

Start	End	Topic	Speakers
13:30	13:35	Introduction	Tufan Tarcan
13:35	13:45	Re-evaluation of the patient after MUS failure	Tufan Tarcan
13:45	13:50	Conservative management	Alex Digesu
13:50	14:05	Re-MUS and Adjustable Slings	Ervin Kocjancic
14:05	14:15	Pubo-Vaginal Slings (PVS)	Alex Digesu
14:15	14:30	When do I go for AUS or Bulking Agents?	David Castro-Diaz
14:30	14:40	Discussion	Tufan Tarcan David Castro-Diaz Ervin Kocjancic Alex Digesu
14:40	15:00	Case Discussion	Tufan Tarcan David Castro-Diaz Ervin Kocjancic Alex Digesu

Aims of Workshop

Mid-urethral slings (MUS) are the most widely used surgical treatment options for female stress urinary incontinence (SUI). With widespread use of MUS, recurrent or persistent SUI is becoming an increasingly common condition where its management is challenging. The aims of our workshop are: 1) to elaborate the preoperative and intraoperative causes of MUS failure; 2) to discuss the clinical and urodynamic assessment of patients after MUS failure and; 3) to assess conservative and surgical management options including re-MUS, adjustable slings, pubovaginal sling, retropubic suspension, artificial urinary sphincter and periurethral bulking agents, in patients with recurrent or persistent SUI after MUS.

Learning Objectives

- 1) To recognise the pre and intraoperative causes of recurrent SUI after MUS surgery.
- 2) To identify patients with recurrent SUI after MUS and assess them with clinical and urodynamic tools for further decision-making.
- 3) To manage recurrent SUI after MUS surgery by utilisation of different conservative and surgical treatment options under the guidance of Evidence Based Medicine.

Learning Outcomes

After taking part in this workshop participants will be able to:

- 1) Describe the preoperative and intraoperative causes of MUS failure leading to recurrent SUI that are either patient and/or surgeon and/or mesh related.
- 2) Diagnose, examine and assess these patients with the proper utilisation of history-taking, physical examination, symptom scores and diaries.
- 3) Plan and interpret the urodynamic studies in this patient group in order to differentiate between different types and causes of urinary incontinence and bladder/sphincter dysfunction such as intrinsic sphincter deficiency, urethral mobility, detrusor overactivity or detrusor underactivity.
- 4) List and explain to the patient the advantages and disadvantages of currently available conservative and surgical treatment options for her recurrent SUI.
- 5) Combine the clinical and urodynamic parameters and suggest the best possible treatment option(s) for the patient under the guidance of Evidence Based Medicine.

Target Audience

Urologists and uro-gynaecologists.

Advanced/Basic

Advanced

Conditions for Learning

This is an interactive course between the audience and speakers including lectures with Q&A and challenging case discussions.

Suggested Learning before Workshop Attendance

1. Heesakkers J, Van der Aa F, Tarcan T: Female stress urinary incontinence. In J. Heesakkers et al. (eds.), Practical Functional Urology. Springer International Publishing Switzerland, 2016. Chapter 5, pp: 89-118.
2. Kocjancic E, Crivellaro S, Ranzoni S, Bonvini D, Grosseti B, Frea B. Adjustable continence therapy for severe intrinsic sphincter deficiency and recurrent female stress urinary incontinence: long-term experience. J Urol. 2010;184(3):1017-21.
3. MacLachlan LS, Rovner ES. Management of failed stress urinary incontinence surgery. Curr Urol Rep. 2014;15(8):429.

Suggested Reading

T. TARCAN

1. Safety and efficacy of retropubic or transobturator midurethral slings in a randomized cohort of Turkish women. Tarcan T, Mangir N, Sahan A, Tanidir Y, Sulukaya M, Iker Y. Urol Int. 2014;93(4):449-53.
2. Management of complications after tension-free midurethral slings. Cetinel B, Tarcan T. Korean J Urol. 2013 Oct;54(10):651-9.

D. CASTRO-DIAZ

1. Urinary retention. Hernández Hernández D, Tesouro RB, Castro-Diaz D. Urologia. 2013 Sep-Dec;80(4):257-64.
2. Summary of European Association of Urology (EAU) Guidelines on Neuro-Urology. Groen J, Pannek J, Castro Diaz D, Del Popolo G, Gross T, Hamid R, Karsenty G, Kessler TM, Schneider M, 't Hoen L, Blok B. Eur Urol. 2016;69(2):324-33.

E. KOCJANCIC

1. Kocjancic E, Tu Lm, Erickson T, Gheiler E, Van Drie D. The safety and efficacy of a new adjustable single incision sling for female stress urinary incontinence. J Urol. 2014;192(5):1477-82.
2. Costantini E, Kocjancic E, Lazzeri M, Giannantoni A, Zucchi A, Carbone A, Bini V, Palleschi G, Pastore AL, Porena M. Long-term efficacy of the trans-obturator and retropubic mid-urethral slings for stress urinary incontinence: update from a randomized clinical trial. World J Urol. 2016;34(4):585-93.

A.DIGESU

1. Salvatore S, Serati M, Khullar V, Ghezzi F, Triacca P, Digesù A, Beretta P, Bolis PF. Opening vesical pressure: a new test to discriminate urethral sphincter deficiency? Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(12):1435-8.
2. Leone Roberti Maggiore U, Finazzi Agrò E, Soligo M, Li Marzi V, Digesu A, Serati M. Long-term outcomes of TOT and TVT procedures for the treatment of female stress urinary incontinence: a systematic review and meta-analysis. Int Urogynecol J. 2017;28(8):1119-1130.

Re-evaluation of the patient after MUS failure

Tufan Tarcan, Urologist, Turkey

Urinary incontinence (UI) may persist or recur any time following the mid-urethral sling (MUS) surgery. The treatment of UI in this patient group constitutes a real challenge for the physician and it is a devastating problem for the patient. The etiology of UI after MUS may be multifactorial and therefore, the evaluation requires a thorough physical, clinical, radiological and urodynamic re-assessment. However, while doing that, every attempt should be made to reach the preoperative clinical data of the patient basically because of two reasons:

- 1) To re-assess the preoperative decision-making process and the intraoperative surgical reports in order to reveal any possible mistake related to the indication or performance of the previous MUS surgery.
- 2) To compare the preoperative anatomical, clinical and urodynamic features of the patient with her current findings and so, analyze any influence of the MUS or concomitant surgery (e.g. prolapse surgery) on these futures.

Unfortunately, it is not uncommon that a wrong or sub-optimal indication for surgery leads to a poor surgical outcome. Common examples for poor outcomes are patients with intrinsic sphincteric deficiency and/or immobile urethras or mixed UI (predominant urge) or detrusor underactivity. If it is available, re-analyzing the preoperative urodynamic study is certainly helpful. However, a major drawback of today's common practice is that few patients undergo urodynamic studies prior to primary MUS because the majority of patients are somehow being mistakenly labelled as index patients with pure stress UI. Studies have shown that the ratio of index patients with pure stress UI are actually much lower than expected.

Another basic step in the reassessment of a patient with persistent or recurrent UI is diagnosing the type of UI. The differential diagnosis mainly includes stress, urgency, overflow and continuous UI due to a fistula. Symptomatic evaluation should include validated questionnaires and bladder diaries. It is to note that if such a discrimination between different UI types is based only on symptoms it may be misleading. Therefore, a careful physical examination with measurement of postvoiding residual urine and flow rate is certainly mandatory. The physical examination should include assessment of pelvic organ prolapse, urethrovesical angle, urethral mobility, cough-induced stress test and detection of mesh complications. Hematuria and urinary tract infection should be excluded by urine analysis and culture. Trans-labial ultrasound is helpful in the localization of the

synthetic mesh where it is not uncommon to detect the mesh under the bladder neck in failed cases. Cystoscopy should be performed in the presence of hematuria and/or pelvic/bladder pain to exclude mesh intrusion to the urinary tract.

Cystometry with pressure-flow study or a video-urodynamic study may not be necessary prior to conservative management but, they are certainly warranted prior to any secondary surgical or invasive therapeutic intervention for persistent or recurrent stress UI. Stress UI after MUS may not always be associated with urodynamic stress UI. For example, it is possible to detect detrusor overactivity UI, stress-induced detrusor overactivity, detrusor underactivity and even infravesical obstruction in this patient group that will certainly influence the decision for further management.

Conservative management

Alex Digesu, Urogynecologist, UK

Stress urinary incontinence (SUI) is a common problem, and to date, no treatment leads to a 100% cure for all patients. With the increasing volume of surgery being performed for the treatment of female SUI, especially with the widespread use of midurethral slings (MUS), recurrent urinary incontinence is becoming an increasingly common condition. Treatment options for failed SUI surgery include conservative management and/or surgical management, which include pubovaginal sling, MUS, retropubic suspension, periurethral bulking agents, and artificial sphincters.

There is not a single best treatment for all patients with recurrent or persistent SUI following prior surgery. There are many considerations and choices that will depend on the etiology of the patient's failure, patient comorbidities, and patient preference.

A recent review and metaanalysis suggests that there is a lack of high quality evidence assessing the various treatments for recurrent SUI as well as there are still no high-quality data exists to recommend or refute any of the different management strategies for recurrent or persistent SUI after failed MUS surgery. Their review highlights the need for well-designed clinical trials evaluating the efficacy of different surgical procedures, as well as comparing conservative treatment and surgical treatment for patients with recurrent SUI. Conservative treatment for recurrent SUI following antiincontinence surgery includes pelvic floor muscle training (PFMT), which is often attempted prior to performing a repeat surgery. Other conservative measures include pelvic floor physiotherapy, incontinence pessary dish, commercially available devices (Uresta[®], Impresa[®]) or medical therapy. Unfortunately, these options have not been well-studied in the context of MUS failure. A national survey performed in the UK found that 77 % of practicing gynaecologists and urogynaecologists would recommend PFMT prior to repeat surgery. There is, however, a lack of evidence that performing PFMT in patients who have failed SUI surgery is effective. Despite this paucity of data, the clinical guidelines from most of the national and international scientific societies recommend conservative management options as the first line of therapy for patients with recurrent urinary incontinence following pelvic floor surgery thus it is reasonable to encourage patients with residual or recurrent minimal leakage pursuing conservative measures prior to considering repeat surgery.

Re-MUS and Adjustable Slings

Ervin Kocjancic, Urologist, USA

Stress urinary female incontinence (SUI) is primary due to intrinsic sphincter deficiency (ISD) and urethral hypermobility. Despite a lack of standardized international definition, ISD needs to be clearly diagnosed in order to be correctly treated.

Although there is no international consensus definition, we can consider that the ISD is a composite concept combining urodynamic data (MUCP < 20 or 30 cmH₂O) and one or more clinical information (no urethral mobility, negative urethral support test, failure of a first surgery, leakage during abdominal straining, high stress incontinence scores). Imaging can provide additional evidence for intrinsic sphincter deficiency diagnosis, but the correlation between imaging and function remains low. ISD should be diagnosed by a composite of Clinical history, urodynamic evaluation, anatomic findings at physical examination and the severity of the incontinence.

For the treatment of ISD and recurrent SUI a retropubic or trans obturator midurethral sling can be performed as a first surgery. In the past there was a misconception that the retropubic option works better for the patients with ISD. However the meta-analysis by Pan-Feng group, show that TVT doesn't offer better results than TOT in recurrent SUI and another RCT showed that TVT and TOT offer similar results in patients with VLPP<60 and also in patients with VLPP>60.

One possible treatment for sever forms of ISD is represented by the Artificial Urinary Sphincter. However the Long term outcome of AUS in women is associated with a significant complication rate such as: erosion, infection, device malfunctioning, persistence of urinary Incontinence. These are the reasons of a very high re-intervention rate of approximately 50 to 60%. The lower efficacy rate of the traditional MUS and high complication rates of the AUS makes the Adjustable MUS an interesting solution for a difficult problem. Adjustable MUS are slings with mechanical properties that permit their re-tensioning in the immediate post-op (24-48 hrs after surgery). In the presentation the different adjustable solution will be presented, including the success and the complication rates.

Conclusion:

There is no clear definition neither consensus on what ISD is.

Sever forms:

- evaluation is easy and particularly in previous operated patients
- conventional therapies are probably not recommended

Moderate forms:

- cure rates are probably reduced
- validated evaluation and comparative studies are still needed

Mild forms:

- no modification of prognosis and management

Re-do sling

may be an option for recurrent SUI after MUT failure but there is no sense to do another MUT if the previous one was properly carried out

Tension:

treatment of ISD requires more than urethral support

Re-adjustable slings

provide better outcome and long-term consistency

Bulking agents

provide poor and not long-lasting outcome

Artificial sphincter

provide good outcome but very high complication rate.

Pubo-Vaginal Slings (PVS)

Alex Digesu, Urogynecologist, UK

Traditionally, the pubovaginal slings (PVS) were reserved for recurrent stress urinary incontinence (SUI) due to intrinsic sphincter deficiency because of the technical difficulty involved and the special surgical skills required for performing the procedure. More recently, the operation has been successfully used for primary SUI, as continence rates were better with greater patient satisfaction despite the higher incidence of postoperative voiding dysfunction compared with Burch colposuspension. This finding is supported by results of a recent meta-analysis of 15,855 patients showing that both synthetic and PVS had similar objective cure rates that were superior to Burch colposuspension. During increased abdominal pressure with coughing the rectus muscle contracts, pulls the sling slightly forward (anteriorly), with rotation of the bladder base posteriorly and inferiorly thus causing compression and kinking of the bladder outlet and preventing incontinence. Understanding this selective dynamic continence mechanism is essential to the pelvic surgeon to avoid excessive tightening of the sling, which will lead to voiding dysfunction.

The pros and cons of PVS, including additional incision to harvest the fascia and more storage symptoms than with mesh slings, should be addressed.

Patients with persistent or recurrent SUI following placement of a prior sling represent a complex patient population. Treatment choice is often dependent on a multitude of factors including surgeon preference and training, patient preference, coexisting urologic problems, anatomic features, and other comorbidities related to the patient. For primary SUI, mid-urethral slings (MUS) are currently considered first line surgical treatment with cure rates as high as 84% at 5 years of follow-up. However, there remains limited data further examining and verifying the utility of MUS used in secondary repair for patients who have failed a prior MUS procedure.

Secondary repair with a retropubic sling is a durable and effective procedure with an objective cure rate of 61-74% without significant differences in outcomes noted between retropubic MUS and PVS. Conversely, the incidence of storage LUTS is significantly higher in PVS compared to MUS. The reported urinary retention rates following secondary repair is 6–13.8% and de novo urgency rate 6–30%. In conclusion there is still no consensus on the management of persistent or recurrent stress incontinence after a failed synthetic MUS. Usually after a mesh complication or sling failure many women and surgeons prefer to avoid a repeat mesh procedure and may choose an autologous PVS as a salvage operation for recurrent SUI after a failed MUS in view of the reported good and durable long-term results.

Cadaveric courses that offer numerous opportunities for practice and hands-on experiences via a mentor–mentee dynamic model can provide the most suitable platform for acquiring these skills, similar to other antiincontinence procedures. The autologous PVS remains a valuable surgical option for both primary and recurrent SUI in women, showing high cure rates and minimal side effects. The operation restores continence through a dynamic hammock mechanism that works mainly during increased intra-abdominal pressure, with minimal effect on resting bladder-outlet resistance. With the recent decline in the use of synthetic MUS, the demand for PVS is expected to increase in urogynecological practice, and this requires specific training in procedural surgical skills during fellowship programs.

When do I go for AUS or Bulking Agents?

David Castro-Diaz, Urologist, Spain

Periurethral or transurethral injection of urethral bulking agents are a feasible option for the management of female stress urinary incontinence (SUI) after a failed midurethral sling. Because its efficacy is rather limited and there are more effective alternative surgical options, bulking agents are best reserved for patients who do not wish major invasive therapy and who are aware that efficacy and duration are inferior to surgery. Many injectable materials have been used although no one has been demonstrated to be better than another. The procedure can be carried out as an office-based procedure and local anesthesia that can be offered to patients with significant ISD (intrinsic sphincter dysfunction) who are not surgical candidates due to co-morbidities or who are not interested in further surgeries. The reported subjective cure rate is lower than 40%. Although many patients express improvement after the procedure, efficacy is not long lasting and multiple reinjections are likely to be needed. Complications include injection of the material in the unintended place, unwanted tissue reaction, de novo retention, exposure and erosion of the implant, pain, urgency urinary tract infection, granuloma and periurethral abscess.

The artificial urinary sphincter (AUS) is an alternative to slings or bulking agents in the management of SUI after a failed mid-urethral sling if ISD is present and is the main reason for SUI. The AUS enhances higher intraurethral pressures by increasing pressure circumferentially around the urethra, lessening the transmission of intraabdominal pressures. Therefore, the AUS may benefit women with urethral weakness and good anterior vaginal wall who have sphincter dysfunction. The AUS provides uniform circumferential compression of the bladder neck, without changing its position. The AUS is indicated for incontinent women with proven ISD and, can be particularly useful in those patients who have undergone previous unsuccessful anti-incontinence procedures. The AUS should be contraindicated after pelvic radiotherapy.

The AUS may be placed either with a transvaginal or trans-abdominal approach. The transvaginal approach affords direct visualization of the difficult dissection of the urethra-vaginal plane, and the option of a supra-meatal incision to allow in the anterior dissection of the urethra. The retropubic approach is recommended over the vaginal approach because of a lower infection rate. Advantages of the transabdominal approach include lack of a vaginal incision and improved exposure of the endopelvic fascia and anterior bladder neck dissection. Additionally, transabdominal exposure allows the opportunity to perform a deliberate cystotomy to assist in a particularly difficult dissection. The endoscopic implantation of the AUS is feasible providing similar outcome in the hands of surgeons who are very experienced in laparoscopy or robotics. Regardless of operative approach, emphasis should be placed on meticulous surgical approach as intraoperative complication places the patient at risk for post-operative problems such as infection and erosion with eventual device explantation. The AUS compares well to the success of more traditional procedures for urinary incontinence (>85%). The data suggests that placement of the AUS is a safe and effective treatment option for the carefully selected patient with ISD.

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Tufan Tarcan, MD, PhD

Affiliations to disclose[†]:

Speaker or advisory board member for:

Pierre Fabre, Astellas, Recordati, Santa Farma

† All financial ties over the last year that you may have with any business organization with respect to the subjects mentioned during your presentation.

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MANAGEMENT OF FEMALE SUI AFTER A FAILED MIDURETHRAL SLING

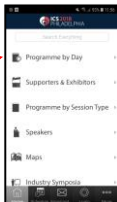
WS 12

Tufan Tarcan, Istanbul, Turkey
David Castro Diaz, Tenerife, Spain
Alex Digesu, London, UK
Ervin Kocjancic, Chicago, USA


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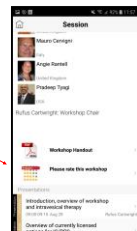


Step 1, open app and select programme by day




Step 2, locate workshop

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Step 3, scroll to find evaluation button



Step 4, complete survey – enter email at end to enter prize drawer

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- A shortened version of the handout has been provided on entrance to the hall
- A full handout for all workshops is available via the ICS website.
- Please silence all mobile phones
- PDF versions of the slides (where approved) will be made available after the meeting via the ICS website so please keep taking photos and video to a minimum.

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Re-evaluation of the patient after MUS failure

Tufan Tarcan, MD, PhD

Professor of Urology
Marmara University School of Medicine and
Koç University School of Medicine
Istanbul

Epidemiology & Help Seeking Behavior



- 20% of women undergo surgery for UI.
 - Smith et al, NU&U 2010
- More than 50% of incontinent women have pure SUI and a further 30% experience mixed incontinence.
 - Reynolds et al, Curr Urol Rep 2011
- High proportion of women do not seek medical advice
 - Sinclair et al, Obstet Gynaecol 2011

Mid-urethral synthetic slings



- TVT was a game changer!
 - Ulmsten&Petros, 1992
- Equal efficacy as Burch, but less morbidity
- Considered as “Gold Standard”, until today!

A gold standard indicates the best tool available at that time to compare different measures



Have we got a perfect treatment option for SUI?

No!

Why?

MUS fail: recurrent SUI after MUS is between 2-23% depending on the definition of failure

De novo voiding dysfunction/retention in up to 40%

Mesh complications leading to restrictions of MUS in several countries

The long-term data does not provide the highest level of evidence in terms of efficacy and safety of MUS

The dilemma: Index patient of SUI



Real life is different than studies!

“A major drawback of today’s common practice is that few patients undergo urodynamic studies prior to primary MUS because the majority of patients are somehow being mistakenly labelled as index patients.”

The dilemma: Index patient of SUI



- A retrospective analysis of 6276 women with UI has shown that only 5.2% had pure SUI.
 - Agur et al, BJU 2009
- A multicenter database study on 2053 patients indicated that only 1/3rd could have been diagnosed as having an “uncomplicated” SUI according to ValUE trial inclusion criteria
 - Serati et al NU&U 2016

What is failure after MUS?



Failure can be defined in many different ways, e.g. also including mesh-related complications and de novo urgency

For purposes of this WS, failure is defined as recurrent or persistent SUI after MUS for which additional treatment is being sought by the patient

Predictors of failure



Patient related

Obesity, (BMI>30)
 Patient age,
 Preoperative urgency incontinence
 Concomitant vaginal prolapse

Surgery related

Intraoperative bleeding, (> 1 L)
 Concomitant pelvic surgeries (vaginal hysterectomy)
 Surgical complications

Poor indication and technique

RE-EVALUATION OF THE PATIENT AFTER MUS FAILURE



- Reach the preoperative clinical data
 - To re-assess the preoperative decision-making process and the intraoperative surgical reports.
 - To compare the preoperative anatomical, clinical and urodynamic features of the patient with her current findings

RE-EVALUATION OF THE PATIENT AFTER MUS FAILURE



- Rule out:
 - Other types of UI
 - Obstruction
 - Detrusor contractility problems
 - Mesh-related complications
 - Infection/UTI
- Is the tape in correct place?
- Why has the operation failed?

Thorough re-assessment is required!



- | | |
|---|---|
| <ul style="list-style-type: none"> • Patient expectations | <ul style="list-style-type: none"> • Radiology <ul style="list-style-type: none"> • Translabial US |
| <ul style="list-style-type: none"> • Symptoms <ul style="list-style-type: none"> • Type of UI • Other LUTS | <ul style="list-style-type: none"> • (Video) Urodynamics <ul style="list-style-type: none"> • Diagnose Urodynamic SUI and ISD • R/O DU,DO and obstruction |
| <ul style="list-style-type: none"> • Physical examination <ul style="list-style-type: none"> • Urethral mobility • Kinking or a swan neck deformity at the bladder neck or urethra? • Cough stress test <ul style="list-style-type: none"> • ICS teaching module, Guralnick et al, 2018 • POP ? | <ul style="list-style-type: none"> • Cystoscopy |

Diagnosis of ISD by (video) UDS



An open bladder neck at rest that is fixed in position with abdominal straining and is associated with a low leak point pressure or urethral closure pressure is strongly suggestive of ISD.

MacLachlan & Rovner, Curr Urol Rep (2014)

Co-existence of SUI and BOO



SUI and BOO have been shown to coexist in up to 18 % of women with urodynamic proven SUI.

Bradley CS, Rovner ES. J Urol. 2004

.....should have their BOO addressed either by urethrolisis or sling incision.

Patient counselling for further treatment



- What is available?
 - Conservative management
 - Re-MUSS
 - Retropubic suspension
 - Pubovaginal sling
 - Adjustable slings
 - Bulking agents
 - Artificial urinary sphincter

Patient counselling



- Considerations
 - Patient expectations
 - Severity of UI
 - Surgeon's experience
 - Anatomical findings (Urethral mobility, length and scarring etc.)
 - Urodynamic findings
 - Co-morbidities (Obesity, cognitive impairment etc.)

MANAGEMENT OF FEMALE SUI AFTER A FAILED
MIDURETHRAL SLING

The cause is multifactorial!

Complete re-evaluation is needed!

There is no easy solution!

There is no single best solution!

The level of evidence for any treatment is low!

Thank you!

Tufan Tarcan, MD, PhD ICS 2018 PHILADELPHIA

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MANAGEMENT OF FEMALE SUI AFTER A FAILED MIDURETHRAL SLING
WS 12
Case Discussion

Case 1: 47-year female patient ICS 2018 PHILADELPHIA

Mixed UI (SUI abundant)

2 VD, hysterectomy

Active sexual life

DM: regulated by one OAD

PE: Mild cystocele, mobile urethra Q-tip 60°, CST supine (-) standing (+)

Normal urine analysis, RFT and US TIT,

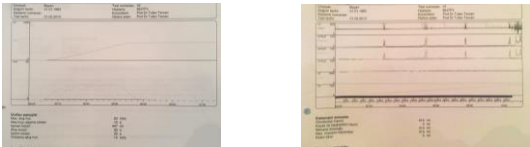
Bladder diary ICS 2018 PHILADELPHIA

Pure SUI

Maximum VV 420 ml

No nocturia, normal frequency

Normal Uroflowmetri, PVR: 0 ml
Cystometry: No DO, maximum capacity 414 ml, (semi-supine) ALPP 104 cmH2O



What would you do? ICS 2018 PHILADELPHIA

Surgery: TVT in February 2010

Outcome: Completely dry, very happy

2018: Left groin pain, dyspareunia



She is now 55

No UI or other LUTS

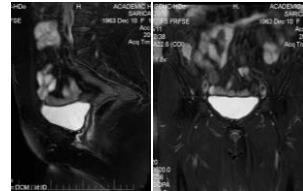
No dysuria

Normal US and urine analysis

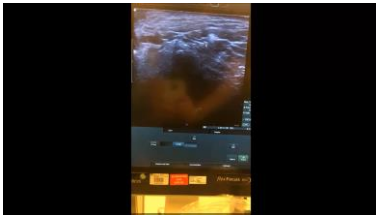
PVR 0 ml

PE: Painful paraurethral vaginal palpation

Normal MRI



Translabial USG: Normal



What would you do?



February 19, 2018



After partial excision of the tape and repair of urethra: No pain, no dyspareunia

**But, SUI +**

Dry during the night, dry at home with frequent emptying, using pads when going out

PE:

- No fistula, mobile urethra

Cystometry at 1st month:

- CST + over 200 ml of bladder capacity
- Urodynamic SUI

What would you do and When?



- Conservative management
- Re-MUSS
- Retropubic suspension
- Pubovaginal sling
- Adjustable slings
- Bulking agents
- Artificial urinary sphincter

Case 2: 59-year old lady early after TOT + native tissue cystocele repair



Postoperative 3rd day

No preoperative UDS

Preop complaint: pure SUI

Her SUI is significantly increased and she is not happy with her emptying, either.

Evaluation



PE:

- No POP
- UI with even a small effort
- Urethra mobile, 30°

PVR 0 ml

Normal US and urine analysis

The patient is extremely nervous!

Urodynamic study



Medicolegal obligation?

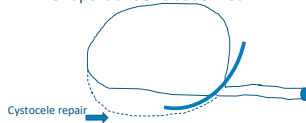
Findings:

- Urodynamic SUI
- Normal detrusor function and compliance, non-obstructive voiding
- PVR 0
- Very low ALPP

Translabial USG



The Tape is under bladder neck



What would you do



Removal of the tape?

Re-MUSS?

PVS?

Other?

Tape was removed.

She refused PVS (too
invasive and morbid)

Re-TOT was applied

Now, she has very mild SUI
Happy



Imperial College Healthcare NHS Trust **NHS** ICS 2018 PHILADELPHIA

Management of Female Stress Urinary Incontinence After a Failed Midurethral Sling

Pubo-Vaginal Slings (PVS)

ALEX DIGESU
Imperial College London - UK

Imperial College Healthcare NHS Trust **NHS** ICS 2018 PHILADELPHIA

Affiliations to disclose[†]:

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Associate Editor Neurourology and Urodynamics Journal
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Investigator for Bluewind Trial
Medtronic

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Cochrane Library Cochrane Database of Systematic Reviews ICS 2018 PHILADELPHIA

Treatment of recurrent stress urinary incontinence after failed minimally invasive synthetic suburethral tape surgery in women (Review)

Bakali E, Buckley BS, Hilton P, Finckler DG

Failure after SUI surgery is not a rare occurrence (2-16%). **Merlin 2001**

Treatment options include conservative management (PFMT) and surgery.

Twelve studies were identified.

There are no data to recommend or refute any of the different management strategies for recurrent/persistent SUI after failed MUS.

Evidence from high quality RCTs is urgently required.

Conservative management ICS 2018 PHILADELPHIA

The clinical guidelines from the Society of Obstetricians and Gynaecologists of Canada recommend conservative management as the first line of therapy for patients with recurrent SUI **Lovatsis 2010**

A national survey performed in the UK found that 77% of gynecologists & urogynecologists would recommend PFMT prior to repeat surgery.

There is, however, a lack of evidence that performing PFMT in patients who have failed SUI surgery is effective. **Riad 2011**

Pubovaginal slings ICS 2018 PHILADELPHIA

Rectus fascia or fascia lata are used to create a hammock on which the bladder neck and urethra can rest.

Placed at the bladder neck and proximal urethra generally through a combined vaginal and retropubic approach.

Applicable to patients with and without urethral hypermobility and are also effective in those with intrinsic sphincter deficiency.

Traditionally used as the procedure of choice after failed incontinence surgery with reported subjective cure/improvement in up to **86%** of patients **Dmochowski 2010, Lovatsis 2010, Petrou 2001**

Pubovaginal slings ICS 2018 PHILADELPHIA

SUCCESS RATE AFTER FAILED MUS

PARKER 2016	52.5%	14.7 MONTHS
MILOSE 2015	69.7%	14.5 MONTHS
PETROU 2016	76.2%	74 MONTHS
	52.4% DRY OR SLIGHT UI 85.7% RECOMMEND PVS	
WELK 2012	64%	14.7 MONTHS
WALSH 2012	71%	5 YEARS

Pubovaginal slings



COMPLICATION RATE

URGENCY	16 - 27%
OBSTRUCTION REQUIRING CIC	8.5 - 18%

Post-op Urine retention resolve after 4 weeks in 61.5% cases

Reversal surgery in 15% cases

Jeon 2008, Albo 2007, Parker 2016, Shapiro 2010

Autologous rectus fascia for recurrent SUI seem to be equally effective as when done with synthetic MUS, but with higher rates of adverse outcomes, including suprapubic pain, pelvic abscesses, a longer hospital stay

Conclusions



Patients with persistent or recurrent SUI following placement of a prior MUS represent a complex patient population.

Treatment choice is often dependent on a multitude of factors including surgeon preference and training, patient preference, coexisting urologic problems.

There remains limited data further examining and verifying the utility of MUS used in secondary repair for patients who have failed a prior MUS procedure.

Conclusions



A recent meta-analysis of **15,855** patients confirmed that both MUS and PVS had similar objective cure rates (**61-74%**) that were superior to Burch colposuspension.

Fusco 2017

There is still no consensus on the management of persistent/recurrent SUI after a failed synthetic MUS.

No high-quality studies exist to provide guidance in this population.

Bakali 2013

Conclusions



ARFPVS not uncommon to be surgeon preference in absence of robust data - aim avoid repeating the same operation while hoping for a different outcome

Surgical skills required for performing the procedure.

Additional incision to harvest the fascia and more storage symptoms than.

The PVS can be used in patients when placement of a synthetic MUS is

contraindicated, such as with:

- concomitant urethral diverticulectomy
- repair of urethrovaginal fistulae
- prior pelvic radiation
- history of prior or concurrent mesh erosion.

If the high residual urine or urinary retention resulting from voiding dysfunction does not resolve after 3 months postoperatively, a sling incision may be required.

Conclusions



Should be managed in a tertiary centre

~40% of patients having a repeat procedure will have had or are having concomitant tape removal

No significant differences between PVS and synthetic MUS in

- Subjective cure rates **60.8%** vs **61.9%**
- Objective cure rates **69.7%** - **79.3%**
- complication rates **16.9%** vs **17.7%**

37.9% had complete cure with no stress or urgency incontinence

Patients with pure SUI were significantly more likely to be cured (**62.5%**) than those women with preoperative MUI (**30.0%**) (p=0.006).

Milose 2015, Nikolopoulos 2015, Aberger 2016

Conclusions



The autologous PVS remains a valuable surgical option for both primary and recurrent SUI in women, showing high cure rates and minimal side effects.

With the recent decline in the use of synthetic MUS, the demand for PVS is expected to increase in clinical practice.

Specific training during fellowship programs as well as cadaveric courses allowing hands-on experiences via a mentor-mentee dynamic model can provide the most suitable platform for acquiring these skills, similar to other antiincontinence procedures.

67 years
P1 – SVD
TAH BSO 1995
TVT 2004

Presenting complaint:
Urgency
Hesitancy
Leaking all the time
Pain to pass urine
Yellow / green discharge

O/E vaginal tenderness
Mesh erosion palpable lateral to the urethra
Urethral-vaginal & vesical-vaginal Fistula suspected

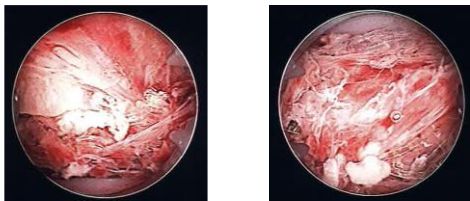
How will you manage this case? ICS 2018 PHILADELPHIA

Videourodynamics
Retrograde urethrocytogram
EUA / Urethro - Cystoscopy
MDT

EUA



Urethro-Cystoscopy ICS 2018 PHILADELPHIA



Urethro-cystoscopy



EUA and VUDS findings

EUA

Tape transecting the urethra – not adherent
Bilateral urethrovaginal fistula
Unable to carry out cystoscopy
Stenosed and retracted bladder neck

VUDS

Difficult catheterization
Severe SUI
Fixed urethra
MUCP < 20 cm/H2O
U-V and V-V fistulas confirmed

Any idea how to manage this case?



- ? Insertion of supra-pubic catheter to rest tract
- ? MRI pelvis
- ? Mesh Removal only
- ? MDT
- ? 1-stage procedure to deal with fistula and SUI
- ? 2-stage procedure to deal with fistula and SUI
- ? Martius Flap
- ? PVS

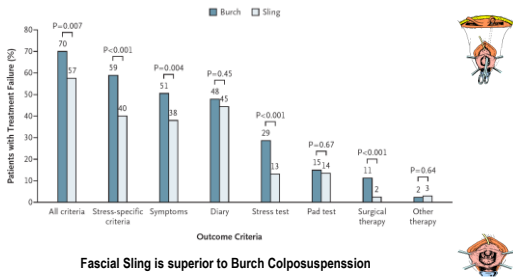
Re-MUS and Adjustable slings

ERVIN KOCJANCIC
Lawrence S. Ross Professor Urology
Vice Chair of Department of Urology
Director of Pelvic Health and
Reconstructive Urology
University of Illinois at Chicago

No technique is perfect for SUI

University of Illinois Medical Center

Fascial Sling



SISTER – Serious adverse events

Event	Burch Procedure (N = 329)	Sling Procedure (N = 326)	P Value†
no. (%)			
Serious adverse events‡	32 (10)	42 (13)	0.20
Patients with event	39	47	
Total events	22	30	0.12
Genitourinary	2	0	
Ureteral injury	1	0	
Ureterovaginal fistula	1	0	
Incidental vaginotomy	10	2	
Incidental cystotomy	1	0	
Erosion of suture into bladder	5	6	
Recurrent cystitis, leading to diagnostic cystoscopy	1	1	
Pyelonephritis	1	1	
Catheter complication	0	20	
Voiding dysfunction leading to surgical revision	0	1	0.25
Pelvic pain	3	1	0.62
Bleeding	13	11	0.83
Wound complication requiring surgical intervention	1	1	1.00
Gastrointestinal	0	1	0.50
Respiratory distress requiring intubation	0	1	0.50
Laryngospasm requiring reintubation	0	1	0.50

Pubovaginal Sling

- Success rates ranging from 50 to 90% in the treatment of women with persistent or recurrent SUI
- A trial of the pubovaginal sling in patients with all types of SUI, after **1-year follow-up**, SUI was cured in 183 women (73%) and improved in 48 (19%). After a **>10-year follow-up** in 20 women, the success rate was 95%
- **Outcomes of patients treated with the pubovaginal sling after failed MUS** have not been reported

Urethral weakness-Intrinsic Sphincter Dysfunction

TO tape → RP tape → Bulk → AUS

100% Functional Urethra | 0% Afunctional Urethra

- Bonney-Marshall / TVT Test
- Q-Tip Test
- Valsalva Leak Point Pressure
- UPPP-MUP
- Bladder neck morphology

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ICS Definitions:

- SUI is the complaint of involuntary loss of urine on effort or physical exertion or sneezing or coughing ...
- Clinically, one will observe leakage of urine per urethra provoked by activity that increases intra-abdominal pressure
- Causes: multifactorial, to some degree is due to HYPERMOBILITY, IMPAIRED SPHINCTERIC FUNCTION OR A COMBINATION OF THE TWO

Typical patient with ISD:

- Low urethral closure pressure
- Stovepipe appearance on cystoscopy
- Opening or funneling of the urethra at rest on cystography



Can Intrinsic Sphincter Deficiency be Diagnosed by Urodynamics?

Lisa M. Parrillo, MD^a, Parvati Ramchandani, MD^{a,b},
Ariana L. Smith, MD^{c,*}

Urol Clin N Am 41 (2014) 375–381
<http://dx.doi.org/10.1016/j.ucl.2014.04.006>
0094-0143/14/\$ – see front matter © 2014 Elsevier Inc. All rights reserved.

ISD

Low MUCP (< 20 cm H₂O)

Low ALPP (< 60 cm H₂O)

Good Urodynamic Practices:

Werner Schfer,* Paul Abrams, Limin Liao, Anders Mattiasson,
Francesco Pesce,
Anders Spangberg, Arthur M. Sterling, Norman R. Zinner,
and Philip van Kerrebroeck

2002

Standardisation of Urethral Pressure

Measurement: Report

from the Standardisation Sub-Committee of the International Continence Society

Gunnar Lose,¹ Derek Griffiths,² Gordon Hosker,³ Sigurd Kulseng-Hanssen,⁴ Daniele Perucchini,⁵ Werner Schfer,⁶ Peter Thind,⁷ and Eboo Versi

The parameters in common use are previously defined by the ICS Standardization Committee [Abrams et al., 1988]. At the present moment,

the clinical utility of urethral pressure measurement is unclear.

There are no urethral pressure measurements that (1) discriminate urethral incompetence from other disorders; (2) provide a measure of the severity of the condition; (3) provide a reliable indicator to surgical success

2002

MUCP varies with :

- Bladder volume
- Patients position
- Catheter size (7 – 10ch)
- Catheter type (air charge vs microtip)
- Speed of catheter withdrawal
- Viscosity of bladder fluid
- Patient's Age

Table 1
Maximal urethral closure pressure by age group

	Women with ISD	Women with SUI	Continent Women
MUCP	<20 mm H ₂ O	Age group: mean (95% CI) 20-29: 70.35 (63.6-77.1) 30-39: 61.38 (59.3-63.5) 40-49: 54.44 (53.31-55.8) 50-59: 38.30 (47.0-49.6) 60-69: 39.42 (37.7-41.1) 70-79: 32.72 (30.5-34.9) 80+: 26.82 (21.52-32.1) MUCP <20 mm H ₂ O in 5.8% of women ²²	Age group: median (interquartile range) Premenopausal: 49 (37-72) Perimenopausal: 35 (29-46) Postmenopausal: 44 (33-43) ²³ Age group: mean (95% CI) 20-29: 92.43 (88.1-96.8) 30-39: 80.71 (77.9-83.5) 40-49: 72.62 (70-74.9) 50-59: 60.84 (58.5-62.3) 60-69: 53.62 (50.5-56.8) 70-79: 46.81 (36.4-45.3) 80+: 39.60 (29.5-49.7) MUCP <20 mm H ₂ O in 1.4% of women ²²

In the literature there are different cut offs: 30 – 15 cm H₂O

With aging

- Reduced density of circular smooth muscle (25 – 30% higher in pts 20's and 30's vs 70s)
- Lower number of striated cell muscles in the ventral wall of the urethra just distal to the BN
- Thinner mucosa
- Less proteoglycans with a decreased urethral wall apposition

ALPP

- Valsalva or Cough???
- Position: Standing /seating/ semi reclined
- Bladder volume (150 – 250)
- Different cut offs in the literature
 - 100
 - 90
 - 60
 - 50

Diagnosing intrinsic sphincteric deficiency: Comparing urethral closure pressure, urethral axis, and Valsalva leak point pressures

Richard C. Bump, MD, Kimberly W. Coates, MD, Geoffrey W. Candiff, MD, Robert L. Harris, MD, and Alison C. Weidner, MD
Durham, North Carolina

Definition of ISD:
MUCP < 20 cm H₂O
ALPP < 52 cm H₂O
Urethral Axis < 22 degrees

Table II. Distribution of low maximum urethral closure pressure (≤ 20 cm H₂O), low Valsalva leak point pressures (≤ 52 cm H₂O), and decreased maximum straining urethral axis (≤ 22 degrees) in 159 women with pure genuine stress urinary incontinence

	MUCP ≤ 20 cm H ₂ O		VLP ≤ 52 cm H ₂ O		Axis ≤ 22 degrees		No.	%
Parameter	Present	Absent	Absent	Present	Present	Absent	Present	Absent
MUCP ≤ 20 cm H ₂ O	Present	Absent	Absent	Present	Present	Absent	Present	Absent
VLP ≤ 52 cm H ₂ O	Absent	Present	Absent	Present	Absent	Present	Present	Absent
Axis ≤ 22 degrees	Absent	Absent	Present	Absent	Present	Present	Present	Absent
No.	8	14	16	14	9	3	16	79
%	5.0	8.8	10.1	8.8	5.7	1.9	10.1	49.7
								100

Conclusion:
ISD should be diagnosed by a composite of

- Historic
- Urodynamics
- Anatomic
- Clinical severity criteria

Key Points

- The mid-urethral sling (MUS) procedure is the most common treatment for women with stress urinary incontinence (SUI).
- 5–20% of patients undergoing MUS experience persistent or recurrent SUI
- Little is known about methods to evaluate and manage patients who fail MUS procedures.

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Non-surgical management of failed MUS

- Pelvic floor muscle exercise is an option, the effects of such exercise after MUS failure have not been examined
- Trials have demonstrated the efficacy of duloxetine in primary SUI
- BUT many women prefer not to perform pelvic floor exercise or take drugs daily for SUI on a long-term basis

➤ **Surgery remains the main treatment for most women with MUS failure**

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Surgical management of failed MUS

- Periurethral injection therapy
- Shortening of pre-implanted tape
- **Repeat Mid Urethral Sling**
- **Re-Adjustable Sling**
- Pubovaginal Sling
- New options for MUS failure

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Shortening of pre-implanted tape

Pros:

- quick procedure
- local anesthesia

Cons:

- No studies with a significant number of patients
- No long term follow-up studies
- No consensus on surgical procedure: dissection or shortening of tape? At what extent?

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Repeat Mid Urethral Sling

- Most studied secondary procedure
- Cure rates ranging from 55 to 92% (differences in the definition of cure and the surgical approach to secondary MUS)

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REVIEW ARTICLE

Management of Recurrent or Persistent Stress Urinary Incontinence after Mid-urethral Sling

Ji-Yeon HAN¹, Kyu-Sung LEE¹ and Myung-Soo CHOO^{2*}

¹Department of Urology, Asan Medical Center, University of Ulsan College of Medicine and ²Department of Urology, Samsung Medical Center, University of Samsung College of Medicine, Seoul, Korea

First sling surgery vs Second sling surgery

Retropubic and transobturator approach, the difference is not statistically significant

Repeat transobturator approach cure rate was significantly lower than for repeat retropubic approach.

Conclusion:

Transobturator approach has poorer outcomes than the retropubic approach in repeat sling surgery.

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Treatment of ISD and Recurrent SUI Traditional MUS

- Is TVT better than TOT?
 - Meta-analysis by Pan-Feng group show that TVT doesn't offer better results than TOT in recurrent SUI ¹
 - Meta-analysis by Agur and Pradhan groups show TVT doesn't offer better results than TOT in recurrent SUI ^{2,3}
 - RCT showing TVT and TOT offer similar results in patients with VLPP<60 and also in patients with VLPP>60 ⁴

1. Pan-Feng T, et al: Saudi Med J 2014; Vol 35 (1)
2. Agur W, et al: Eur Urol (2013) <http://dx.doi.org/10.1016/j.eururo.2013.04.034>
3. Pradhan A, et al: Int Urogynecol J (2012) 23:831-841
4. Costantini, E et al: Braz J Urol Vol 34 (1): 73-83, January-February, 2008

Int Urogynecol J (2015) 26:1285–1291
DOI 10.1007/s00192-015-2696-7

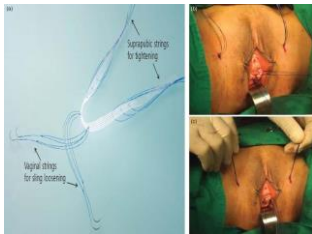
ORIGINAL ARTICLE

Management of recurrent stress urinary incontinence after failed midurethral sling: a survey of members of the International Urogynecological Association (IUGA)

Elis Glarens¹ · Ganesh Thilagamoorthy¹ · Martino Zacchi¹ · Duffley Robinson¹ · Linda Cardoso¹

	Offered, N (%) ^a	Top three ranking, N (%) ^b
Retropubic sling	270 (81.5)	296 (89.4)
Urethral bulking agents	161 (48.6)	148 (44.7)
Transobturator sling	89 (26.9)	138 (41.7)
Open colposuspension	77 (23.3)	89 (26.9)
Autologous fascial sling	65 (19.6)	124 (37.4)
Sling tightening	45 (13.6)	72 (21.7)
Laparoscopic colposuspension	23 (6.9)	55 (16.6)
Single-incision sling	8 (2.4)	25 (7.6)
Artificial sphincter	5 (1.5)	43 (12.9)
Urinary diversion	5 (1.5)	4 (1.2)

Re-Adjustable Sling: AMI



AMI adjustable suburethral sling (Agency for Medical Innovation GmbH, 6800 Feldkirch, Austria)

A prospective study on the AMI adjustable suburethral sling implanted through the retropubic route in 25 patients with recurrent urodynamic SUI showed that 21 of the patients were uroynamically continent after 12 months.

Re-Adjustable Sling: SAFYRE T Plus Sling



Safyre T Plus sling (Promedon, Córdoba, Argentina)

The Safyre plus sling is a transobturator crossover re-adjustable sling used in a salvage procedure for failed anti-incontinence procedures and it consists of a monofilament polypropylene mesh between two self-anchoring columns. Re-adjustments are easily performed under local anesthesia by moving the washers until there is no urine leakage during Valsalva maneuver. After 12 months, the overall cure rate was 93.7% (15/16), with only one patient requiring re-adjustment.

Re-Adjustable Sling: Remeex

- Use of a re-adjustable sling for recurrent SUI with sphincteric deficiency is currently under investigation
- Use of the Remeex re-adjustable sling showed that, after 3 years, 109 of 125 (87.2%) women were continent under stress after initial surgery, including 49 of 55 (84%) with recurrent SUI and 60 of 70 (85.7%) with Intrinsic Sphincter Deficiency
- 19 of these patients showed additional benefit from a subsequent re-adjustment

Remeex Adjustable Sling

Gilberti, C, et al BJUI 2011; 108:1140-4

- 5 year retrospective study of 30 women with severe SUI, fixed urethra and low MUCP/ALPP
- Improved patients: "Readjustment was refused by the two improved patients because of their satisfaction"
- Erosion: "No cases of urethral erosion"
- Complications: "Seroma formation (3%) and de novo urgency (7%) were"
- "No complication in the mid-term follow-up"



TABLE 2 Outcomes of the Remeex procedure regarding physical examination, pad test and quality of life (QoL) score after a mean of 60.6 months of follow-up

Patients	No. of patients (n)	Mean pad weight ± SD (g) (% improvement; P value)	QoL score ± SD (% improvement; P value)
Cured	26 (86.0)	0.6 ± 0.3 (89.0; <0.05)	102.0 ± 6.2 (88.0; <0.05)
Improved	2 (7.0)	27.6 ± 12.1 (76.0; <0.05)	89.3 ± 7.6 (74.0; <0.05)
Failed	2 (7.0)	111.5 ± 39.6 (0.02; ns)	25 ± 0.8 (2.0; ns)
Total	30 (100)	33.2 ± 15.6 (71.0; <0.05)	86.9 ± 6.7 (74.0; <0.05)

ORIGINAL CLINICAL ARTICLE

WILEY *Open Access* ICS *Open Access*

A re-adjustable sling for female recurrent stress incontinence and intrinsic sphincteric deficiency: Long-term results in 205 patients using the Remeex sling system

Carlos Errando-Smet | Cristina Gutiérrez Ruiz | Pedro Arañó Bertrán | Humberto Villavicencio Mavrich




FIGURE 1 Detail of the Remeex sling system




FIGURE 2 Appearance of the end of surgery with the suspensory appearing through the skin

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N. Of Patients: 205 (96 recurrent SUI)
 Follow up: 89 months (26 – 159)
 Cure rate: 71%
 Failure rate: 17%
 De Novo OAB: 15%
 Need for re-adjustment: 81%
 82 patients increased tension (persistent SUI)
 6 patients reduced tension (Outlet obstruction)
 Overall Complication rate 28%
 3% Clavien III (Urethral Erosion/Infection)

University of Illinois Medical Center

TABLE 2 Stress urinary incontinence (SUI) results


	rSUI (n = 107)	ISD (n = 123)
Intention to treat analysis, N = 230. Lost of follow-up: 25 patients		
No SUI	81 (75.7%)	84 (68.2%)
SUI	15 (14%)	25 (20.3%)
chi-square test, P = 0.8 (ns)		
Lost follow-up	11 (10.2)	14 (11.4)

University of Illinois Medical Center

FUNDACION SANTA FE DE BOGOTA

Universidad de los Andes

IUGA *International Urogynaecological Association*



Feasibility of an adjustable autologous fascia sling using the TRT Remeex System™ for the treatment of recurrent stress urinary incontinence

Piñero M¹, Castañeda J, GC², Alvarez J¹, Bravo-Balado A¹, Zuluaga L¹, Moreno M, GC²

1. Dept. of Urology, Hospital Universitario Fundación Santa Fe de Bogotá and Universidad de los Andes School of Medicine, Bogotá, Colombia
 2. Dept. of Urology, Hospital Pablo Toboín Uribe, Medellín, Colombia

University of Illinois Medical Center

Conclusion

- There is no clear definition neither consensus on what ISD is
- Sever forms:
 - evaluation is easy and particularly in previous operated patients
 - conventional therapies are probably not recommended
- Moderate forms:
 - cure rate are probably reduced
 - validated evaluation and comparative studies are still needed
- Mild forms:
 - no modification of prognosis and management

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- **Re-do sling**
 may be an option for recurrent SUI after MUT failure but there is no sense to do another MUT is the previous one was properly carried out
- **Tension:**
 treatment of ISD requires more than urethral support
- **Re-adjustable slings**
 provide better outcome and long term consistency
- **Bulking agents**
 provide poor and not long lasting outcome
- **Artificial sphincter**
 provide good outcome but very high complication rate.

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More than 100 procedures are described in the medical literature, leading to confusion rather than clarification.

I've had 2 operations and I'm still wet

I've had 3

We've lost count

I'm so wet even my makeup runs

I need a holiday

Are these patients waiting to see you?



Management of Female Stress Urinary Incontinence After a Failed Midurethral Sling

ICS 2018 PHILADELPHIA

When do I go for AUS or Bulking Agents?

David Castro-Diaz
Hospital Universitario de Canarias / Universidad de La Laguna
Santa Cruz de Tenerife (ES)

David Castro-Diaz

ICS 2018 PHILADELPHIA

Affiliations to disclose*:

Allergan
Astellas
Boston Scientific
Contura

* All financial ties (over the last year) that you disclose with any business organization with respect to the subjects mentioned during your presentation.

Funding for speaker to attend:

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 Institution (non-industry) funded
 Sponsored by:

Surgical procedures for recurrent SUI

ICS 2018 PHILADELPHIA

TO tape → RP tape → Bulk → AUS

Management of recurrent stress urinary incontinence after failed midurethral sling: a survey of members of the International Urogynecological Association (IUGA)

Hsu Chien-shi*, Gaochun Wang*, Martin Zacher*, Shuhua Robinson*, Linda Cardenas*

	Offered, N (%) ^a	Top three ranking, N (%) ^b
Retropubic sling	270 (81.5)	296 (89.4)
Urethral bulking agents	161 (48.6)	148 (44.7)
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Sling tightening	45 (13.6)	72 (21.7)
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Single incision sling	8 (2.4)	23 (7.0)
Artificial sphincter	5 (1.5)	43 (12.9)
Urinary diversion	5 (1.5)	4 (1.2)

Offered surgical procedures and their ranking for persistent or recurrent SUI after failed MUS

"The injection of bulking agents into the urethral submucosa is designed to create artificial urethral cushions that can improve urethral coaptation and hence restore continence" (Cochrane Review – 2003)

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Effective coaptation of the urethra during increases in intra-abdominal pressure

Trans-urethral or peri-urethral Cystoscopy, ultrasound or implacer guide
Local, regional or general anaesthesia

1 Urethral resistance
1 Abdominal leak point pressure
1 Urethral length
1 Mucosal coaptation - seal effect
Additional control (filler volume → 1 sarcoplasm length
1 power of the urethral sphincter.

Urethral Bulking Agents

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Optimum attributes for the ideal bulking agent

- Autologous fat
- Polytetrafluoroethylene (Teflon)
- Collagen (Contigen)
- Ethylene vinyl alcohol) (Tegress/Uryx)
- Hyaluronic gel(Zuidex)
- Durasphere (Carbon coated zirconium beads)
- Coaptite (Calcium hydroxyl apatite)
- Macroplastique (Polydimethylsiloxane)
- Permacol(Porcine dermal Implant)
- Urolastic (combination of PDMS+tetrapropoxylate, siloxane, titanium dioxide radiopacifying agent)
- Bulkamid (Polyacrylamide gel)

- Biocompatibility
- No immunogenicity
- Integrity of the material formulation
- Adequate viscosity
- Minimal fibrosis
- Little inflammatory response
- Volume should be retained after injection
- No re-injections needed over time
- Total incorporation in the tissue

Efficacy of Bulking Agents

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Modest efficacy rates	Efficacy reduced over time ³	Repeat injections
48 ¹ – 80.3% (subjective measurements)		7 ⁴ – 52.5% (all bulking agents)

Many patient studies have been performed within the 'salvage' category or on those who were not suitable for a surgical procedure.

1. Sphaer P, et al. (1999) JAMA 281: 2682-2684.
2. Sphaer P, et al. (2000) JAMA 283: 2682-2684.
3. Sphaer P, et al. (2002) JAMA 287: 2682-2684.
4. Hsu C, Wang G, Gao C, Robinson S, Zacher M, Cardenas L. (2003) BJU Int 91: 101-105.

Outcome of bulking agents

ICS 2018 PHILADELPHIA

Objective success
25.4%-73.3%
Siddiqui ZA 2017

Modest Improvement /cure
Re-injection required often
Complications exist

- Outcomes are similar regardless of bulking agent used
- No single bulking agent demonstrating superiority to bovine collagen.
- No difference whether the transurethral or periurethral technique is used
- Bulking is inferior to surgical therapy for both primary and recurrent SUI
- Benefit of bulking therapy in special populations (ex. following radiotherapy)
- Low complication rate but unknown long-term implications

E. Rovner ICI 2017

Efficacy and Safety of Polyacrylamide Hydrogel for the Treatment of Female Stress Incontinence: A Randomized, Prospective, Multicenter North American Study

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Eric R. Sokol, Mickey M. Karram and Roger Dmochowski, et al.

North-American Bulkamid study achieves efficacy and safety endpoints

- Primary endpoint achieved (p<0.0003)
- 76.5% of patients were subjectively improved with Bulkamid versus 70.6% with Contigen
- 50% of patients achieved "zero SUI episodes"
- There were no serious adverse events related to Bulkamid

Patient subjective efficacy perception at last follow up visit (%)

Incontinence episodes (median daily)

Sokol E, Karram M, Dmochowski R. Journal of Urology. 2014 Sep;192(3):863-8

Complications of Bulking Agents

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Meta-analysis according to PRISMA (1996-2014)
(Preferred Reporting Items for Systematic Reviews and Meta-Analyses)

1022 studies, 4326 patients from eligible 78 samples
1999 reported in the 78 studies
3% were considered major (Clavien III); 70.6% required incision & drainage
29.3% required more invasive procedures

M Islam, H Wadhwan R Dobbs and E Kojancic, AUA 2018

Bulking Agent	%Complication	P value
Durasphere	9.4	0.003
Coaptite	7.4	0.0014
Zuidax	17.8	0.0001
Bulkamid	0.8	0.2749
Tegress	5.9	0.0071
Macroplastique	NA	NA
Contigen	1.8	

Siddiqui ZA 2017

Complication	Bulkamid, n (%)	Macroplastique, n (%)
UTI	85 (11)	33 (9)
Implantation site pain	76 (10)	6 (2)
RAO	27 (3)	32 (9)
De novo urgency	18 (2)	11 (3)
Dysuria	5 (1)	24 (7)
Persistent UII	8 (1)	7 (2)
Haematuria	9 (1)	9 (3)

Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review

Urolastic for the treatment of women with stress urinary incontinence: 24-month follow-up

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Urolastic (combination of PDMS+tetrapropoxylate, siloxane, titanium dioxide radiopaque agent)

	Baseline	12-month follow-up	24-month follow-up
Number of patients	24	19	18
Overall success*	-	89%	66%
Stamey grade = 0	0%	68%	45%
Urgency	0%	0%	22%
Urinary retention	0%	15%	0%
Erosion	0%	0%	5%
Urinary tract infection	0%	15%	0%

*Defined as a decrease in the Stamey Score by 1 grade compared to the baseline continence status.

Of the 24 women at baseline, 1 patient did not respond and 4 responders reported removal of the Urolastic implant.

Urethral bulking agents

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Indications	Advantages
<ul style="list-style-type: none"> Physically frail Anaesthetic risk Mild stress incontinence Family incomplete High risk of retention after sling operation ?Anticoagulant therapy ?SUI with inadequate bladder emptying 	<ul style="list-style-type: none"> Minimally invasive approach May be performed under local anaesthesia May be performed in clinic setting Low morbidity Reduced voiding difficulties and de novo UII&DOA Suitable in women with medical co-morbidity Patient choice

EAU Guidelines Recommendations (2018)

Recommendation	Strength
Offer a MUS to women with uncomplicated SUI	Strong
Inform women undergoing colposuspension that there is a longer duration of surgery, hospital stay and recovery, as well as a high risk of development of pelvic organ prolapse and voiding dysfunction post-operatively.	Strong
Only offer new devices, for which there is no level 1 evidence base, as part of a structured research programme.	Strong
Only offer adjustable MUS as a primary surgical treatment for SUI as part of a structured research programme.	Strong
Offer bulking agents to women with SUI who request a low-risk procedure with the understanding that repeat injections are likely and long-term durability is not established.	Strong

Adjustable Continence Therapy (ACT®)

Two balloons each attached to an injectable port placed in the labia majora

8 studies between 2007-2013
 Mean age= 62-73
 40–100% had previous surgery
 Mean F-U= 1-6-years

Significant reduction on number of pads used Per day after ACT
Pad test reduction from 49.6 to 77.3 g preoperatively to 11.2-25.7g after ACT
44% considered cured & 66-78.4 % were satisfied
QoL improvement
Explantation rate between 18.7% and 30.8 %

Pha V. 2014 (systematic review)

Artificial Urinary Sphincter

Indications: Intrinsic sphincter dysfunction

Minimal requirements

- Highly motivated personality
- Good manual dexterity
- Normal detrusor
- Absence of urinary tract infection
- Realistic expectations

Surgical approach for AUS implantation in females

Vaginal (Abbassian) Retropubic Endoscopic

- The most crucial step
- Need to dissect through urethral-vaginal septum on both sides of the urethra
- No anatomical plane
- 2 specific instruments used to facilitate the dissection : angle clamp an scissors

Long-Term Results of Artificial Urinary Sphincter for Women with Type III Stress Urinary Incontinence

24/366 post TVT-TOT FUP = 10 y

86% Dry cont, 14% Social cont

High re-intervention rate (50-60%)

Author	N° of patients	Mean Follow-up (Years)	Success	Revisions	Explantation
Peters/Overson	55	5.3	84%	30%	13%
Vaysses et al	215	6	73.5% dry satisfied	37%	7%
Cocile	344	8.8	38.6%	26%	30%
Pha	34	17	15%-73%	35.2%	25%

Lower survival risk factors

- Number of previous SUJ surgeries (0-1 vs ≥2)
- Non neurogenic vs Neurogenic

Success Rates for Laparoscopic Implantation of AUS-800

Author	N° of patients	Success	Complications	Revisions
Nginiakou et al	4	75%-100%	Balloon replacement	1
Hoda et al	2	100%		
Mandron et al	25	92%	1 vaginal perforation 2 vaginal erosions 20% retention	
Rouprêt et al	12	88%	45% Urinary retention	
Troillet et al	26	61%	30% acute retention, 2 pump migration, 1 vaginal injury, 1 vaginal erosion (2 explantation)	
Yates et al	6	100%		

Less general morbidity
 To decrease prosthetic infection rate
 To reduce surgical trauma with limited and improved dissection

Need for vaginal palpation

- Complex to use with laparoscopic and moreover robotic route
- Need for trained surgical assistants

Laparoscopic tools

- Nothing has been designed for bladder neck dissection
- We use the traditional angle clamp even with the laparoscopic approach

Robot-assisted artificial urinary sphincter implantation in female patients: A multicentre study

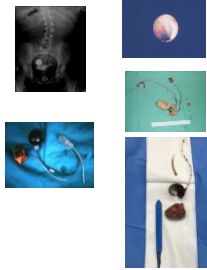
Aim: to report the perioperative and functional outcomes of robotic AUS implantation in women

1 AUS Explantation (vaginal erosion) 2.5%
 35 patients (57.5%) were cured of incontinence
 3 patients improved (7.5%)
 2 Failures (5%)

Parameter	N= 40	Parameter	N= 40
Median age (years)	68.5 (38-84)	Median length of AUS cuff (mm)	75 (60-90)
Body Mass Index (kg/m2)	27 (21-39)	Median operative time (min)	150-200
Score ASA		Median length of hospital stay (days)	5 (2-8)
1	7 (18%)	Intraoperative complications	6 (15%)
2	29 (72%)	Bladder neck injury	4
3	4 (10%)	Vaginal injury	2
History of previous pelvic surgery	34 (85%)	Postoperative complications	9
History of previous suburethral sling	35 (87%)	Clavien 1	(22.5%)
Median preoperative urethral closure pressure (cm H2O)	22 (11-40)	Clavien 2	4
History of pelvic radiation therapy	0 (0%)	Clavien 3b	3
		Clavien 3c	2

Complications of AUS in women ICS 2018 PHILADELPHIA

- Erosion
- infection
- Malfunctioning
- Incontinence
- Upper tract damage



EAU Guidelines 2018 ICS 2018 PHILADELPHIA

Recommendations	Strength rating
Management of complicated SUI should only be offered in expert** centres	Weak
The choice of surgery for recurrent SUI should be based on careful evaluation of the individual patient including multichannel urodynamics and imaging as appropriate	Weak
Inform women with recurrent SUI that the outcome of a surgical procedure, when used as a second-line treatment, is generally inferior to its use as a first-line treatment, both in terms of reduced efficacy and increased risk of complications	Weak
Consider secondary synthetic sling, colposuspension or autologous sling as first options for women with complicated SUI	Weak
Inform women receiving AUS or ACT® that although cure is possible, even in expert centres, there is a high risk of complications, mechanical failure or a need for explantation	Weak

ACT® = Adjustable compression device, AUS = artificial urinary sphincter, SUI = stress urinary incontinence, UI = urinary incontinence.
** Expert centres refers to the comments on surgeon volume in the introduction to the surgical chapter.

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Case report ICS 2018 PHILADELPHIA

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Referred because of refractory urinary incontinence after hysterectomy

Physical examination: mobile urethra, no pelvic organ prolapse. No evidence of fistula by the gynaecologists at that moment.

Urodynamics: total incontinence

Case report ICS 2018 PHILADELPHIA

Ultrasound: two kidneys, no hydronephrosis, no lithiasis.

Cystoscopy: no bladder masses, orthotopic meatus plus one other foramen next to the trigone that was supposed to be the fistula.

Case report ICS 2018 PHILADELPHIA

A vesico-vaginal fistula repair through an open abdominal approach is planned.

After cystostomy, no fistula is identified! The three foramina are catheterised and contrast is introduced:

- Complete ureteral duplicity on the left side
- Incomplete ureteral duplicity on the right side

Vagina is again explored: 1 fistulous tract entering through the bladder neck is identified

Primary closure of the fistula is performed

Follow-up



After two weeks, urethral catheter is removed and suprapubic cystostomy is maintained

Cystography: bilateral vesico-ureteral reflux and persistence of the fistula with uncontrolled urinary leakage to the vagina

What should we do next?

2nd Surgery

1. Endoscopic approach with catheterisation of the three ureters and suprapubic catheter's replacement
2. Vaginal approach
Identification of the fistulous tract and performance of an inverted-U opening of the mucosa
Dissection of the fistula and identification of the normal, non-fibrotic tissue
Closure of the bladder neck hole

2nd Surgery

3. Martius flap
Longitudinal incision of the right major labia
Isolation of the fatty tissue filling the labia and transposition to the vagina
Anchoring over the former fistula
4. Closure of both incisions. Both suprapubic and urethral catheters are left in place. Ureteral catheters are removed

Follow-up



Removal of the urethral catheter in two weeks, and suprapubic catheter in one month after a new cystography: V-U reflux remains, but no urinary leakage is identified
Wounds healed correctly

Two weeks later, the patient reports urge incontinence & Antimuscarinic was prescribed

Follow-up



After 3 weeks of treatment, the patient has improved, with better continence.

Video-urodynamics:

- VU low grade reflux appears with a higher volume, better compliance
- No urinary leakage through the former fistula, but SUI

Follow-up



3 months later the patient refers SUI
Bulkamid agent was offered and implanted
The patient is satisfied with the outcome

