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# Comparison between Tunica Vaginalis Free Graft and BuccalMucosa FreeGraft in Treatment in Anterior Urethral StrictureRepair: A Controlled Clinical Trial Pilot Study

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**Abstract**

**Background:** Urethral stricture is defined as the scarring involving the urethral epithelium or spongy erectile tissue of corpus spongiosum.The aim of the study was to compare the tunicavaginalis graft and buccal mucosa graft (BMG) urethroplasty for anterior urethral stricture with respect to intraoperative, postoperative parameters, and urethroplasty outcomes.

**Methods:**This controlled clinical trial pilot study was carried out on 30 male patients aged >18 years with penile, penobulbar, and bulbar stricture, strictures >2.5 cm in length, and patients requiring repeated optical internal urethrotomy or dilatations. Twenty patients were allocated randomly into two equal categories: group I (BMG group) and group II (tunica vaginalis graft group). All patients were preoperativelyevaluated by complete history taking and full clinical assessment including general examination of chest, heart, abdomen and vitals and laboratory investigations including complete blood picture and renal function tests. Further evaluations were performed with preoperative retrograde urethrogram, voiding cystourethrogram, uroflowmetryand urethroscopy.

**Results:**At 6 months, the successful outcome was 70 % in group I and was 60 % in group II, whereas at 12 months, the successful outcome was 80 % in group I and was 70 % in group II, with no significant difference between both groups regarding successful outcome at 6 and 12 months.

**Conclusions:**Tunica vaginalis provides outcomes equivalent to those of BMG urethroplasty. Tunica vaginalis easy to perform, and beneficial in patients with poor oral hygienehygiene and complications that restricted BMG procedures.

**Keywords:**Tunica Vaginalis Free Graft; Buccal Mucosa Free Graft; Anterior; Urethral Stricture Repair

## Introduction

Urethral stricture is defined as the scarring involving theurethral epithelium or spongy erectiletissue of corpusspongiosum[1]. Urethral stricture is a complex problem andvarious modalities of treatment have been advocated overthe years, and even today there is not much consensusonthe best mode of treatment[2]. Study showed that in 4196 menof urethral diseases, most common surgery performed wasurethroplasty (bulbar, penobulbar, or penile) in 55.2% patients[3].Now that the role of urethrotomy has been drastically reduced, due to highlong-

termrecurrence rates, urethroplasty is currentlythe best option to obtain a definitive cure for mosturethral strictures[4].

Although an end-to-end anastomosis following resection of the diseasedtissue is feasible for short, localized strictures, additional tissue is oftennecessary for longer segments. Autologousnonurethral tissue grafts or flaps from genital andextragenital skin, bladder, rectal and buccal mucosahave been used[5].The gold standard treatment of short segmentbulbar urethral stricture is end-to-end anastomosis and, in some conditions, augmented anastomotic urethroplasty[6]. However, for anterior urethral stricture more than 2 cmthe treatment of choice is buccal mucosa graft (BMG) urethroplasty.BMG for urethroplasty of both urethral stricture and hypospadias repair has gained widespread acceptance during the past10 years[7].

There are few conditions which make the patient notideal for BMG harvesting including patients with restrictedmouth opening due to previous mouth or tongue surgery,submucous fibrosis (tobacco chewer), or active oral infections (candida, lichen, varicella-virus, or herpes virus)[8, 9]. Moreover, the donor site complications like oralpain, numbness, and difficulty in mouth opening andspeech, changed salivation demands for substitution[10, 11].

To explore the possibility of urethral reconstruction with a graft of tunica vaginalis to treat long

strictures, it was previously reported the use of tunicavaginalis graft as a novel substitute for urethral reconstruction in rabbits before performing the operation in patients[12].

To the best of our knowledge, this is the first study that compare BMG with new technique tunica vaginalis. The aim of the study was to compare the tunicavaginalis graft and BMGurethroplasty for anterior urethral stricture with respect to intraoperative, postoperative parameters, and urethroplasty outcomes. To our knowledge, there is no previous randomized study comparing the two techniques.

**Materials and methods**

This prospectivepilotrandomizeddouble blinded clinicaltrial was carried out on30male patients aged >18 years with penile, penobulbar, and bulbar stricture, strictures >2.5 cm in length, and patients requiring repeated optical internal urethrotomy (OIU) or dilatations. Thepatients provided informed written consent before participating in the study. The research was conducted within the approved guidelines of the institutional ethical committee of Suez Canal University. This manuscript adheres to the CONSORT guidelines.

The study excluded multiple urethral strictures, previous failed urethroplasty, periurethral phlegmon, urethrocutaneous fistula, associated with chronic kidney disease or balanitis xerotica obliterans, scarred perineum, oral diseases, and those who refused to be enrolled in the study

**Randomization:**

Twenty patients were allocated randomly by a computer-generated sequence through sealed opaque envelopes into two equal categories. The Care Provider and patient were blinded in this trial. Group I(BMG group) and group II(tunica vaginalis graft group).

All patients were preoperativelyevaluated by complete history takingand full clinical assessment includinggeneral examination of chest, heart, abdomen and vitals of the patient and laboratory investigations including complete blood picture and renal function tests.A detailed preoperative assessment along with history taking and physical examination was done on the first visit in the hospital. Further evaluations were performed with preoperativeretrograde urethrogram (RGU), voiding cystourethrogram, uroflowmetry (UFM), andurethroscopy.

**BMG urethroplasty procedure:**

The procedure was performed under general anesthesia with nasal intubation. The patient was placed in a simple lithotomy position, anda midline perineal incision was made. The bulbarurethrawas mobilized from the corpora cavernosa on one side,leaving the

bulbospongiosus muscle and the central tendonof the perineum intact. On the left side, the urethra waspartially rotated, and the lateral urethral surface wasunderlined. The distal extent of the stricture was identified,and the stricture was incised along its entire length on thedorsolateral aspect by extending the urethrotomy distallyand proximally. After incision of entire stricture segment,the length and the width of the remaining urethral platewere measured. The oral mucosal graft was trimmed to anappropriate size according to the length and width of theurethrotomy, and then quilting of graft over the tunicaalbuginea of corpora cavernosa was done. The two apicesof the graft were sutured to the proximal and distal apicesof the urethrotomy by Vicryl 3-0suture. The right margin ofthe oral graft was sutured to the left margin of the urethralmucosal plate. A 16 Fr foley catheter was inserted.After completion of graft suturing, the graft wascompletely covered by the urethra, and then by the muscles. Colles' fascia, the perineal fat, andthe skin wereclosed with interrupted absorbable sutures.

**Tunica vaginalis graft procedures:**

The surgical procedure was performed withthe patient under epidural anesthesia. With the patientin the lithotomy position, through a perineal midlineincision, the bulbocavernosusmuscle was divided andthe bulbar urethra exposed.The urethra was freed from thebulbocavernousmuscles for its entire length and the muscles were fixedto a retractor using four stitches. The bulbar urethrawas dissected from the corpora cavernosa.The urethra was rotated 180º and the distal extent of thestenosis was identified by gently inserting a 18F catheter with a soft round tip until it met resistance.The dorsal urethral surface was incised in themidline until the catheter tip and urethral lumen wereexposed. The stricture was then incised alongits entire length by extending the urethrotomy bothdistally and proximally. Once the entire stricture hadbeen incised, the length and width of the remainingurethral plate was measured.

The tunica vaginalis graft was trimmed to anappropriate size according to the length and width ofthe urethral defect. All harvests were performed using our standard technique. The graft wasthen defatted and kept in saline until it was ready tobe placed on the recipient site.The opened urethra was rotated onto the rightside and the graft is sutured, splayed and quilted overthe corpora cavernosa using 6-zero running stitches. The right urethral margin was sutured on theright side of the graft. The urethra was rotated over thegraft and the left side of the graft was sutured to the leftside of the urethra. At the end of the procedure thegraft was completely covered by the urethra.A 18 Fr silicone catheter was inserted in the reconstructed urethra and urinary diversion was performedusing a suprapubic catheter for 2 weeks. A non-adhesive compressive dressing was used and left in placefor 3 days. Patients were mobilized on the first postoperative day and were discharged from home 3 days after surgery.Transurethralmicturition started after 2weeks, when voiding cystography showed a patenturethra without extravasation.

The intraoperative parameters recorded during surgery were the duration of surgery, graft harvesting time and blood loss.

**Postoperative care:**

Postoperative management and follow-up: Injectable antibiotics (ceftriaxone, amikacin, and metronidazole) were given for 5 days postoperatively and changed to oral ciprofloxacin 500 mg and ornidazole 200 mg BD subsequently. Injectable analgesic (diclofenac sodium 75 mg BD) was given for initial 2 days postoperatively and then changed to oral formulation. Patients were advised to continue povidone iodine mouthwash thrice daily. The perineal wound was left open from postoperative day-4 onwards. The perineal wound was closed by absorbable sutures, so there was no need for suture removal.Orally, liquid diet was allowed on postoperative day 1 and from postoperative day 2 patients were allowed to take his normal diet. Patients were routinely discharged on the seventh postoperative day if otherwise fit.

The urethral catheter was left in its place for three weeksand was removed after confirming its healing, by performing peri-catheter urethrogram. They were assessed based on UFM on eachfollow-up along with RGU and voiding cystourethrogram at3 months of follow-up and urethroscopy at 6 months offollow-up period to evaluate the outcomes. The follow up included clinical observation of thepatient, the process of healing of the wound and routineflexible urethrocystoscopy.

Success criteria were defined as when patient wasvoiding well without any need of urethral dilatation,maximum urine flow rate (Qmax) of >15mL/s without anyobstructed flow pattern on uroflowmetry (UFM) or without any narrowingon retrograde urethrogram(RGU) or urethroscopy[13]. If the patient required catheterisation in postoperative period, then the outcome wasconsidered as failure.

**Outcome measures:**

The primary endpointof the study was the success rate, and the secondary outcomes were the complications and recurrence of both theprocedures.

**Statistical analysis:**

Statistical analysis was done by SPSS v26 (IBM Inc., Armonk, NY, USA). Quantitative variables were presented as mean and standard deviation (SD) and compared between the two groups utilizing unpaired Student's t- test. Qualitative variables were presented as frequency and percentage (%) and were analysed utilizing the Chi-square test or Fisher's exact test when appropriate. Paired sample t-test is a statistical technique that is used to compare two population means in the case of two samples that are correlated. A two tailed P value < 0.05 was considered statistically significant.

**Results**

In this study, 49 patients were assessed for eligibility, 13 patients did not meet the criteria and 6 patients refused to participate in the study. The remaining 30 patients were randomly allocated into two groups (15 patients in each). All allocated patients were followed-up and analysed statistically. **Figure 1**

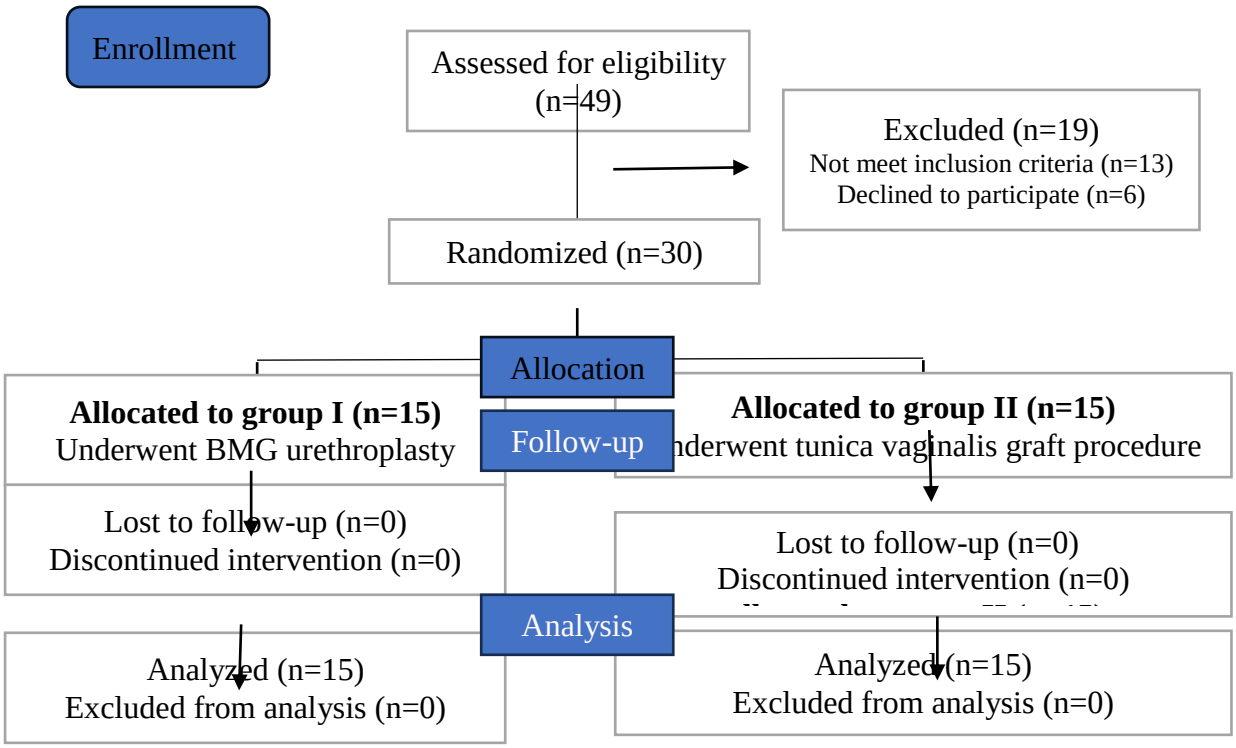

**Figure 1: CONSORT flowchart of the enrolled patients**

**Table 1** shows that there were insignificant differences between the studied groups regarding the age and associated comorbidities (HTN, DM and hyperlipidaemia).

**Table 1: Demographic data and comorbidities of the studied groups**

| | Group I (n=15) | Group II (n=15) | P value |
|---|---|---|---|
| **Age (years)** | 41.5 ± 5.93 | 42.6 ± 6.35 | 0.62 |
| **HTN** | 6 (40%) | 5 (33.3%) | 0.7 |
| **DM** | 3 (20%) | 2 (13.3%) | 0.62 |
| **Hyperlipidemia** | 2 (13.3%) | 0 (0%) | 0.14 |

Data presented as mean ± SD or frequency (%). HTN: hypertension, DM: diabetes mellitus.

Regarding the clinical data, etiology, length of stricture, width of urethral plate, duration of stricture, location of the stricture and duration of surgery were insignificantly different between both groups.**Table 2**

**Table 2: Clinical data of the studied groups**

| | | Group I (n=15) | Group II (n=15) | P value |
|---|---|---|---|---|
| **Etiology** | **Idiopathic** | 9 (60%) | 7 (46.7%) | 0.68 |
| | **Inflammatory** | 3 (20%) | 5 (33.3%) | |
| | **Traumatic** | 3 (20%) | 3 (20%) | |
| **Length of stricture (cm)** | | 5.7 ± 1.16 | 5.7 ± 0.99 | 0.99 |
| **Width of urethral plate (cm)** | | 3.2 ± 0.33 | 3.4 ± 0.41 | 0.15 |
| **Duration of stricture (months)** | | 9.2 ± 1.75 | 9.8 ± 1.32 | 0.29 |
| **Location of the stricture** | **Penile urethra** | 5 (33.3%) | 3 (20%) | 0.65 |
| | **Penobulbar urethra** | 5 (33.3%) | 5 (33.3%) | |
| | **Bulbar urethra** | 5 (33.3%) | 7 (46.7%) | |
| **Duration of surgery (min)** | | 118.4 ± 5.89 | 116.2 ± 5.03 | 0.28 |

Data presented as mean ± SD or frequency (%).

Preoperative and postoperative Qmax were insignificantly different between both groups. In both groups, postoperative Qmax was significantly increased compared to preoperative Qmax (29.5 ± 1.1vs. 13.91 ± 1.18in group I, 30.3 ± 1.52vs. 13.92 ± 1.19in group II, P<0.001). Additionally, PVR was insignificantly different between both groups.**Table 3**

**Table 3: Qmax and PVR of the studied groups**

| | | Group I (n=15) | Group II (n=15) | P value |
|---|---|---|---|---|
| **Qmax** | **Preoperative** | 13.91 ± 1.18 | 13.92 ± 1.19 | 0.98 |
| | **Postoperative** | 29.5 ± 1.1 | 30.3 ± 1.52 | 0.10 |
| | **P value** | **<0.001*** | **<0.001*** | |
| **PVR** | | 68.8 ± 6.41 | 70.3 ± 5.88 | 0.50 |

Data presented as mean ± SD. Qmax: maximum urine flow rate, PVR: post-void residual, *: statistically significant as P value <0.05.

**Table 4** shows that at 6 months, the successful outcome was 73.3 % in group I and was 60 % in group II, whereas at 12 months, the successful outcome was 80 % in group I and was 73.3 % in group II, with no significant difference between both groups regarding successful outcome at 6 and 12 months.

Regarding complications, only 5 (33.3%) patients in group I suffered from pain. 2 (13.3%) patient in group II had a small scrotal hematoma that resolved with drainage. In group I, 2 (13.3%) patient had difficulty inopening the mouth (assessed by measuring the inter-

incisaldistance at maximum opening), and another 2 (13.3%) patientdeveloped erectile dysfunction (according to InternationalIndex of Erectile Function-5 criteria) as complications ofthe procedure. All these complications were managedconservatively. No periurethral leakage at voiding cystourethrogram was observed. None of the patients complained of postoperative testicular discomfort

**Table 4: Successful outcomeof the studied groups**

| | | Group I (n=15) | Group II (n=15) | P value |
|---|---|---|---|---|
| **At 6 months** | **Yes** | 11 (73.3%) | 9 (60%) | 0.43 |
| | **No** | 4 (26.7%) | 6 (40%) | |
| **At 12 months** | **Yes** | 12 (80%) | 11 (73.3%) | 0.66 |
| | **No** | 3 (20%) | 4 (26.7%) | |

Data presented as frequency (%). Qmax: maximum urine flow rate, PVR: post-void residual, *: statistically significant as P value <0.05.

**Discussion**

The first preliminary report for successful use of buccalmucosa for the urethral reconstruction in adults was in1992[14]. El-Kasaby et al.[15]reported 90% success rate with buccal mucosa urethroplasty in 20 patients. The buccal mucosa is a preferred substituteof the urethra. It is accustomed to wet condition, resilient to infection, easy to harvest and handle with goodtake after engraftment[16].The preferred technique for pendulous urethralstricture reconstruction is urethroplasty using penileskin flap, after the description of the Orandi procedure[17].

There are few conditions which make the patient notideal for BMG harvesting including patients with restrictedmouth opening due to previous mouth or tongue surgery,submucous fibrosis (tobacco chewer), or active oral infections (candida, lichen, varicella-virus, or herpesvirus)[8, 9]. Moreover, the donor site complications like oralpain, numbness, and difficulty in mouth opening andspeech, changed salivation demands for substitution[10, 11].

To overcome the graft site morbidities and unsuitabilityof harvesting BMG, there is a requirement of an alternativewith equivalent outcomes as BMG urethroplasty[18].

We hypothesized that there was no difference in the endpoints between the BMG and tunica vaginalis group.

In the current study,at 6 months, the successful outcome was 73.3 % in group I and was 60 % in group II, whereas at 12 months, the successful outcome was 80 % in group I and was 73.3 % in group II, with no significant difference between both groups regarding successful outcome at 6 and 12 months.

Literature on success rate of BMG urethroplasty was80% at mean follow-up of 45 months[19, 20], whereas inFaridi et al.[11]study the success rate decreases from 93% at 6 monthsfollow-up to 87% at 1-year duration. The difference maybe due to short follow-up. However, when Faridi et al. [11]compared thetwo studied groups in their study, the overall success rate ofthe two procedures declined with time, but the differencewas not statistically significant.

A systematic review ofBMGs evaluating more than 2,000 urethroplasties noted nodifference in dorsal vs. ventral onlay procedures (88.4% and88.8% at 42.2 and 34.4 months, respectively), lateral onlay (83%at 77 months), the Asopa technique (86.7% at 28.9 months), and thePalminteri technique (90.1% at 21.9 months)[21].

A previous meta-analysisbe Lumen et al.[22]comparing urethral reconstruction witheither a penile skin or buccal mucosa demonstrated a successrate of 81.8% vs. 85.9% respectively, P=0.01. The long-term durability of penile skin grafts could not be assessed inthis analysis, as the follow-up was only 64 months. However,a previous publication by Barbagli et al. demonstrated thelong-term outcomes of 359 patients who had either an oralmucosa or penile

skin graft urethroplasty. With a minimumfollow-up of 6 years, patients with penile skin grafts hada success rate of 59.7% as compared to 77.7% of patientswith an oral mucosa graft[23].
Barbagli et al.[24] popularized the concept ofdorsal grafts anchored directly to the corpora, whichhas possible advantages compared to ventral grafturethroplasty that include better mechanical support,a better blood supply to the graft, and prevention ofurethral diverticula. The Barbagli technique also hasanother advantage. The incision through the corpusspongiosum is through the thinnest and, therefore, leastvascular part of the urethra, making bleeding substantially less than after ventral incision of the stricture.Using an animal model,Foinquinos et al. evaluated tunicavaginalis graft as a substitute for buccal mucosa indorsal urethroplasty[25]. All animals demonstrated a patentand functional urethra, as evidenced by radiographicand histological analyses. There was no evidence ofinfection or fistula[26].
Tunica vaginalis graft is much easier to harvest than other materials and their application is faster.In addition, the donor site is near, and the tissue isabundant. Use of the tunica vaginalis graft has thepotential to significantly decrease operative time. Thereduced operative time has remarkable advantagesand helps prevent troublesome complications fromprolonged high lithotomy position[27].
Foinquinos et al. [25] in their initial experience on total of 11 patients with anterior urethral strictures were treated with a tunica vaginalis graft urethroplasty and they concluded that their experience indicates that tunica vaginalis dorsal graft urethroplasty may be considered within the reconstructive armamentarium of genitourinary surgeons.
Regarding complications, previousstudies found lower rates of long-term complications,includingpain, oral tightness, numbness, and difficulty with mastication,mouth opening, and speech [20, 28, 29]. Pain at the donor sitecan be a transient side effect after surgery reported postoperatively in50%–70% of patients in the first week[30]. A multivariable analysisfrom a cohort of 553 patients undergoing BMG harvest reported that53.2% of patients did not have postoperative pain, 32.4% had slightpain, and rare long-term difficulty with opening the mouth (95.5%),difficulty smiling (98.2%), and dry mouth (95.8%)[31].
This pilot study wasof small sample size of30 patients with mean follow-up of 1 year only.Therefore,this study also suggests the need for larger sample sizes instudies designed to have sufficientpower to demonstratethat both the procedures are comparable. Moreover,histoanatomical properties of tunica albuginea and buccalmucosa are different.

**Conclusions:**

Tunica vaginalis provides outcomes equivalent to those of BMG urethroplasty. Tunica vaginaliseasy to perform, and beneficial in patients with poor oral hygiene and complications that restricted BMG procedures.

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**Conflict of Interest:** Nil

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