization, Data curation, Formal analysis, and Methodology; S.H. contributed to Data curation, Investigation, and Methodology; K.L. and Q.H. contributed to Methodology and Software; C.M. and X.H. contributed to Formal analysis and Validation; Q.Y. contributed to

Conceptualization, Funding acquisition, Methodology, Supervision, and Writing – review & editing. All authors reviewed the manuscript.

Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Figures

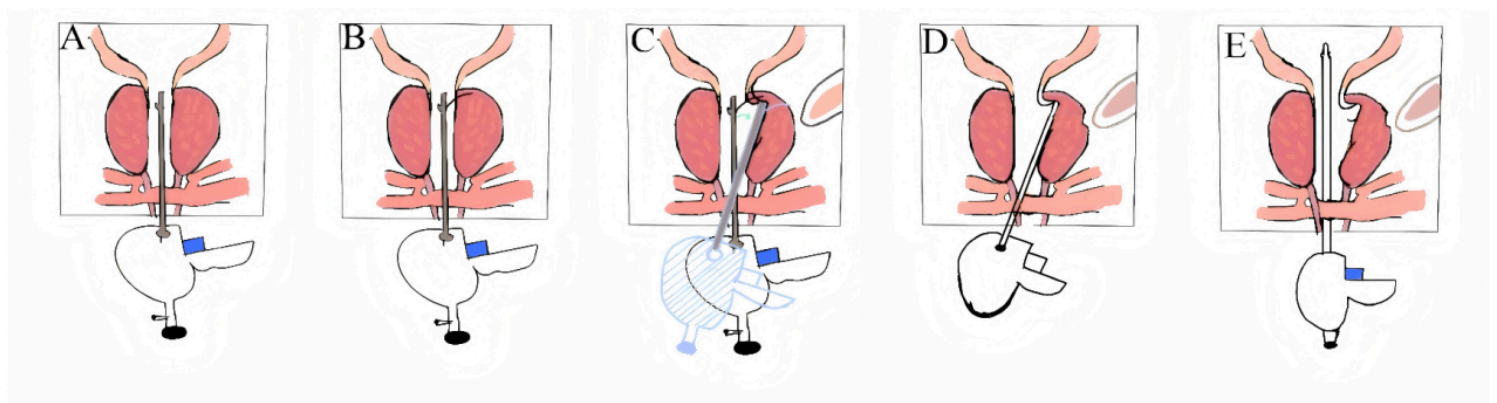


Figure 1

Key procedural steps of the modified prostatic urethral lift using the zero-angle firing and needle-guided puncture technique.

(A) The delivery device is positioned at the midline in the neutral orientation. (B) The delivery device is positioned at the midline in the neutral orientation for zero-angle firing. (C) Manual compression is increased to achieve needle-guided puncture and adequate capsular penetration. (D) The needle is retracted and the implant is tensioned. (E) The urethral end piece is deployed and the excess monofilament is cut.

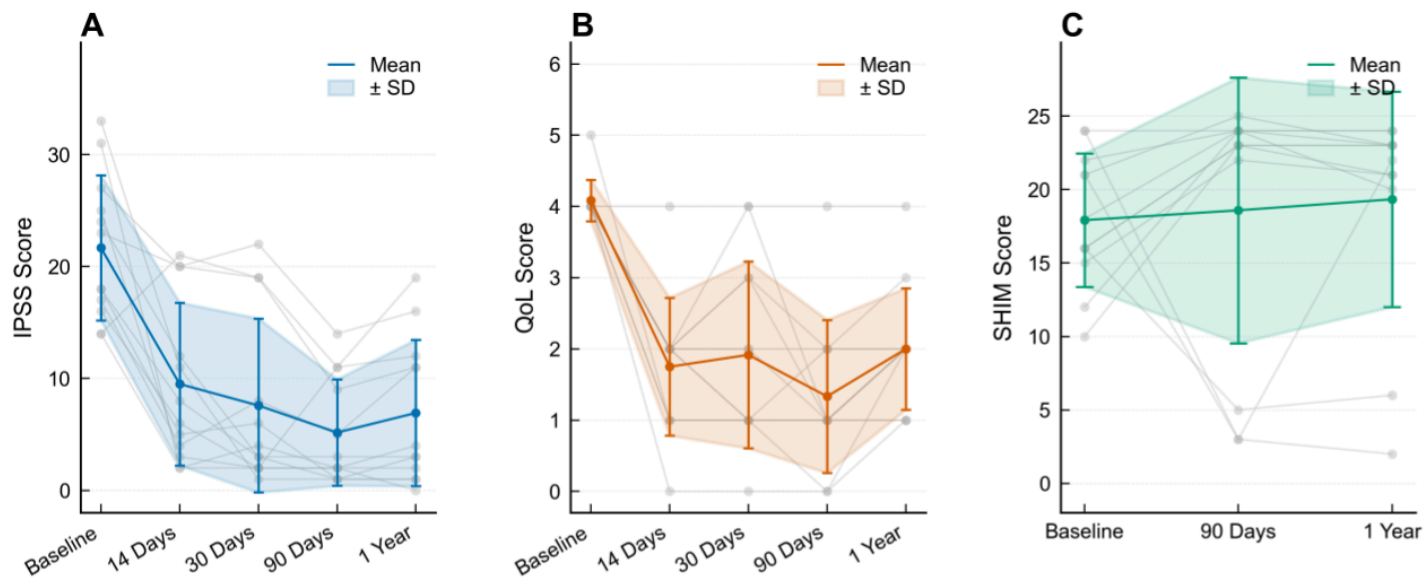


Figure 2

Longitudinal changes in IPSS and QoL score and SHIM scores before surgery and during follow-up.