



# Urethral ligament plication operation (ULP) for minimal invasive cure of SUI without tapes

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## ABSTRACT

**Objectives:** To present 12-month data of the urethral ligament plication (ULP) operation for cure of stress urinary incontinence (SUI).

**Materials and Methods:** Thirty-six women, mean age 58.6 years from two centres underwent the ULP operation. Operation: Two full thickness parallel incisions in the vaginal sulcus were made, extending from bladder neck to urethral meatus. The incision was opened out to reveal external urethral ligament and both branches of pubourethral ligaments, which were plicated with no 2 or 3 polyester sutures. The vaginal incisions were closed with polyglactin sutures. The 36 women constitute the learning curve of the surgeons. Inclusion criterion: Demonstrated urine loss on coughing controlled by a hemostat at midurethra. Exclusion criteria: None. Criterion for cure: No urine on coughing with a full bladder.

**Results:** All women were discharged the of day of surgery. Six-month results 31/36 women (86%) were cured of SUI. Twelve-month results 29/35 women (83%) remained cured of SUI.

**Conclusion:** The 12-month data is encouraging, especially as it included the learning curve of the authors. Minimum deterioration in SUI cure from 6 to 12 months suggested ongoing new collagen formation in response to the polyester sutures. Absence of tapes and tape related complications has much to recommend this new direction for SUI surgery. The ULP is a low-cost, low-resource operation which requires only moderate skills, and is especially suitable for the developing world. However, further well-monitored studies by other surgeons will be required before this operation can be recommended for general use.

**Keywords:** ULP operation for SUI; polyester repair of pubourethral ligament; collagen; PUL neoligament

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## INTRODUCTION

The midurethral sling (MUS) operation for cure of stress urinary incontinence (SUI),<sup>1</sup> is a day-care surgery procedure, the gold standard for SUI for some 20 years, with some 10 million operations to date, and reported cure rates of 80-90%, with acceptable complications.

Despite its effectiveness, the MUS has become one of the most litigated operations in the history of surgery. The medicolegal issues seem to be based on tissue reactions from tapes, about 2-3%. Yet that is how the MUS works!<sup>2,3</sup> The MUS harnesses the wound reaction from an implanted tape to create new collagen, to reinforce collagen-deficient ligaments, a very different modus operandi from mesh sheets, which block organ descent, but do not address root causes of the prolapse.<sup>4</sup>

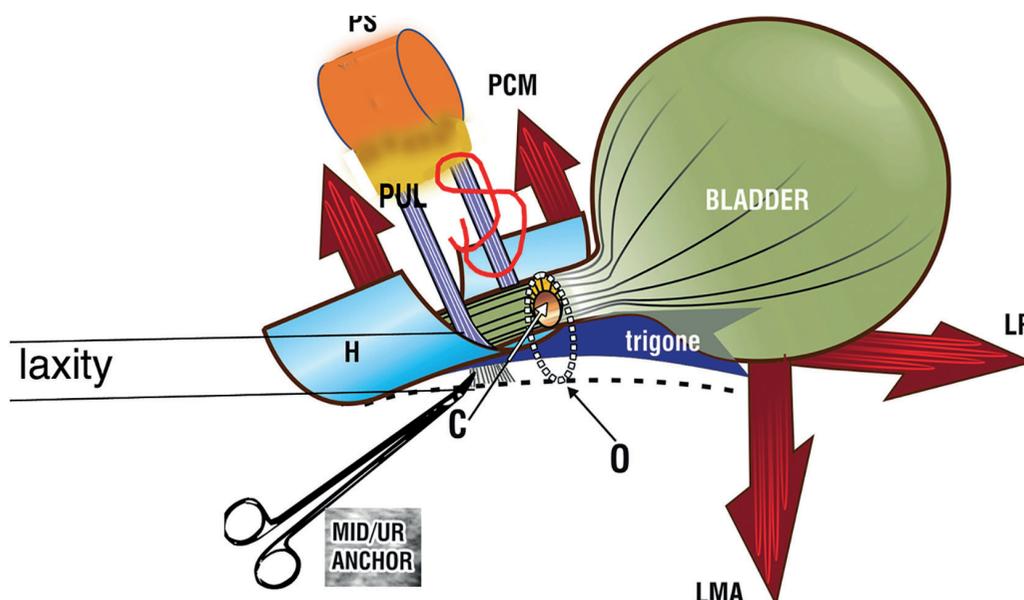
Serious complications from vaginal implantation of large mesh sheets<sup>4</sup> caused massive condemnations in social media, leading to banning of mesh sheets and in some places, MUS also. Where not banned, increasing numbers of women are refusing even the well-tried MUS.

The two research questions which led to the conception of the urethral ligament plication (ULP),<sup>5</sup> Figures 1-3, were 1. “Would

wide-bore No 2 or 3 polyester sutures create sufficient collagen tissue reaction to repair PUL and cure SUI?. 2. “How to do it?” With reference to 1. Review of collagen from a rejected polyester aortic graft as part of a Doctor of Surgery thesis<sup>6</sup> indicated No 2 polyester sutures could produce new collagen two orders of magnitude (X100) beyond normal ligament strength. The answers to the 2<sup>nd</sup> question, how to do it?, came from a live anatomy study of the pubourethral ligament,<sup>7</sup> Figure 2, during a 1997 MUS operation which was performed via two parallel incisions in the distal vaginal sulci.<sup>8</sup> The anatomical and biomechanical basis of the ULP operation as shown in Figure 1, and “very very early results” were reported previously.<sup>5</sup>

Our aim in this work was to test the ULP operation as proposed, for safety and efficacy, then, based on our experience, to critically examine the possible advantages previously quoted:<sup>5</sup>

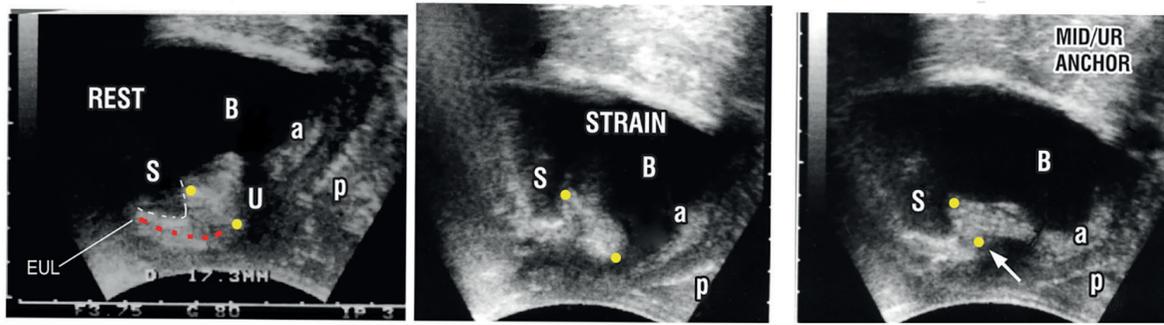
1. No tape. Little cost: A polyester suture.
2. Simplicity: Less surgical skill required; local anaesthetic methodology makes the operation widely scalable especially in countries with few facilities.
3. Built-in safety: No tape to compress urethra; no applicators to damage bladder, nerves, blood vessels, bowel.



**Figure 1A.** Sagittal schematic view, woman with stress urinary incontinence (SUI)

At REST (unbroken lines). Pubourethral ligament (PUL) extends from pubic symphysis (PS) to attach to midurethra. STRAIN (broken lines) on effort, LMA pulls down the trigone. A weak or loose PUL is stretched by LMA, opening posterior urethral wall from “C” closed to “O” open; urine is lost (SUI). Hemostat test hemostat inserted behind the symphysis as in the Video 1 mechanically supports PUL. Urethral closure at bladder neck and distally by pelvic muscles (arrows) is restored (white arrow, right ultrasound frame). No 2 or 3 polyester suturing (red) of both PULs would prevent PUL elongating on stress in the same manner as a sling below the urethra

PS=symphysis; C=closed urethra; O=open urethra; H=distal vagina “hammock”; PCM=pubococcygeus muscle; LP=levator plate; LMA=conjoint longitudinal muscle of the anus



**Figure 1B.** Transperineal ultrasound of a woman with SUI4

At rest (left frame) S=symphysis; U=urethra;B=bladder; a&p are the anterior and posterior walls of the vagina; the two yellow circles mark length of pubourethral ligament (PUL) extending from behind lower border of the symphysis to the midurethra. Strain (middle frame) PUL extends. a&p are stretched backwards/downwards to open out the posterior wall of the urethra along its length. Mid/urethral anchor (right frame). A hemostat (white arrow) inserted behind the symphysis creates closure at the bladder neck and distally; a&p are obviously tensioned. EUL marks position of the external urethral ligament as it attaches the external meatus to the anterior part of the symphysis; the red broken lines below “S” indicate the position of the distal urethra  
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## METHODS

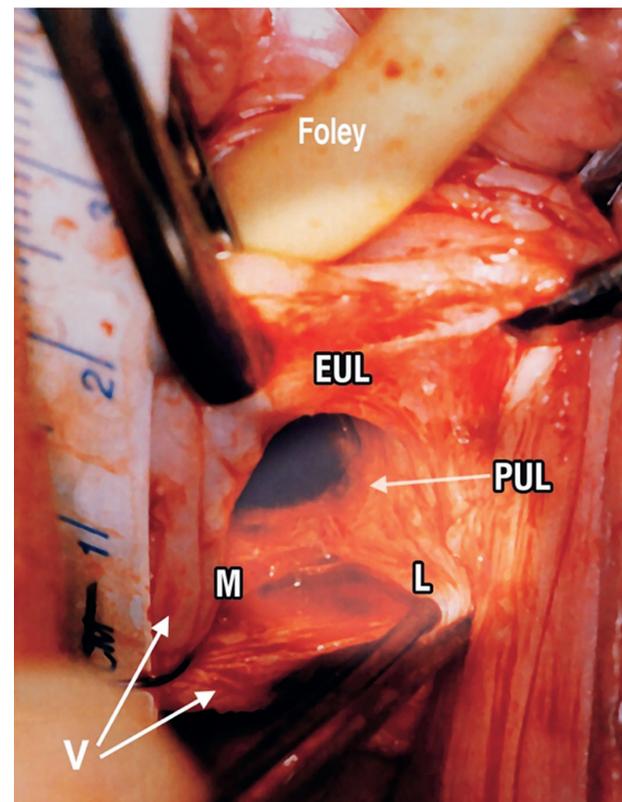
The ULP surgical study was approved by the Ethical Committee of Muğla Sıtkı Koçman University (date and number: 8<sup>th</sup> June 2022 & 11/VII). Patient permission was obtained to publish de-identified surgical results and videos. Trial registration details: ClinicalTrials ID: ID05733052.

ULP surgery was performed in 36 women with SUI from two different locations, Türkiye (n=30, using No 3 polyester sutures), and Australia (n=6, using No 2 polyester sutures). Surgery was performed under spinal anesthesia, following the same surgical protocol described.<sup>5</sup> The main inclusion criterion was urine loss on coughing controlled by a hemostat behind the symphysis, Figures 1A, B. There were no exclusion criteria. The criterion for cure was no urine loss on coughing with a full bladder.

## Technique

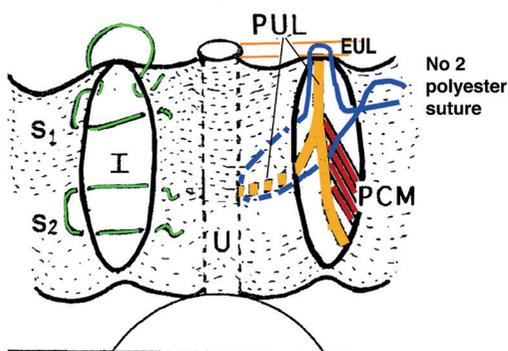
After vulvar and vaginal cleansing, under spinal anaesthesia, with patients in lithotomy position, full thickness vaginal incisions were made in the periurethral sulci extending from bladder neck to the urethral meatus. The incision was opened with dissecting scissors to reveal descending and midurethral branches of pubourethral ligament, Figure 2. Local anesthetic (LA) infiltration of the sulcus was used only in the Australia cohort (n=6).

With reference to Figure 2, the operation was performed in a space of approximately 2.5 cm<sup>2</sup>. A No 3 polyester suture (AAS) or No 2 (RH) was inserted into the urethral part of pubourethral ligament, then pubic part of pubourethral ligament, then external urethral ligament (EUL), then laterally into the pubococcygeus muscle, then tied, but not tightly (Figure 3). Incisions were closed



**Figure 2.** Live anatomy-surgical binding of loose PULs

Original live anatomical dissection of PUL from the two incision sites operation.<sup>8</sup> The tape measure overlies the urethra. The left paraurethral sulcus has been incised along its length and opened out laterally with forceps. EUL is the external urethral ligament which sits in front of the pubic symphysis (PS) and is attached to the external urethral meatus. The pubourethral ligament (PUL), originates behind PS, 1.5 cm from its lower border. Coming down from PS, PUL splits into two parts, medial (M) to insert into the side of the midurethra and L (lateral). “L” attaches laterally to pubococcygeus muscle (not seen) then down to attach to the vagina (V)  
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**Figure 3.** ULP operation. Perspective: Looking into the anterior vaginal wall. Two full thickness parallel incisions “I” are made in each sulcus to the level of bladder neck, and are opened out. The midurethral and descending branches of the pubourethral ligament (PUL) are located and sutured with no 2 or no 3 wide-bore polyester sutures as indicated, into the midurethral part of PUL, then its upper part, then into the external urethral ligament (EUL), then into the medial part of pubococcygeus muscle PCM and tied, but not too tightly.

The vaginal skin is sutured with two vicryl sutures S1 and S2.

U=urethra; PCM=pubococcygeus muscle. EUL is the external urethral ligament inserting into the urethral meatus “U” on the anterior surface of the pubic symphysis Copyright Peter Petros published by permission

with vicryl sutures. In 6 women, the ULP operation was carried out with 300 mL in the bladder. In these 6 women, the No 18 Foley catheter was inserted and removed as required, so cough tests could be carried out for continence at relevant stages of the operation, before starting, after the polyester suture on one side, then after suturing was completed on both sides.

### Statistical Analysis

The SPSS.22 program was used for the analysis of the dataset. Statistical analysis was conducted using standard descriptive statistical methods for continuous quantitative variables (mean, standard deviation). Categorical variables (frequency of occurrence) were presented with frequencies and percentages of the total. The evaluation of quantitative measurements was performed using the “Student’s t-test”. *P*-value was set at <0.05 for statistical significance.

### RESULTS

The 36 cases constitute the learning curve for both surgeons (AAS and RH).

Age:  $58.6 \pm 16.4$  years

BMI:  $27.3 \pm 14.2$  kg/m<sup>2</sup>

Parity:  $2.6 \pm 3.4$

**Preoperative UDI-6 score:**  $64.58 \pm 9.87$ ;

Postoperative (6 months) at 6 months post-operatively, 31/36 (86%) women with leakage on cough test were cured of SUI. There were 5 surgical failures, 4 immediately post-operatively, and one after 3 months. UDI-6 score (6 months):  $18.75 \pm 15.50$  ( $p=0.001$ ). Though classified as failure at 3 months because of a positive cough test, the self-assessed 75% improvement in her SUI, was, for her, a satisfactory outcome. No post-operative retention problems were reported.

Postoperative (12 months) at 12 months post-operatively, 29/35 (83%) remained cured of their SUI. There were 6 surgical failures, 4 immediately post-operatively, one at 3<sup>rd</sup> months, and one at 7<sup>th</sup> month. One patient was not able to be contacted. UDI-6 score: (12 months)  $16.66 \pm 13.40$  (Student’s t-test  $p=0.001$ ).

With intra-operative testing 300 mL in the bladder ( $n=6$ ) prior to surgery commencing, a hemostat behind the symphysis as in Video 1) confirmed urine loss on coughing. Testing after the polyester suture was applied on one side showed restoration of continence in the 3 women in whom the test was able to be successfully completed. Urine leakage on coughing ceased after the sutures were tied on one side.

### DISCUSSION

We have demonstrated that cure of SUI by native tissue repair of pubourethral ligaments (PUL), using wide-bore polyester sutures to structurally reinforce weakened PULs, is possible, without the need for a tape. Minimum deterioration in SUI cure from 6 to 12 months is encouraging. It suggests ongoing new collagen formation in response to the polyester sutures has lasted well beyond the 2-6 month post-operative period, where 40% SUI failure was seen in women where the collagenopoietic stimulus (tape) had been removed.<sup>2</sup>

The TVT data indicate, that once collagen 1 has formed, the restoration of continence is likely to continue.<sup>9</sup> However, this has to be proven by longer-term studies in the ULP operations.

The MUS and ULP are based on the same anatomical principle, surgical repair of the pubourethral ligament “PUL”,<sup>5</sup> but with one important difference. The MUS, creates a completely new, U-shaped neocollagenous PUL, whereas the ULP uses a large bore polyester suture to repair PUL and to prevent it from lengthening, Figures 1A, B (Frame 2).

The ULP operation avoids serious problems reported with MUS, such as urethral perforations by tapes, urinary retention, nerve and vascular damage by instruments. Instead, it relies on anatomically accurate confinement of ligaments (PUL, EUL), to restore the muscle forces important for continence,<sup>2</sup> (3 large arrows, Figure 1A). The ULP operation can fail if the polyester

suture is too loose, as seems to have occurred in 4 women in this study who were discharged still leaking on coughing. The suture needs to secure the PUL close to its origin and insertion points, midurethra, symphysis, external ligament, Figure 2.

Our results seem to (cautiously!) answer the key research question, “Do wide bore polyester sutures create sufficient collagen for longer-term efficacy of the ULP?”. The original animal experimental, biomechanical and anatomical data on which the MUS is based,<sup>2,3</sup> showed a progression from wound reaction, to initial collagen 3, and conversion to collagen 1 within 12 weeks. Based on these data, the 86% SUI cure at 6 months in 31/36 operations, and 83% at 12 months in 29/35 ULP operations indicates collagen 1 had formed, at least for these 29 women.

The results to date appear to confirm statements from:<sup>5</sup> “Built-in safety”, “no tape to compress urethra; no applicators to damage bladder, nerves, blood vessels, bowel”, day surgery with no significant intra-operative complications, and virtual absence of post-operative urinary retention. We do not necessarily agree with the concept paper’s comment:<sup>5</sup> “Simplicity: less surgical skill required.” The paraurethral sulci can be deep, and may pose some difficulties in dissection in some women. However, injection of LA elevates the sulcus and facilitates the dissection.

## CONCLUSION

The ULP operation is essentially a native tissue repair of the PUL, but using collagen creating wide-bore polyester sutures. Its anatomical pathway for cure is very similar to that of the MUS; it reinforces PUL and prevents its lengthening during stress. Our past studies in neocollagen production from implanted material makes us cautiously optimistic about the long-term effectiveness of the ULP operation, but uncertainties remain. Well monitored studies by other surgeons under EC supervision will be required before the ULP operation can become more widely recommended. If longer-term cure for SUI can be maintained, the ULP methodology could, at least theoretically, be applied to repair pelvic organ prolapse caused by any ligament in the pelvis.

## ETHICS

**Ethics Committee Approval:** The ULP surgical study was approved by the Ethical Committee of Muğla Sıtkı Koçman University (date and number: 8<sup>th</sup> June 2022 & 11/VII). Patient permission was obtained to publish de-identified surgical results and videos. Trial registration details: ClinicalTrials ID: ID05733052.

**Informed Consent:** Written consent from each patient was obtained to publish de-identified surgical results and videos.

## Contributions

Surgical and Medical Practices: A.A.S., F.M., R.H.; Concept: A.A.S., F.M.; Design: A.A.S., F.M.; Data Collection or Processing: A.A.S., F.M., R.H.; Analysis or Interpretation: A.A.S., P.P.; Literature Search: A.A.S., F.M., R.H., P.P.; Figures and Video: P.P., A.A.S.; Writing: A.A.S., R.H., P.P.

## DISCLOSURES

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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Video 1 Link: <https://youtu.be/Sjxrult0Xko>