# *Improvement in International Prostate Symptom Score after prostatic urethral lifts is dependent on prostatic volume*

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***Introduction:*** *Prostatic urethral lifts (PUL) provide improvement in urinary symptoms for men with benign prostatic hyperplasia (BPH). The aim of this study is to determine operative factors associated with improvement in urinary symptoms after PUL in men with bothersome BPH.*

***Materials and methods:*** *Men with BPH undergoing PUL at a single, tertiary center were identified from 2019 to 2022. Inclusion criteria included documented prostate volume as well as preoperative and postoperative cystoscopic images of the prostatic urethra. Multivariate regression modeling was performed to determine the predictive factors—including prostate volume, number of implants, and degree of unobstructed prostatic urethral channel—for improvement in International Prostate Symptom Score (IPSS) after PUL.*

***Results:*** *Of the 47 men, the distribution of prostate volume was 1 patient with < 30 grams, 33 patients with 30-79 grams, five patients with 80-100 grams, and six patients with > 100 grams. The mean number of implants used was six implants. The mean preoperative and postoperative IPSS were 23 and 14, respectively. The mean (standard error (SE)) change and percent change in IPSS score following PUL was 14 and 60%, respectively. The mean percent improvement in prostatic urethral channel after anterior clip placements was 67%. On multivariate analysis, larger prostate volume was associated with greater change in IPPS follow surgery ($p = 0.0091$) while number of implants and percent of prostatic urethral opening were not associated with change in IPSS ($p = 0.3094$ and $p = 0.2249$, respectively).*

***Conclusion:*** *Men with larger prostates are associated with greater improvement in urinary symptom after PUL regardless of number of implants utilized and degree of prostatic urethral channel opening after prostatic implants.*

**Key Words:** prostatic urethral lift, benign prostatic hyperplasia, lower urinary tract symptoms, International Prostate Symptom Score

## Introduction

Benign prostatic hyperplasia (BPH) is a chronic urologic condition amongst older men associated with lower urinary tract symptoms (LUTS) including urinary frequency, incomplete emptying, and nocturia. The prevalence of BPH is high and affects nearly 50% of men between 50 and 60 years.[1,2] Progression of BPH often impacts quality of life ranging from impaired sleep to social isolation to limited sexual function.[3] In severe cases, untreated BPH may lead to renal insufficiency, bladder stones, recurrent urinary tract infections, and non-functional bladders.[4]

Due to the high discontinuation rates of pharmacologic therapy for BPH, minimally invasive

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surgical therapy has become more utilized for the treatment of LUTS.[5] From 1998 to 2017, surgical procedures for BPH has increased by 79% due to the emerging interventions for BPH.[6] Of the these surgical options, prostatic urethral lifts (PUL, UroLift System) have lower morbidity than surgical resection and ablative therapy while preserving sexual function.[7] The American Urological Association recommends the utilization of PUL for men with prostate sizes between 30 and 80 grams and without central lobes.[8] In 2020, the United States Food and Drug Administration approved Urolift for prostate volumes up to 100 grams including lateral and median lobe enlargement. However, recent studies suggest that PUL may be a feasible option for larger prostate volumes and central lobes with improvement in quality of life index, adequate durability, and low safety profile.[9,10] The clinical significance of preoperative and intraoperative findings such as prostate volume, number of implants placed, and compression of anterior prostatic lobes for improvements in LUTS remains unclear.

The aim of this study is to determine preoperative and intraoperative factors associated with improvement in LUTS after PUL in men with bothersome BPH. We hypothesize that men with larger prostate volumes and more unobstructed prostatic lobes may experience greater improvement in urinary complaints.

## Materials and methods

An Institutional Review Board (IRB) approval was obtained for this retrospective cohort study at our institution. Men that underwent PUL at Baylor Saint Luke's Medical Center, Houston, Texas by a single surgeon were identified from 2019 to 2022. Individuals without transurethral ultrasound of the prostate (TRUS) as well as preoperative and postoperative cystoscopic images of prostatic urethra were excluded from the study. Clinical and demographic information was collected from the electronic medical records. International Prostate Symptom Score (IPSS) was calculated at initial consultation and postoperative follow up at 4 weeks or 4 months. Prostate volumes were obtained from TRUS. Operative report was used to determine the number of implants utilized for the case. Cystoscopic images of the prostate were taken proximal to the verumontanum prior to and after PUL placement. The cystoscopic images were analyzed using ImageJ to determine surface area of the proximal urethra prior to anterior clip implant placement and after anterior clip implant placement, Figure 1. Prostatic urethral opening or channel was defined as the area of open urethral lumen captured on cystoscopy. The difference and percent change in the opening of the urethral channel was calculated. IPSS was determined at postoperative follow up to determine the change in IPSS after PUL.

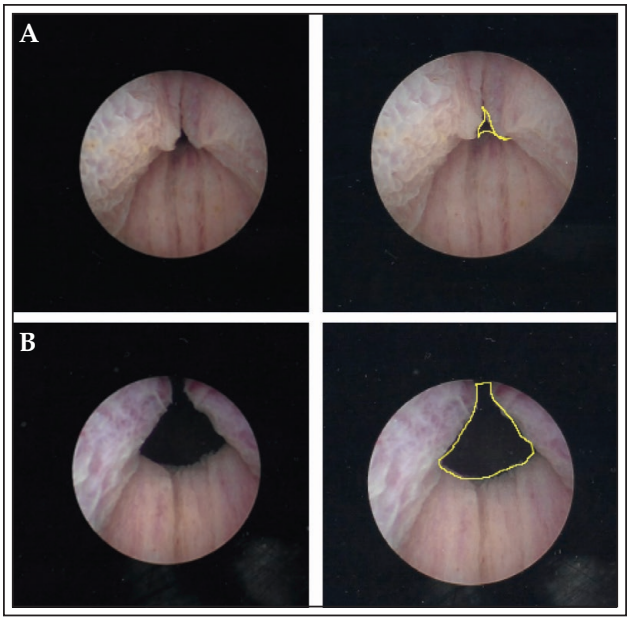


**Figure 1.** Cystoscopic images of prostatic urethral lumen before and after placement prostatic urethral lifts. **(A)** Cystoscopy images prior to implants and area of prostatic urethral lumen. **(B)** Cystoscopy images after implants and area of prostatic urethral lumen.

PUL placement (Teleflex, Pleasanton, CA, USA) was performed in the operating room with general anesthesia. Preoperative images of the prostate were taken with a rigid cystoscope prior to implant placement. A minimum of four implants were placed—two at the proximal prostatic urethra 1.5 cm distal to the bladder neck and two just proximal to the veru montanum; additional implants were placed depending on the degree of prostatic obstruction. Postoperative images of the prostate were taken with the rigid cystoscope. A urethral catheter was placed in the operating room on traction and removed one hour later in the recovery unit with serial voiding trials. If patients failed voiding trial, patients were sent home with an indwelling catheter. Follow up was at 4 and 12 weeks to evaluate symptom improvement.

Mean and standard error (SE) were used for continues variables, and count and percentages were used for categorical variables. JMP 15 Pro was utilized

TABLE 1. **Clinical and demographic parameters of patients undergoing prostatic urethral lifts**

| | |
|---|---|
| Number of patients | 47 |
| Age, mean (SE), year | 67 (1.5) |
| Prostate volume, %, g | |
| < 30 | 1 (2.1) |
| 30-79 | 33 (70.2) |
| 80-100 | 5 (10.7) |
| > 100 | 6 (12.8) |
| Implants used, mean (SE) | 6 (0.2) |
| Percent Increase in prostatic urethral channel, mean (SE) | 67 (0.03) |
| Preoperative IPSS, mean (SE) | 23 (0.8) |
| Postoperative IPSS, mean (SE) | 10 (0.9) |
| Change in IPSS, mean (SE) | 14 (0.9) |
| Follow up, mean (SE), months | 6 (0.4) |

IPSS = International Prostate Symptoms Score; SE = standard error

to perform statistical tests. Multivariate regression modeling was performed to determine the predictive factors for improvement in IPSS after PUL. A $p < 0.05$ indicated statistical significance.

## Results

For this retrospective analysis, 47 men were included in the study. Table 1 depicts the clinical and demographic information of the cohort. The mean (SE) age was 67 (1.5) years. The distribution of prostate volume was 1 patient with < 30 grams, 33 patients with 30-79 grams, 5 patients with 80-100 grams, and 6 patients with > 100 grams. The mean (SE) number of implants used was 6 (0.2) implants. The mean (SE) preoperative and postoperative IPSS were 23 (0.8) and 14 (0.9), respectively. The mean (SE) change and percent change in IPSS score following PUL was 14 (0.9) and 60% (3.2), respectively. The mean (SE) percent improvement in prostatic urethral channel after anterior clip placements was 67% (0.03). No patients required additional intervention. No complications were noted postoperatively.

Table 2 demonstrates the multivariate regression modeling of preoperative and intraoperative parameters to predict change in IPPS after PUL. On multivariate analysis, larger prostate volume was associated with greater change in IPPS follow surgery ($p = 0.0091$) while number of implants and percent of prostatic urethral opening were not associated with change in IPSS ($p = 0.3094$ and $p = 0.2249$, respectively).

## Discussion

BPH is the fifth most prevalent non-cancer related condition among older men with significant disease progression without medical attention and subsequent, financial cost to healthcare.[11] Approved by the Food and Drug Administration in 2003, PUL implantation is an efficacious therapy for LUTS associated with BPH with low safety profile and preserved ejaculatory function.[12] Placements of implants can be performed with minimal anesthesia without need for hospitalization.[13] Although PUL was originally approved for moderately enlarged prostate glands, evolving evidence suggests that PUL implantation may be beneficial for larger prostate glands as well.[14] After PUL implantation, the prostatic urethra lumen was opened by approximately 65% compared to baseline cystoscopy. Interestingly, this study demonstrated that improvement in LUTS after PUL is associated with prostate volume regardless of number of implants utilized and degree of unobstructed opening of the prostatic urethra.

The L.I.F.T trial demonstrated that PUL improved urinary symptoms and flow while preserving sexual function. However, the study excluded patients younger than 50 years old, American Urological Symptom Index less than 13, maximum flow rate greater than 12 mL/second and prostate volumes

TABLE 2. **Multivariate regression modeling for predicting total change in IPPS after prostatic urethral lifts**

| | **ß** | **SE** | **95% CI** | **p value** |
|---|---|---|---|---|
| Prostate volume, grams | 0.0982909 | 0.035865 | 0.03-0.17 | 0.0091* |
| Implants used | -0.63387 | 0.615712 | -1.87-0.61 | 0.3094 |
| Anterior lip elevation | 0.2265394 | 0.18378 | -0.14-0.60 | 0.2249 |

ß = estimated coefficient; SE = standard error; CI = confidence intervals

greater than 80 grams.[15] Our analysis demonstrated that prostate size may be an integral factor to predict degree of improvement in urinary symptoms. In larger series, PUL has been efficacious in men with larger prostate glands (e.g. > 80 grams) with pinning or resection of central lobes.[12,14] Prior studies have noted that larger glands for the approved gland size (e.g., 30-80 grams) may experience symptomatic failure requiring further prostate intervention for LUTS. For example, Beurrier et al reported that of the 23 PUL implantations, 4 patients required additional intervention—3 (75%) patients were noted to have prostate gland sizes measuring greater than 60 grams.[16] In our series, no additional urologic intervention was necessary after PUL, suggesting short term durability of implants even for larger gland size.

One of the technical aspects of PUL implantation is pinning the obstructive lobes to mechanically reduce the obstruction of the prostatic urethra and thereby increasing the prostatic urethral lumen.[17] To our knowledge, we are the first to report a metric to calculate improvement in prostatic urethral channel after PUL. The average improvement in the proximal prostatic urethral channel after PUL placement is 67% compared to baseline urethral channel area noted during cystoscopy. On multivariate analysis, we report that the change in prostatic urethral channel after PUL implantation does not correlate with change in IPSS. We suspect that once obstructive prostatic lobes are pinned with PUL, the degree that the prostatic urethral opening is developed does not impact overall improvement in urinary symptoms.

The number of implants placed was not associated with improvement in IPSS score on multivariate analysis. In our practice, a minimum of four PUL implants are deployed, and additional implants are needed depending on the length of the prostatic urethra and size of obstructive lobes. Although the implants are biologically and chemically inactive material with minimal unfavorable interaction with host tissue, the number of implants placed while controlling for prostate volume does not impact overall improvement in urinary symptoms.[17]

There are several limitations to consider for this retrospective study. First, although a standard template was used to obtain cystoscopic images of the prostatic urethra prior to and after PUL placement, variability in the imaging may impact the calculated urethral channel opening. Nonetheless, this is the first study to quantify the change in prostatic urethral channel after PUL placement. Second, objective measures such as maximum peak flow and post-void residuals were not available for this cohort. Third, approximately 70% of men had prostate volumes between 30 and 80 grams, thus extrapolation to larger gland size may be underpowered by the study. However, the distribution of prostate size in our cohort is similar to other published datasets for PUL.[9]

## Conclusion

BPH is a common condition amongst older men often associated impacting quality of life. PUL provides significant improvement in urinary symptoms for men with BPH. Men with larger prostates are associated with greater improvement in urinary symptom after PUL regardless of number of implants utilized and degree of prostatic urethral channel opening after prostatic implants. □

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