Original Article on Surgical Management of Stress Urinary Incontinence in Men

Long-term assessment of the safety and effectivity of the mini-jupette sling: 5-year follow-up of the original series

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Contributions: (I) Conception and design: All authors; (II) Administrative support: All authors; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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Background: In 2017, a prospective multicenter, multinational, investigational pilot study was conducted examining outcomes using a novel surgical technique, the Mini-Jupette sling, for the management of erectile dysfunction (ED) patients with climacturia and/or minimal stress urinary incontinence (SUI) after prostate procedures. Climacturia has been reported in up to 64% of patients following radical prostatectomy (RP). We sought to report the 5-year outcomes from this original cohort to assess long-term safety and effectivity of the mini-jupette sling in the treatment of ED and concomitant mild SUI and/or climacturia.

Methods: This is a single-arm, multicenter, retrospective, observational study. We identified patients who were enrolled in the previous multicenter study with post-RP ED and climacturia and/or mild SUI- 2 PADS PER DAY (PPD) and underwent inflatable penile prosthesis (IPP) insertion with simultaneous placement of a mini-jupette sling. Data were collected including current PPD, subjective improvement in climacturia/SUI, complications, need for revision of IPP or additional urinary incontinence surgery, and date of most recent follow-up. SPSS was used for statistical analysis.

Results: Of the original 38 patients, 5 have since died and 10 were lost to follow-up with 23/38 (61%) patients available for evaluation of long-term outcomes. The average follow-up time was 59 months (SD =8.8) with a mean age of 69 years (SD =6.8). Most patients (n=21, 91%) had subjective improvement of SUI and climacturia. One patient with persistent bothersome incontinence underwent artificial urinary sphincter (AUS) placement in 2018 with no complications, while the other is still considering a repeat procedure due to minor but persistent SUI. The mean PPD decreased from 1.4 preoperatively to 0.4 at a mean of 5 years of follow-up. Most patients reported satisfaction in their urinary symptoms with 91% and 73% reporting improvement in SUI and climacturia respectively, compared to 86% and 93% respectively in the original series. One (4.3%) patient had an IPP revision for pump malfunction. There were no device infections reported.

Conclusions: The mini-jupette sling appears to be a safe and effective procedure with durable improvements in SUI and climacturia at 5 years of follow-up.

Keywords: Erectile dysfunction (ED); radical prostatectomy (RP); penile prosthesis; stress urinary incontinence (SUI); climacturia

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Submitted Oct 08, 2022. Accepted for publication Feb 08, 2023. Published online Mar 14, 2023.
doi: 10.21037/tau-22-661
View this article at: https://dx.doi.org/10.21037/tau-22-661

Introduction

Following radical prostatectomy (RP) for prostate cancer, erectile dysfunction (ED) has been reported to occur in up to 68% of men (1). In refractory cases, inflatable penile prosthesis (IPP) has been associated with high patient and partner satisfaction (2-4). Stress urinary incontinence (SUI) is also common after RP and can often coexist with ED (5). The surgical treatment of SUI centers around artificial urinary sphincter (AUS) and male slings depending on the severity of incontinence and radiation history (6).

Climacturia or orgasm-associated incontinence is a less commonly discussed side effect of RP, but it has been shown to occur in 20–68% of men following prostate surgery (7,8). Conservative treatment options include the use of condoms, pre-coital voiding, and constriction bands. However, the effectiveness of these treatments is poor (9). In 2005, Professor Robert Andrianne first began using the mini-jupette sling for men with climacturia and/or mild stress incontinence; however, he did not initially publish his experience (10,11).

Our multicenter collaborative published the first experience with the mini-jupette sling in 2018 in which we found promising early results (11). Subjective improvement in climacturia and SUI was 92.8% and 85.7%, respectively. However, the mean follow-up was only 5 months in this original cohort (11). The durability of continence outcomes using the mini-jupette sling is unknown. Long-term effectiveness and safety data are needed to validate the use of the mini-jupette for the concomitant treatment of ED and climacturia/mild SUI (12). We report on the long-term follow-up of patients included in the original pilot study to assess the safety and effectiveness of the mini-jupette sling (11).

Highlight box

Key findings

- We demonstrated the durability of the continence outcomes of the mini-jupette sling for the treatment of stress urinary incontinence and climacturia with 5 years of follow-up.

What is known and what is new?

- The mini-jupette procedure was previously reported to be safe and effective with only 5 months of follow-up.
- This manuscript provides a 5-year follow-up of the patients who previously underwent the mini-jupette sling procedure to determine whether the sling has maintained its initial promising results.

What is the implication, and what should change now?

- The mini-jupette sling appeared to be safe and effective for SUI and/or climacturia with long-term follow-up.
- Report here about implications and actions needed.
- A large cohort with a control arm is needed to confirm results. Further work evaluating outcomes using different types of sling materials is needed to optimize the mini-jupette sling.

Methods

Following Institutional Review Board (IRB) approval, a retrospective review was performed from 8 centers that participated in the original multicenter pilot study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by IRB of University of California, Irvine (No. IORG 0000236), and individual consent for this retrospective analysis was waived. We identified patients who were enrolled in the previous multicenter study with post prostatectomy ED plus climacturia and/or mild SUI [<2 pads per day (PPD)]. All patients underwent IPP placement with simultaneous placement of a mini-jupette sling. The specific graft material for the mini-jupette sling was left up to the discretion of the surgeon. Follow-up data regarding erectile function, SUI, climacturia, new post-operative complications, and satisfaction were collected. Patients were asked about subjective improvement in climacturia and SUI symptoms at each follow-up visit. Continuous variables were summarized as mean and standard deviation (SD) or median and range. Categorical variables were summarized as frequencies and percentages.

Results

Of the 38 men included in the original series, 5 patients have since died, and 10 were lost to follow-up. (*Figure 1*) Thus, leaving 23/38 (60.5%) men available for assessment of long-term outcomes. The mean follow-up time was 59 months (SD =8.8) with a mean age of 69 years (SD =6.8). Baseline comorbidities were similar between the current long-

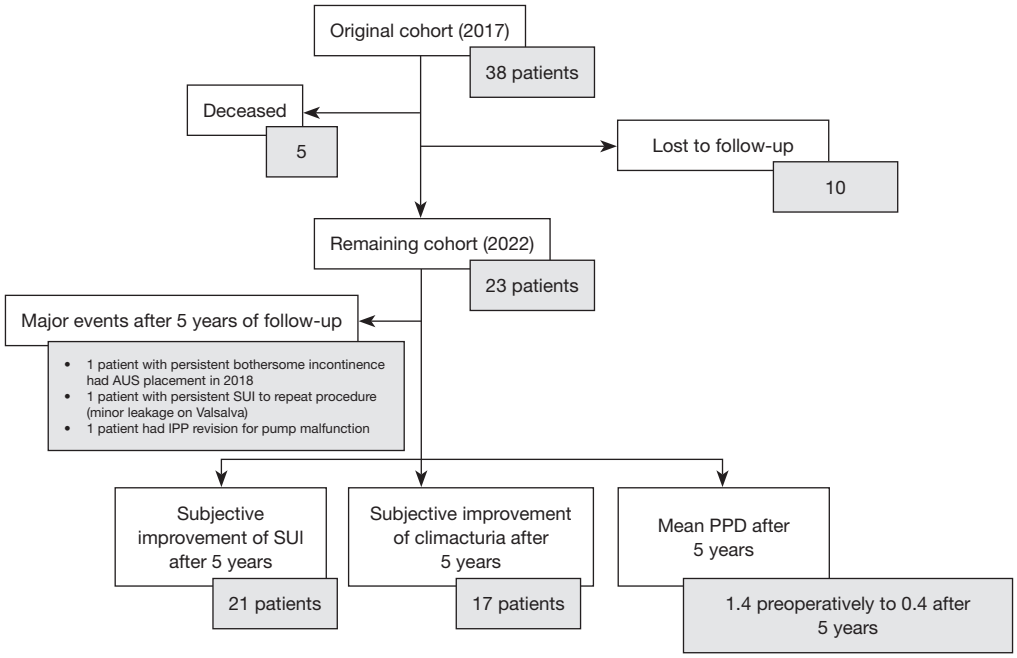

Figure 1 Summary of 5-year follow-up for patients with mini-jupette slings. AUS, artificial urinary sphincter; IPP, inflatable penile prosthesis; SUI, stress urinary incontinence; PPD, pads per day.

Table 1 Clinical parameters of 23 patients after 5 years' follow-up

Parameters	Data
Age (years), mean (SD)	69 (6.8)
BMI (kg/m^2), mean (SD)	25.5 (8.5)
Radical prostatectomy approach, n (%)	
Open	10 (43.5)
Laparoscopic or robotic	11 (47.8)
TURP, n (%)	2 (8.7)
Time from prostatic procedure (months), mean (SD)	117.9 (68.6)
Duration of follow-up after mini-jupette (months), mean (SD)	59 (8.8)
Radiation therapy, n (%)	4 (17.4)
Diabetes type II, n (%)	5 (21.7)
Cardiovascular disease, n (%)	2 (8.7)
Hypertension, n (%)	13 (56.5)

BMI, body mass index; TURP, transurethral resection of the prostate.

term follow-up group and original cohort. The incidence of diabetes mellitus type II (DM), hypertension, and cardiovascular in the original cohort was 18.0%, 55.0%, and 7.0% respectively. Of the 23 men in this cohort, 5 (21.7%) had DM, 13 (56.5%) had hypertension, and 2 (8.7%) had cardiovascular disease. The mean body mass index (BMI) was 25.5 (SD =8.5). Prior prostate cancer history and surgical history are displayed in *Table 1*. The majority (78.3%) of the cohort had a Coloplast Titan placed. Tutoplast (39.1%) and polypropylene mesh (26.1%) were the most common graft materials used. Full IPP and graft details can be found in *Table 2*.

Regarding SUI outcomes (*Table 3*), the current mean PPD was 0.4 compared to 1.4 preoperatively. Most patients (n=21, 91.3%) reported subjective improvement of SUI. Climacturia was present in 18 (78.3%) men preoperatively. With additional follow-up, climacturia has resolved in 14 (77.8%) of these 18 men compared to 69% in the original series. Most patients reported satisfaction in their urinary symptoms with 91% and 73% reporting improvement in SUI and climacturia, respectively. One patient with persistent bothersome SUI underwent AUS placement with no complications. One other patient is considering a repeat incontinence procedure due to mild persistent leakage.

Mean current IIEF-5 score for the cohort was 22.75 (SD =2.62) compared to 4.8 (SD =2.8) preoperatively. One (4.3%) patient had an IPP revision for pump malfunction. There were no device infections reported. There were no

Table 2 Surgical parameters of 23 patients after 5 years' follow-up

Parameters	Data
Inflatable penile prosthesis model, n (%)	
AMS 700 CX	2 (8.70)
AMS 700 LGX	3 (13.0)
Coloplast Titan	18 (78.3)
Size of corporotomy (cm), mean (SD)	2.8 (1.23)
Graft size, mean (SD)	
Width (cm)	3.3 (1.0)
Length (cm)	2.9 (1.2)
Surface area (cm^2)	10.4 (6.4)
Graft type, n (%)	
Tutoplast (human pericardium)	9 (39.1)
Biomesh (Polypropylene)	6 (26.1)
Virtue mesh	1 (4.3)
Bovine pericardium	3 (13.0)
Vicryl-prolene	2 (8.7)
Dynamesh (polymer, polyvinylidene fluoride)	1 (4.3)
Surgimend (fetal bovine dermis)	1 (4.3)
Drain, n (%)	15 (65.2)

Table 3 Reported outcomes of 23 patients after 5 years' follow-up

Reported outcomes	Data
Subjective improvement of SUI, n (%)	21 (91.3)
Subjective improvement of climacturia, n (%)	17 (73.9)
Preoperative mean pads per day	1.4
Postoperative mean pads per day	0.4

SUI, stress urinary incontinence.

other late complications reported with durable symptomatic improvement.

Discussion

In this multicenter follow-up study, we found good durability of the mini-jupette sling in regards to continence. Specifically, we found 91% of men continued to report subjective improvement in SUI. Mean PPD remained low at 0.4 which is similar to the original series of 0.3 PPD, thus demonstrating good longevity in SUI outcomes following mini-jupette sling (3). Similarly, climacturia outcomes were also durable. Complete resolution of climacturia occurred in 78% of 23 men included in the new cohort at a mean follow-up of 59 months. This is comparable with the original pilot study where complete resolution of climacturia occurred in 69% of 38 patients at 5.1 months follow-up (11). The reason for late continued improvement in complete climacturia resolution is unclear. It is possible that the graft continues to scar in beyond 5 months providing more urethral support and compression when the IPP is inflated. Overall patient satisfaction remained high with 91.3% and 73.9% of patients being satisfied with SUI and climacturia symptoms.

Although the mini-jupette sling was first developed in 2005, the current literature is limited to small single surgeon series or multicenter cohorts with limited follow-up (10,11,13). The need for validation of the mini-jupette procedure with long-term outcomes is needed (12). Our results provide the first long-term assessment of incontinence outcomes for the mini-jupette procedure. We also evaluated the long-term safety profile and found no late complications such as urethral erosion which can be seen with AUS (14). These findings support the continued and potentially increased use of the mini-jupette at time of IPP placement for patients with climacturia and/or mild SUI.

The continence mechanism of action is unique with the mini-jupette sling (*Figure 2*). The lateral edges of the graft are sewn to the medial edge of the corporotomies and when the IPP is inflated the graft tightens across the urethra providing the continence mechanism (4). Thus, the mini-jupette is a convenient solution for men with climacturia undergoing IPP as the prosthesis will be inflated during sexual activity providing tension across the urethra and continence at the desired time. Since the IPP is more frequently in the deflated state, the urethra is not always compressed which may lead to a lower incidence of urethral erosion and complications compared to an AUS. However, the mini-jupette is not limited to treating climacturia. As we demonstrate in this series, improvement of mild SUI is achievable with the mini-jupette sling. We advise patients with mild SUI to leave the IPP partially inflated with a few pumps to help treat SUI. We have found that doing this provides good continence results and does not leave the device noticeably inflated.

Climacturia is common and may occur in up to 68% of men after prostatectomy (8). Just as post prostatectomy patients are evaluated for SUI and ED, all patients who

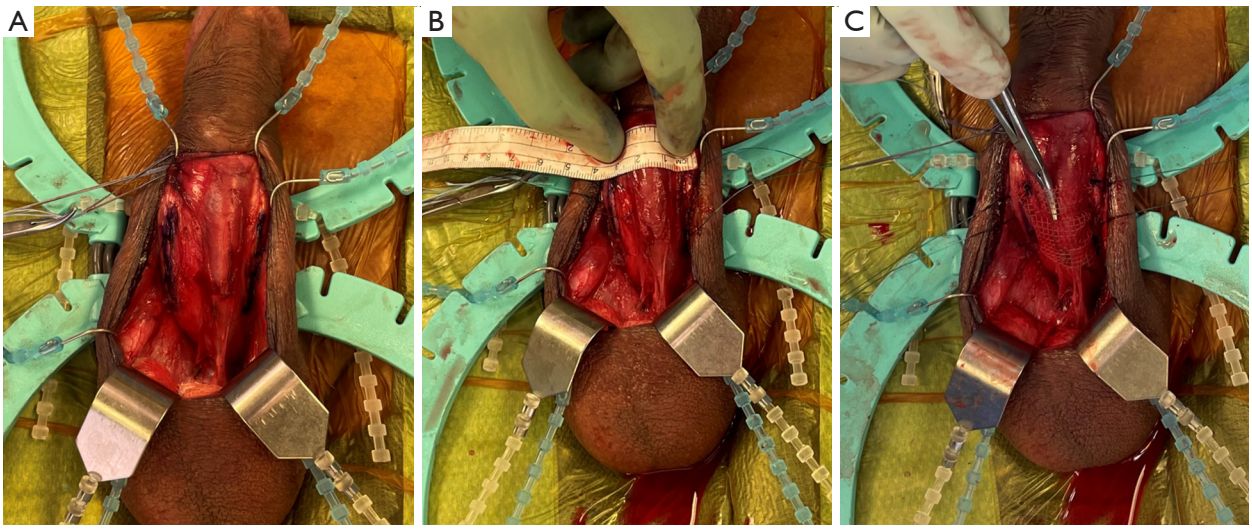

Figure 2 The different steps involved in performing a mini-jupette procedure. (A) 3 cm long corporotomy incisions are marked lateral on the corpora. (B) Width of graft being measured from medial aspect of each corporotomy. (C) When IPP is deflated the tip of an instrument should easily slide between the graft and the urethera. IPP, inflatable penile prosthesis.

have undergone RP should be investigated for the presence, severity, and duration of climacturia. When conservative treatments such as pre-coital bladder emptying and pelvic floor physical therapy fail, surgical treatment can be considered. As the body of literature supporting the safety and effectiveness of the mini-jupette continues to grow, it adds to the surgical armamentarium available to prosthetic urologists to treat climacturia and mild SUI in men with ED.

No patients in our series had late complications with continued follow-up at a mean of 5 years. Two patients had a second prosthetic surgery. One had an AUS placed for persistent and bothersome SUI. Placement of the AUS was unremarkable due to the more proximal location of the AUS cuff placement compared to the mini-jupette sling location. The other patient had IPP revision due to pump malfunction which was unlikely related to the mini-jupette procedure. These results demonstrate the long-term safety profile of the mini-jupette procedure out to 5 years.

Our study is limited by the retrospective nature. Additionally, 39% of the original cohort for the pilot study was not available for long-term follow-up due to patient death or being lost to follow-up. Moreover, several graft materials were used which could confound our results. We are not able to make a recommendation on which graft material may be best; however, our overall good results may suggest the specific graft material is less important than technique. Further, we did not have validated patient reported outcome measures (PROMs) related to urinary symptoms or IPP satisfaction. Larger studies using validated PROMs are needed to further our knowledge of the mini-jupette procedure. Additionally, prospective studies assessing outcomes and complications of specific graft materials are also needed. Despite these limitations, our series is the first long-term report of outcomes and complications of the mini-jupette procedure.

Conclusions

The mini-jupette sling is a safe and effective procedure with durable improvements in SUI and climacturia at 5 years of follow-up. Larger, prospective studies are needed to further assess outcomes of specific graft materials used for the mini-jupette sling.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editors (Paul H Chung and Lindsay Hampson) for the series “Surgical Management of Stress Urinary Incontinence in Men” published in *Translational*

Andrology and Urology. The article has undergone external peer review.

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-22-661/dss

Peer Review File: Available at https://tau.amegroups.com/article/view/10.21037/tau-22-661/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-22-661/coif). The series "Surgical Management of Stress Urinary Incontinence in Men" was commissioned by the editorial office without any funding or sponsorship. DO receives consulting fees from Coloplast, Intuitive Surgical, Fidelis; KR receives consulting fees from Boston Scientific, Coloplast, Rigicon; RA receives consulting fees from Boston Scientific, Coloplast; SHP receives consulting fees from Coloplast; TK serves as an unpaid Associate Editor-in-Chief of *Translational Andrology and Urology* and he receives consulting fees from Coloplast; WH serves as an unpaid Editorial Board Member of *Translational Andrology and Urology*, and he receives consulting fees from Acerus Pharma, Boston Scientific, Coloplast, Endo, Jazz Pharmaceuticals, Gilead, Promescent, Theralogix; LJ receives consulting fees from Hims & Hers Health Inc; FY receives consulting fees from Coloplast, Clarus Therapeutics, Antares Pharma, Acerus. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional review board of University of California, Irvine (No. IORG 0000236), and individual consent for this retrospective analysis was waived.

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Cite this article as: Hammad MAM, Barham DW, Osmonov D, Hatzichristodoulou G, van Renterghem K, Andrianne R, Park SH, Kohler TS, Hellstrom WJG, Jenkins L, Yafi FA. Long-term assessment of the safety and effectivity of the mini-jupette sling: 5-year follow-up of the original series. Transl Androl Urol 2023;12(5):859-865. doi: 10.21037/tau-22-661

