W20: Intrinsic Sphincteric Deficiency, Diagnosis and Management

Workshop Chair: Sherif Mourad, Egypt
07 October 2015 14:00 - 17:00

Start	End	Topic	Speakers
14:00	14:05	Introduction	Sherif Mourad
14:05	14:20	Pathophysiology of ISD	Patrick Woodman
14:20	14:35	Diagnostic Measures	Ervin Kocjancic
14:35	14:50	Urodynamics for ISD	Sherif Mourad
14:50	15:05	Conservative Management	Maura Seleme
15:05	15:20	Integral Theory Approach to ISD	Rogério de Fraga
15:20	15:30	Discussion	All
15:30	16:00	Break	None
16:00	16:15	Injectable Bulking Agents	Sherif Mourad
16:15	16:30	Inflatable Balloons # AS	Ervin Kocjancic
16:30	16:45	Slings for Female ISD	Patrick Woodman
16:45	17:00	Slings for Male ISD	Rogério de Fraga

Aims of course/workshop

The aims and objectives are: giving a broad review of the diagnostic tools and measures to help identify Intrinsic Sphincteric Deficiency and to evaluate the degree of sphincteric weakness. The audience will be able to understand better how to decide upon the suitable mode of treatment for such cases according to the etiology and whether there is a concomitant lesion or not.

Learning Objectives

1. To provide a range of knowledge about refractory overactive bladder syndrome.

2. Discussion about difficult cases of lower urinary tract reconstruction including vesicovaginal fistula.

3. Controversial of female urology and pelvic organ prolapse will be discussed.

Pathophysiology of Intrinsic Sphincteric Deficiency

Patrick J. Woodman, DO, MS; FACS, FACOOG

Associate Clinical Professor Obstetrics & Gynecology
Instructor, Female Pelvic Medicine & Reconstructive Surgery Fellowship
Department of Obstetrics & Gynecology
Indiana University School of Medicine
Associate Professor & Chairman, Specialty Care
Marian University College of Osteopathic Medicine

Introduction

- Intrinsic Sphincteric Deficiency (ISD) is significant problem in :
  - Planning of surgical procedure[1]
  - Certain populations
    - Elderly
    - Multiple previous or radical surgery
    - Radiation
  - Discussion of prognosis and post-operative expectations
    - Lower your surgical success rates
    - Lower your patients' satisfaction → lower reimbursement (?)
- No universally agreed upon definition, work-up
  - Urethral weakness or low resistance to bladder leakage

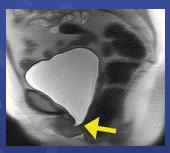
1. Davila, GW, et al. Pelvic floor dysfunction management practice patterns: a survey of members of the International Urogynecological Association. *Int Urogynecol J*, 2002;13:319-25.

Definition

- ICS (2002): "Urodynamic stress incontinence is noted during filling cystometry and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction... *Any delineation into categories such as… 'intrinsic sphincter deficiency' may be simplistic and arbitrary, and requires further research.*"
- ICS-IUGA (2010): "…"
- ICS 2011 (Bristol): "Terminology should permit improved definition of the sphincteric mechanism, allow individual patient characterization and serve as useful waypoints in treatment decisions."

1. Abrams P, et al. Standardization of terminology of lower... *Neurourol Urodynam*, 2002; 21:167-78.
2. Haylen BT, et al. An Urogynecologic Association (IUGA)/Internat… *Int Urogynecol J*, 2010; 21:5-26.
3. Smith PP, et al. Can we, and do we need to, define bladder neck hypermobility and intrinsic sphincteric deficiency?: ICI-RS 2011. *Neurourol Urodynam*, 2012;31:309-12.

Definitions[1]



- VLPP less than 60 cm H_2O
- MUCP less than 20/35 cm H_2O
- Type III Stress Incontinence
  - Fixed, "Lead-Pipe" or "Stove-pipe" Urethra
  - <20º mobility of UVJ on Valsalva
  - Proximal urethra open at rest
  - Proximal urethra no longer function as a "sphincter"
- "Open" bladder neck on cystoscopy, U/S or MRI
- "Beaking" or "Funnelling" of the bladder neck on VCUG

1. Murphy M, et al. Is the leak point pressure alone an accurate indicator of intrinsic sphincteric deficiency? *Int Urogynecol J*, 2004; 15:294-7.
2. Krissi H, et al. Maximum urethral closure pressure < 20cm H2O: Does it predict intrinsic sphincteric deficiency? *J Reprod Med*, 2005;50:824-6.
3. Macura KJ, et al. MR Imaging of the female urethra an supporting ligaments in assessment…Radiographic, 2006;26: 1135-49.

Causes of ISD

- Previous Pelvic Surgery[1] (75%)
  - Anti-incontinence surgery
  - Urethral diverticulectomy
  - Radical Hysterectomy
  - Urethrotomy
  - Resection or incision of vesical neck
- Nosocomial (13%)
- Pelvic Irradiation
- Neurologic Conditions
  - Myelodysplasia
  - Anterior spinal artery syndrome
  - Lumbosacral neurologic conditions
  - Shy-Drager syndrome
  - end-stage Diabetes
- Aging & Hypoestrogenic States

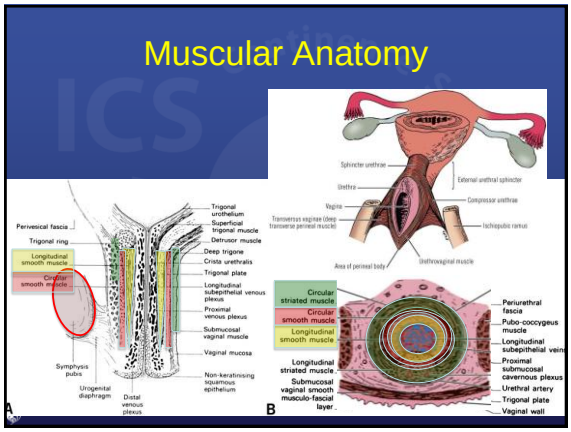
1. McGuire EJ, Lytton B. Pubovaginal sling procedure for stress incontinence. J Urol, 1978; 119:82-84.
2. Various.

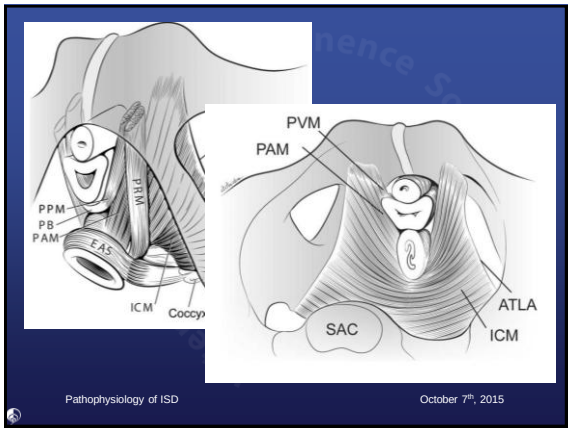
Components of Urethral "Health"

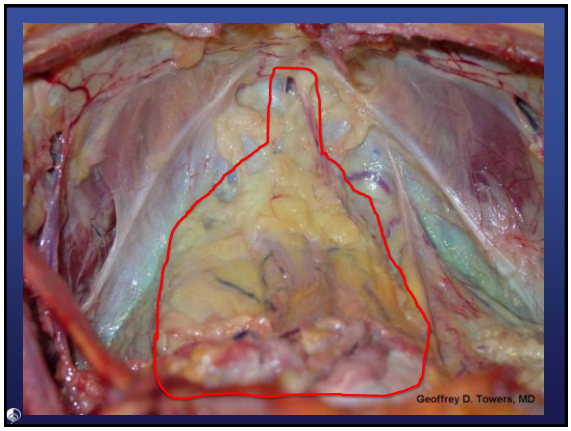
- Intact fascial and muscular support
- Good blood supply
- Good nervous system supply

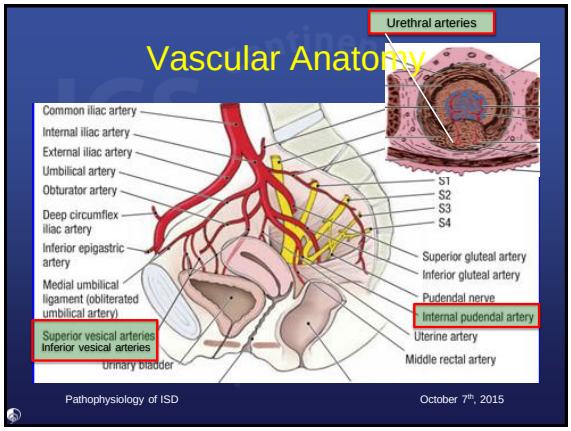
So…

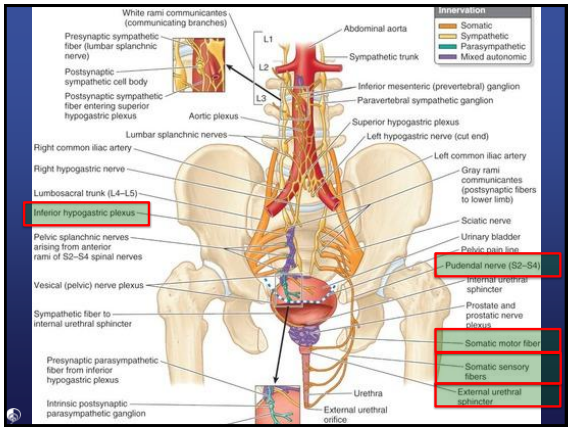
- Any disruption of these features may result in decrease in functional capacity of the urethra

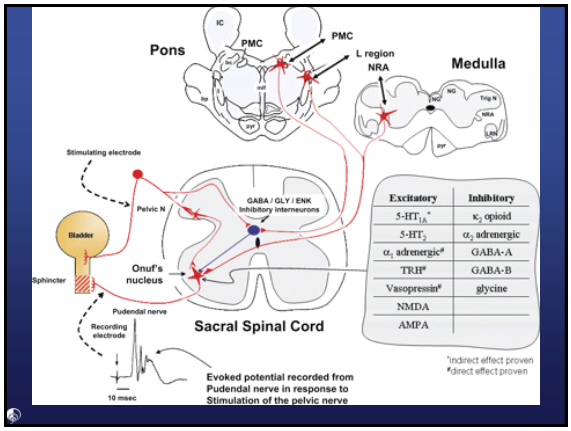

Muscular Anatomy
Perivesical fascia
Trigonal ring
Longitudinal smooth muscle
Circular smooth muscle
Trigonal urothelium
Superficial trigonal muscle
Detrusor muscle
Deep trigone
Crista urethralis
Trigonal plate
Longitudinal subepithelial venous plexus
Proximal venous plexus
Submucosal vaginal muscle
Vaginal mucosa
Non-keratinising squamous epithelium
Symphysis pubis
Urogenital diaphragm
Distal venous plexus
A
Sphincter urethrae
Urethra
Vagina
Transversus vaginae (deep transverse perineal muscle)
Area of perineal body
External urethral sphincter
Compressor urethrae
Ischiopubic ramus
Urethrovaginal muscle
Circular striated muscle
Circular smooth muscle
Longitudinal smooth muscle
Longitudinal striated muscle
Submucosal vaginal smooth musculo-fascial layer
Periurethral fascia
Pubo-coccygeus muscle
Longitudinal subepithelial vein
Proximal submucosal cavernous plexus
Urethral artery
Trigonal plate
Vaginal wall
B


PVM
PAM
PRM
PPM
PB
PAM
EAS
ICM
Coccyx
SAC
ATLA
ICM
Pathophysiology of ISD
October 7th, 2015


Geoffrey D. Towers, MD

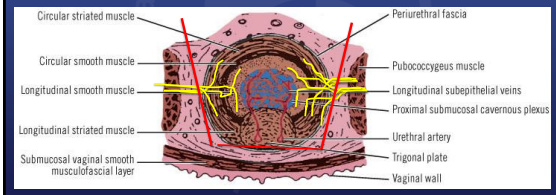

Urethral arteries
Vascular Anatomy
Common iliac artery
Internal iliac artery
External iliac artery
Umbilical artery
Obturator artery
Deep circumflex iliac artery
Inferior epigastric artery
Medial umbilical ligament (obliterated umbilical artery)
Superior vesical arteries
Inferior vesical arteries
Urinary bladder
S1
S2
S3
S4
Superior gluteal artery
Inferior gluteal artery
Pudendal nerve
Internal pudendal artery
Uterine artery
Middle rectal artery
Pathophysiology of ISD
October 7th, 2015


White rami communicantes (communicating branches)
Presynaptic sympathetic fiber (lumbar splanchnic nerve)
Postsynaptic sympathetic cell body
Postsynaptic sympathetic fiber entering superior hypogastric plexus
Aortic plexus
Lumbar splanchnic nerves
Right common iliac artery
Right hypogastric nerve
Lumbosacral trunk (L4–L5)
Inferior hypogastric plexus
Pelvic splanchnic nerves arising from anterior rami of S2–S4 spinal nerves
Vesical (pelvic) nerve plexus
Sympathetic fiber to internal urethral sphincter
Presynaptic parasympathetic fiber from inferior hypogastric plexus
Intrinsic postsynaptic parasympathetic ganglion
L1
L2
L3
Abdominal aorta
Sympathetic trunk
Inferior mesenteric (prevertebral) ganglion
Paravertebral sympathetic ganglion
Superior hypogastric plexus
Left hypogastric nerve (cut end)
Left common iliac artery
Gray rami communicantes (postsynaptic fibers to lower limb)
Sciatic nerve
Urinary bladder
Pelvic pain line
Pudendal nerve (S2–S4)
Internal urethral sphincter
Prostate and prostatic nerve plexus
Somatic motor fiber
Somatic sensory fibers
External urethral sphincter
Urethra
External urethral orifice
Innervation
Somatic
Sympathetic
Parasympathetic
Mixed autonomic


Pons
IC
PMC
PMC
L region NRA
Medulla
Stimulating electrode
Pelvic N
GABA / GLY / ENK Inhibitory interneurons
Bladder
Sphincter
Onuf's nucleus
Pudendal nerve
Recording electrode
Sacral Spinal Cord
10 msec
Evoked potential recorded from Pudendal nerve in response to Stimulation of the pelvic nerve
Excitatory
Inhibitory
5-HT1A*
κ2 opioid
5-HT2
α2 adrenergic
α1 adrenergic#
GABA-A
TRH#
GABA-B
Vasopressin#
glycine
NMDA
AMPA
*indirect effect proven
#direct effect proven

The Verdict?

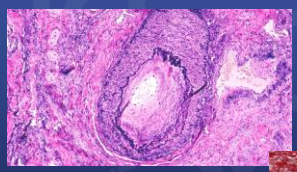
- Anything that damages lateral urethra or supporting tissue
- Anything that restricts or interrupts blood flow caudally
- Anything that stretches the nerves repeatedly



Components of Urethral "Health"

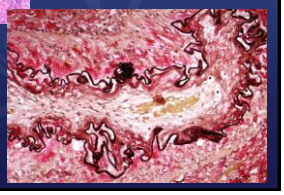
- Intact fascial and muscular support
  - Previous or Radical surgery
  - Birth Trauma
  - Collective stretch, pressure & trauma aging
- Good blood supply
  - Previous surgery
  - Birth Trauma
  - Radiation*
- Good nervous system supply
  - Previous surgery
  - Birth trauma leading to neuropathy
  - Neuropathy due to NS disease, progressive (ie. DM, aging)

Radiation Cystitis / Vasculitis



Endarteritis obliterans
With fibrous intimal thickening of arterial wall due to radiation

Contorted internal elastic membrane artery due to radiation



Animal Model of ISD

- In search of animal model to manipulate in ISD research, a group at the University of Pittsburgh attempted to use a common bladder surrogate for urodynamics, the Sprague-Dawley rat.
- Cauterization of tissues lateral to the mid-urethra decreased LPP without affecting bladder function.
- This electrocauterization model produced low LPPs that, after 2 weeks, were maintained for up to 16 weeks. Histology suggests that damage to striated muscle and nerves might have contributed to the change in LPP in this model for ISD.

1. Chermansky, et al. A model of intrinsic sphincteric deficiency in the rat: electrocauterization. *Neurourol Urodynam*, 2004; 23:166-71.

Questions?

References

- Davila, GW, et al. Pelvic floor dysfunction management practice patterns: a survey of members of the International Urogynecological Association. *Int Urogynecol J*, 2002;13:319-25.
- Abrams P, et al. Standardization of terminology of lower urinary tract function. *Neurourol Urodynam*, 2002; 21:167-78.
- Haylen BT, et al. An Urogynecologic Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Int Urogynecol J*, 2010; 21:5-26.
- Smith PP, et al. Can we, and do we need to, define bladder neck hypermobility and intrinsic sphincteric deficiency?: ICI-RS 2011. *Neurourol Urodynam*, 2012;31:309-12.
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References

- Chermansky, et al. A model of intrinsic sphincteric deficiency in the rat: electrocauterization. *Neurourol Urodynam*, 2004; 23:166-71.
- Park, et al. Comparison of cystographic findings of intrinsic sphincteric deficiency with urethral hypermobility causing urinary incontinence. *Urol Int* 2007;78:116–120.

Adjustable Continence Therapy (ACT)

Ervin KOCJANCIC MD[1];

Intrinsic Sphincter Deficiency represents a challenge in the treatment of Urodynamic Stress Urinary Incontinence (SUI). Diagnosis of Intrinsic Sphincter Deficiency (ISD) should address urethral elements, including pudendal innervation; striated sphincter mass and function; urethral smooth muscle, mucosa and submucosal cushions. Treatment should be focused on increasing urethral resistance. In patients with severe ISD creating an adequate intrinsic urethral resistance might be more beneficial than the correction of urethral hypermobility, which in itself may not result in stress urinary incontinence. Even if corrective surgery provides initial improvement; when factors affecting continence change, eg weight fluctuation and estrogen changes, there may be a need for secondary or even tertiary surgical intervention over time. Indeed, if no benefit was first achieved, a further alternative surgical option should ideally be considered. Given these parameters, we decided to assess the safety and efficacy of an implantable device, the Adjustable Continence Therapy (ACT®) which could be titrated over time as required in a group of women with recurrent stress urinary incontinence.

The ACT device:

The Adjustable Continence Therapy was developed by Uromedica, Inc. (Plymouth, MN). The device consists of two silicone elastomer balloons on each side of the proximal urethra with each connected via a conduit to a titanium port buried superficially in the fatty tissue of the labia majora . Placement of the balloons at either side of the bladder neck is achieved using two specially designed reusable blunt and sharp trocars and a U shaped cannula. There are 4 different device lengths; 6, 7, 8 and 9cm, which equates to the distance from bladder neck to skin with an additional 3-4cm for burial of the port.

Each balloon has a recommended maximum volume of 8cc. At any time post operatively, each balloon can be volumetrically increased or decreased by percutaneous injection through the port using a 23G Huber non coring needle in order to achieve optimum continence.

Surgical Procedure:

The procedure can be performed using general, regional or local anaesthesia, based on patients' needs and physician discretion. The patient is placed in standard lithotomy position and the bladder is filled with 100 ml of dilute contrast through a 16Fr Foley catheter. The balloon of the catheter is filled with 10cc of pure contrast to enable fluoroscopic visualisation of the bladder neck. Bilateral 1cm small incisions are made in the Labial Sulcus at the level of vaginal introitus below the urethral meatus. Using fluoroscopic guidance and digital vaginal palpation, a sharp trocar loadedin a U shaped cannula is directed through the incision, perforating the pelvic diaphragm towards the bladder neck parallel to the proximal urethra anterior to the vagina. A blunt trocar may be employed to reduce the risk of urethral or bladder perforation. Once the tip of the trocar is at the bladder neck, the trocar is withdrawn and incremental markers along its shaft used to measure the required length of device to be implanted. The trocar is removed completely leaving the U shaped cannula in place. The ACT device is then inserted into the U shaped cannula using a pre loaded guide wire as a pusher. Once the correct position is confirmed on the image intensification screen, the balloon is filled with 1-1.5cc of isotonic contrast solution to stabilise its position, and the process is repeated on the contralateral side. The guide wire and U shaped cannula are removed after a fluoroscopic check. The ports are buried in the labia majora in a superior ventral position and the incision closed in two layers. A 16Fr urethral catheter remains in situ overnight as a precautionary measure. At our institution, we soak the devices in an

antibiotic solution before insertion and prescribe preoperative antibiotics consisting of 160mg Gentamycin and a post operative course of oral Ciprofloxacin 500mg once a day for 5 days as a prophylactic measure. First balloon adjustments may be conducted at 4-6 weeks to allow for creation of a pseudo capsule to occur around the balloon. Subsequent increments should be spaced with a minimum of 4-week intervals and continued until optimum continence has been achieved. A maximum of 1ml of isotonic solution should be inflated per balloon at each visit to avoid splitting of the pseudo capsule and increasing the risk of possible balloon erosion and migration.

From May 2001 until May 2006, 57 patients (mean age 62.59 years, (range 18-86 years) were enrolled, implanted with the Adjustable Continence Therapy device and evaluated post operatively with a minimum of 12 months follow up. A number of patients were treated prior to this date but not included in this evaluation due to the use of an earlier generation device, and the learning curve required for such an innovative procedure. Mean follow up was 72 months (range 12-84) with a median follow up of 58 months All patients had undergone at least one previous pelvic surgery. Twenty seven patients had undergone one or more anti incontinence surgical procedures including Burch colposuspension; injectable bulking agents (Collagen, Macroplastique, Zuidex), Pubo Vaginal slings or tensionless tapes (TVT, TOT). No statistically significant differences were found between the different groups of each previous intervention. Six patients had also previously undergone prolapse repair. Nineteen (33.3%) patients had coexistent grade I prolapse which did not require concomitant surgical intervention. Mean duration of incontinence since failure of previous surgical treatment was 1.74 years (range 1-5 years). Twenty nine patients (50.9%) were obese (a BMI of ≥ 35) at time of surgery .
Operative time was 20.3 mins (range 10-30 mins) with a blood loss of <50mls in all cases. Fourteen (24.6)% patients underwent implantation utilising local anaesthesia comprising

of 10mls per side 4% Bupivacaine and 1% lidocaine; 37 (64.9)% required spinal anaesthesia whilst 5 (8.8%) underwent general anaesthesia. Screening time for verification of balloon positioning using image intensification was 2.03 mins (range 1-3.6 mins

devices. Intra operatively, bladder perforations occurred in 2 patients, visualised by leakage of contrast from the bladder through the cannula and on fluoroscopic image. On each occasion, the trocar and cannula were removed, repositioned via a more lateral access and balloons inserted. In these 2 patients, the urethral catheter was retained for 48 hours. No further post operative sequale resulted. All other patients were able to void following catheter removal within 24 hours with no post void residual detectable on ultrasound. No postoperative analgesia was required and all patients were discharged within 24 hours of surgery.

There was a statistically significant improvement in Quality of Life based on I-QoL from 27.2 at baseline at each of the post operative evaluation points ($p=<0.001$). Pad count significantly decreased from 5.6 at baseline to 1.24 at 12 months which was maintained over time (Table 1). Patient self perception reported on Visual Analogue Score improved by 50% within 3 months and continued to improve over time as further adjustments improved continence

Postoperative adjustments were performed if incontinence persisted or recurred, or until optimum continence had been achieved. Eighteen patients (31.6%) did not require any postoperative adjustments. The remainder (68.4%) required singular or multiple adjustments range (1 -11) during the course of 6 years demonstrating the ability to titrate the ACT balloons long term.

Postoperative Urodynamics performed at 12 months was available on 30 patients and showed a statistically significant increase in VLPP from a mean value at base line of 48.18 cm H_2O +/- 24.38 to 86.0 cm H_2O +/-21.44. ($p<0.01$). However, there were no

statistically significant changes observed in the Maximum Urethral Closure Pressure following surgery (47.39 cm H2O +/- 24.35 at baseline compared to 51.06 +/- 19.31 post operatively).

Complications.

Labial haematomas were observed in 3 pre menopausal patients within 24 hours of implantation. The haematomas spontaneously reabsorbed without intervention and presumably resulted from inadvertent damage by the trocar to the vestibular bulb[6]. On questioning, none of these patients reported any deterioration in sexual function post operatively.

Postoperative complications necessitating device removal included migration seen in 8/57 patients (14.1%) and urethral erosion in 2/57 (3.5%) patients. Additionally, 5 balloons were explanted due to device failure. Of these, 1 balloon containing 5.5cc deflated after one month. The other two balloons failed at 3 years, one containing 6cc and the other with 2cc. In total, 15/114 balloons (13.2%) were removed in 12 patients with only 3 patients requiring bilateral removal. Removal was performed in the outpatient office utilising topical anaesthesia only. A small incision was made over the port, the port grasped with forceps, the balloon deflated and the device was easily retrieved using a simple grasping technique. Five replacement balloons were implanted in in 5 patients 6 weeks after removal. Two out of 5 patients became dry (no pads), 2 were significantly improved (< 1 pad a day) and 1 was unchanged.

Two (3.5%) patients had portal erosions occurring within a few days of implantation resulting from placement of the port directly inferior to the incision. The ports were cleaned with antibiotic flush, repositioned and the incision was resutured without any further problem. Had there been any question of infection associated with the erosion, the balloons would have been explanted and new balloons reimplanted at a later date.

The reported positive outcomes of tensionless tapes for the treatment of female stress urinary incontinence[14] has given rise to a larger number of patients undergoing this procedure performed by an increasing number of surgeons across a number of specialities. Recent literature reviews suggest a dichotomy between patient satisfaction and dry rates with one study comparing a number of different commercially available slings indicating that dry rates range between 36.1% and 45.2%. This would suggest that there is a proportion of women who may require further intervention for treatment of their persistent incontinence, and for whom an alternative treatment option should be offered. Bulking agents provide relatively non invasive methods of treatment of stress urinary incontinence. Short term data suggests a cure rate of 59% and additional improvement rate of 16% at 12 months. Longer term results suggest a greater decline in success rates than retropubic suspension and sling procedures. Although the exact mechanism of placement of periurethral injectables has not been defined, an obstructive effect has been described which supports the entire wall, thereby increasing urethral resistance,albeit in the short tems. In our experience ACT results have not declined over time. Figure 2 demonstrates the different effects created. There may be a number of reasons why the ACT appears to be of benefit. Primarily, because continence is not a static state in women whose anatomy may alter due to weight fluctuation, estrogen changes, aging and unassociated surgery, the opportunity to post operatively regulate the urethral resistance is very beneficial to patient and physician. Secondly, 47.4% of the patients in this group had failed previous anti incontinence surgery thus reducing the likelihood of success of further surgery; and thirdly the ability to perform a titratable procedure which can easily be reversed without sequelae if necessary is very attractive and contrasts to the removal of other prosthetic devices implanted for the treatment of SUI.

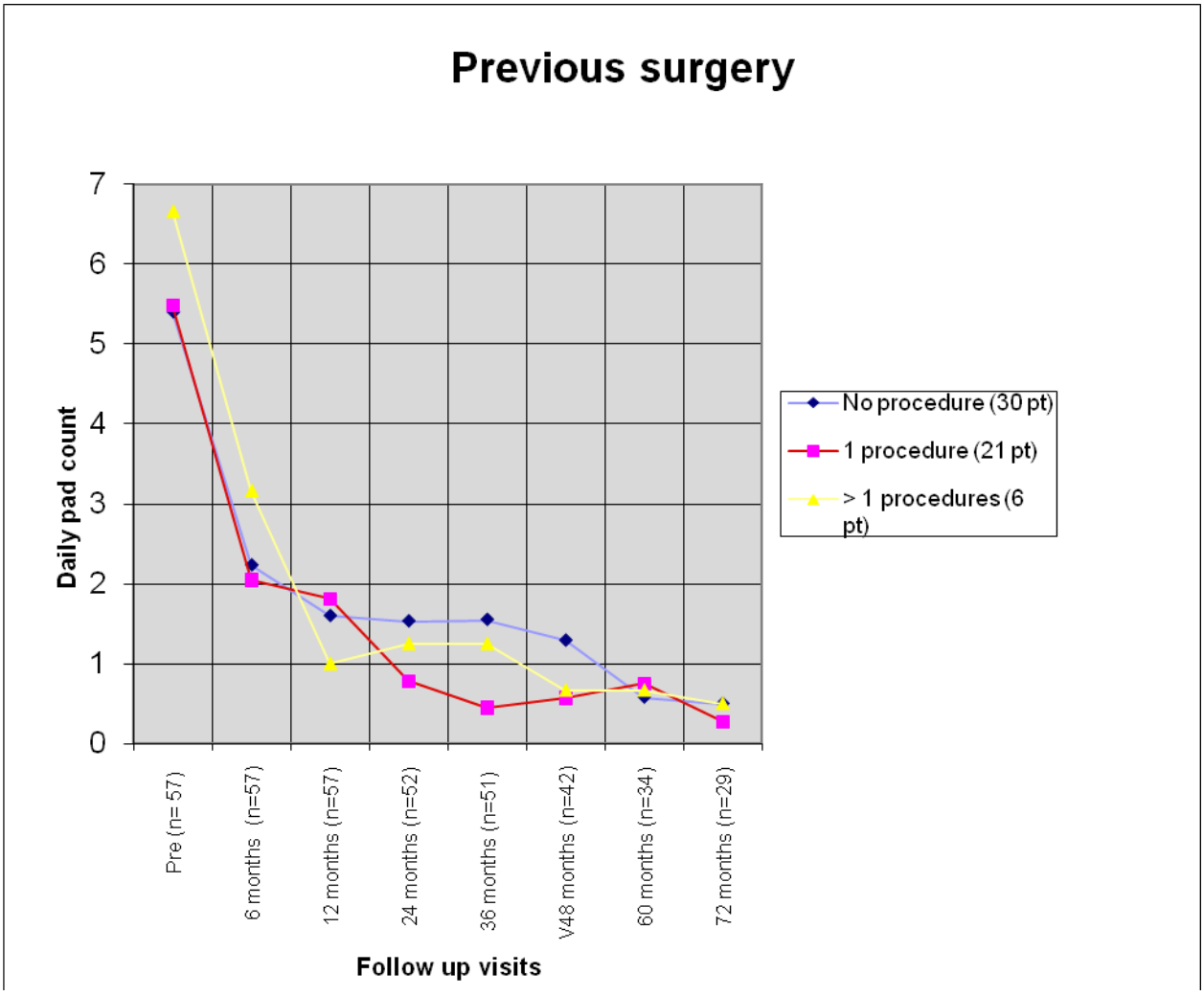
Conclusion:

Dealing with failed incontinence surgery and recurrent stress urinary incontinence has enormous social implications for the patient and represents a big surgical challenge for the physician.

Whilst our findings were encouraging particularly in terms of patients subjective outcomes, our study was limited in terms of the numbers of patients treated over the time period; the modification in procedural technique and the lack of more objective data. There is a need to conduct further study to establish the actual mechanism of action of the ACT in previous surgical failures, and to more closely monitor objective outcomes in the light of procedural and post operative management. We will continue to follow up our patients and await the results of other international studies to confirm whether these promising results can be replicated.

List of Figures:

List of Tables:


Previous surgery
Daily pad count
0
1
2
3
4
5
6
7
Pre (n= 57)
6 months (n=57)
12 months (n=57)
24 months (n=52)
36 months (n=51)
V48 months (n=42)
60 months (n=34)
72 months (n=29)
Follow up visits
No procedure (30 pt)
1 procedure (21 pt)
> 1 procedures (6 pt)

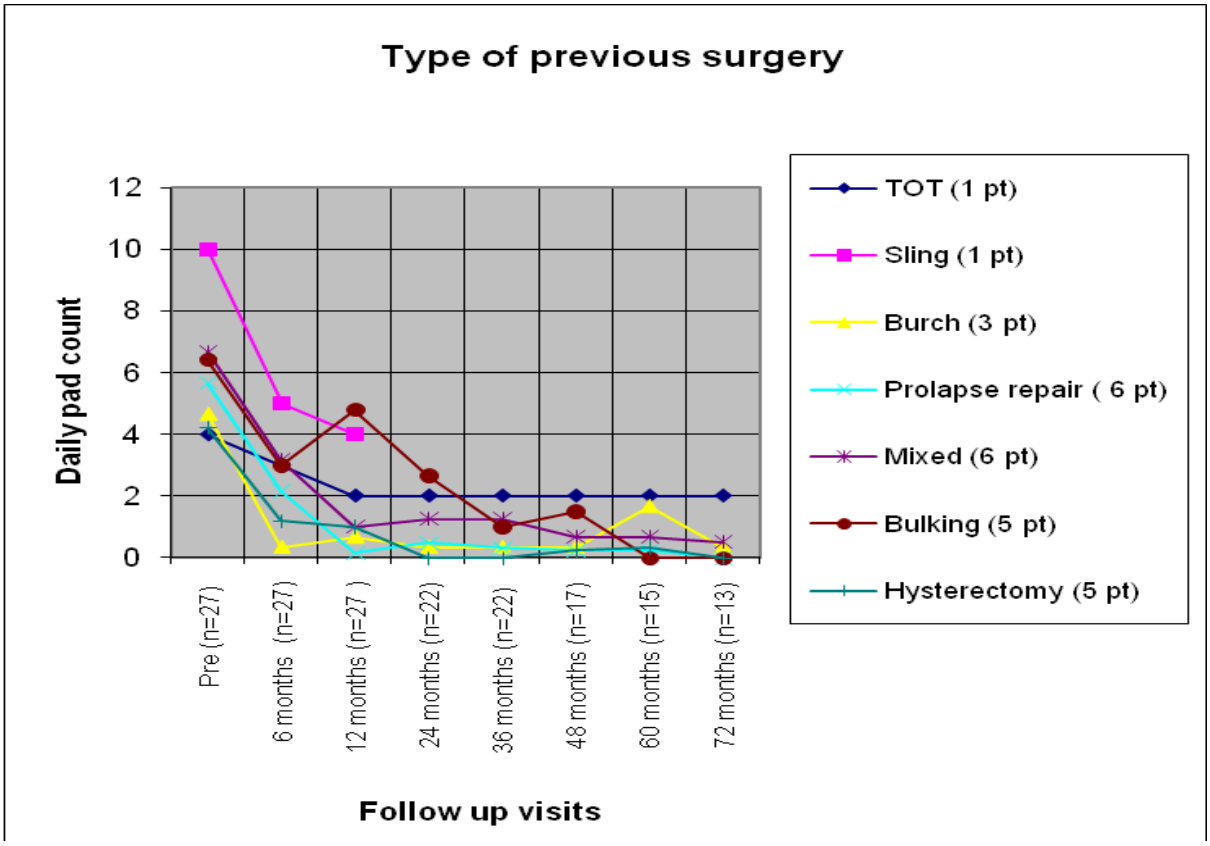

Type of previous surgery
Daily pad count
0
2
4
6
8
10
12
Pre (n=27)
6 months (n=27)
12 months (n=27)
24 months (n=22)
36 months (n=22)
48 months (n=17)
60 months (n=15)
72 months (n=13)
Follow up visits
TOT (1 pt)
Sling (1 pt)
Burch (3 pt)
Prolapse repair (6 pt)
Mixed (6 pt)
Bulking (5 pt)
Hysterectomy (5 pt)

Table 1.

	Baseline (n=57)	12 Month (n=52)	24 Month (n=52)	36 Month (n=51)	48 Month (n=41)	60 Month (n=34)	72 Month (n=29)
IQo L	27.2 (SD 15)	65.9 (SD 17)	70.4 (SD 16)	70.4 (SD 16)	76.1 (SD 17)	78.4 (SD 17)	78.6 (SD 18)
Pad Usage	5.6 (SD 2.28)	1.61 (SD 2.10)	1.24 (SD 1.45)	1.14 (SD 1.84)	1 (SD 1.72)	0.65 (SD 1.10)	0.41 (SD 0.78)
PGI		2.33 (SD 1.04)	1.98 (SD 0.92)	1.78 (SD 0.86)	1.88 (SD 1.29)	1.76 (SD 1.0)	1.62 (SD 0.94)

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Bulking Agents in Intrinsic Sphincteric Deficiency

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Professor of Urology, Ain Shams University, Cairo
President of Pan Arab Continence Society

Urinary incontinence following radical prostatectomy has a reported incidence of 5 to 12% [1]. Post-prostatectomy incontinence and other forms of male urinary incontinence have a significantly negative impact on Quality of Life. Urethral incompetence usually requires interventional therapy. Treatment of ISD in men after radical prostatectomy is a technically challenging procedure.

Surgical augmentation of intraurethral pressure includes slings and implants, such as artificial sphincters or periurethral bulking agents. The latter involves injection of a bulking agent at the area of the bladder neck and proximal urethra to enhance urethral resistance to urine flow by approximating the urethral mucosa.

The artificial urinary sphincter is a known effective solution in managing ISD. However, it carries the risk of disturbed bladder compliance and function to a degree that may affect the upper urinary tract. Moreover, there is the possibility of urethral erosion, especially in patients with a history of difficult pelvic operation and/or significant blood loss.

Complications such as infections and mechanical problems, requiring revisions are additional disadvantages. The sling operation is proving to be technically difficult in males, especially after radical pelvic surgery. Extensive fibrosis associated with male incontinence after surgery or trauma, and pelvic irradiation after radical prostatectomy further complicates the procedure, therefore, it is rarely performed.

Alternatively, injection or placement of a bulking agent has the advantages of being easily performed as an outpatient procedure because of the use of local anesthesia and a low complication rate, which makes it suitable especially in the elderly incontinent population.

Stress Urinary Incontinence (SUI), which is the involuntary loss of urine during stressful activities, develops in 10 to 30% of women of all ages [2]. In women, two types of sphincter abnormality are diagnosed,

bladder neck hypermobility and Intrinsic Sphincter Deficiency (ISD).

ISD may account for a higher failure rate of surgical procedures performed to treat Stress Urinary Incontinence (SUI) due to ISD.

Historically, slings have been the procedure of choice, however this procedure may increase and/or produce a significant incidence of urinary retention. Peri-urethral or trans-urethral bulking agents, which are less invasive, have been used to treat ISD for many years and avoid recurrent surgical procedures. Bulking agents are able to coapt the urethral mucosa and as a consequence produce higher resistance to increased abdominal pressure.

Injection of bulking agents into the urethral wall has been attempted with a variety of substances. The materials used to date have a wide range of success rates. The following are the so far studied agents:

Resorbable

Animal Origin - Bovine Glutaraldehyde Cross Linked Collagen
Human Origin - Fat
Chondrocytes (cell cultured, Reprogenesis Inc.)

Non-resorbable

Polytetrafluoroethylene (Teflon)
Silicone microimplants (Macroplastique)
Carbon particles (Durasphere)
Dextranomer and stabilized Hyaluronic acid (Zuidex)
Polyacrilamide Hydrogel (Aquamid)
Ethylene Vinyl Alcohol in Dimethyl Sulfoxide (Tegress)
Inflatable Silicon Balloons (ACT & ProACT)

Good results were reported with the use of polytetrafluoroethylene (PTFE) in the 1960s and 1970s [3]. PTFE (Teflon) paste consists of particles that vary in size from 1 to 100 μm, with 90% smaller than 40 μm, resulting in distant migration and granuloma formation [4]. The long-term results have been disappointing, Kiilholma and Mäkinen reported that only 18% of patients were continent 5 years after polytetrafluoroethylene injection [5].

Collagen (Contigen) is expensive and may cause allergic reactions in around 3% of patients. In most studies incontinence returned gradually with a median continence duration of 23 months [6]. Repeat injections are necessary to achieve sustained continence, which increases the cost.

The main disadvantages of using autologous fat relate to the variability of resorbtion as well as repeated injections. At 1-year follow-up only 28% of patients are cured with this therapy [7].

Numerous reports on PDMS for the treatment of female SUI have been published [8]. Encouraging results are reported in these studies, including 1 with over 5-year follow-up.

The Dextranomer is a type of sugar molecule that has been used for a number of years in the treatment of wounds. Hyaluronic acid is a naturally occurring substance produced by the body to firm tissues and lubricate joints. The hyaluronic acid used in ZUIDEX is synthetically produced. Neither of the ingredients in ZUIDEX gel is derived from animals, thus avoiding rejection risks that exist with animal-based products.

Aquamid is a Polyacrilamide hydrogel which is an atoxic, non-resorbable sterile watery gel. It is homogeneous, stable, not biodegradable, and has tissue-like viscosity and elasticity [9].

Tegress is Ethylene Vinyl Alcohol copolymer (EVOH) dissolved in Dimethyl Sulfoxide (DMSO) carrier. Upon injection, the DMSO carrier rapidly dissipates from the EVOH copolymer, forming a ccohosive, spongy mass that serves to bulk surrounding tissue. Long term results are not available.

The ACT Device consists of two small implantable balloons. During a short procedure, the balloons are surgically placed under the skin next to the bladder. ACT Therapy has been used in more than 1,000 women in Europe, Canada and Australia. It is currently being studied in the United States in a Food and Drug Administration clinical study. Results of a previous study suggest that after a mean follow-up of 36 months, 62% of patients were dry and another 16% were much improved [10].

The use of bulking agents is a good, safe and effective alternative for the treatment of intrinsic sphincter deficiency in male and female patients. Although having lower efficacy than other surgical procedures, represent an alternative minimally invasive approach and may be particularly suited to those who have recurrent urodynamic stress incontinence following previous surgery.

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ICS 2015 Montreal

W20 Intrinsic Sphincteric Deficiency, Diagnosis and Management
Wednesday 7th October 2015
14:00-17:00

Conservative Management and Functional Training

Maura Seleme PhD, PT

introduction

- Maura Regina Seleme, PhD - PT
- Pelvic Physiotherapist - Brazil, France and The Netherlands
- Coordinator and teacher Specialization in Pelvic Floor Dysfunctions for physiotherapists at Faculty Inspirar – since 2011
- Specialized in Urogynecology, Dysfunction ano-rectal and Sexology – France
- DU in Urodynamics - University of Medicine Xavier Bichat in the School of Medicine – Sorbone – France
- IUGA ambassador SIG Pelvic Floor Rehabilitation for Brazil - since 2009.
- Director abafi-BRASIL and abafi-HOLLAND www.abafi.com.br and www.abafiholland.com

intrinsic sphincteric deficiency

- type III stress urinary incontinence (SUI) is generally defined as a condition that involves intrinsic sphincter deficiency (ISD). Although the clinical parameters for ISD are loosely defined as a Valsalva leak-point pressure <60 cmH2O or a maximal urethral closure pressure <20 cmH2O, consensus is lacking.

Treatment options for intrinsic sphincter deficiency.
Nat Rev Urol. 2012 Nov;9(11):638-51. doi: 10.1038/nrurol.2012.177. Epub 2012 Oct 2.
Shah SM, Gaunay GS.

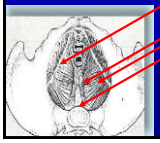
intrinsic sphincteric deficiency and conservative management ?

proper diagnostic tools SUI

type I SUI
dysfunction PF: PFMT + - no awareness PF: Knack
- awareness PF: BF/ES +
+ function compromised RES/TL: PFMT/EX +
+ general obstructing factors: PFMT/EX/info +/-

type II SUI
yes/no dysfunction PF: PFMT +/-

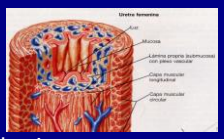
type III SUI
no dysfunction PF:
PFMT -, only compensation!!



Luqinbuehl 2014

intrinsic closure mechanism

- continence
  - intrinsic urethral closing mechanism:
    - tunica mucosa
    - tunica spongiosa
    - tunica muscularis

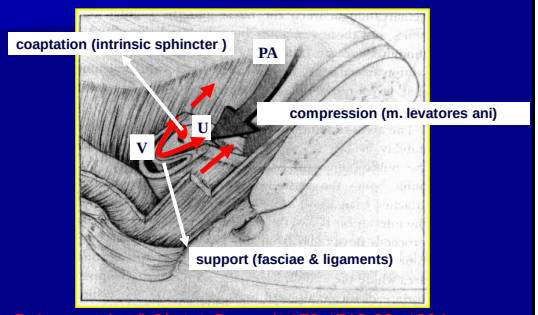


  - supporting extrinsic mechanism
    - function pelvic floor

Guidelines on Stress Urinary Incontinence -Royal Dutch Society for Physiotherapy (KNGF) – 2011

structures of urethral support

PROPERTIES FEMALE URINARY SPHINCTER



DeLancey, Am J Obstet Gynecol, 170:1713-23, 1994

stress continence control system

- urethral support system pelvic floor
  - levator ani muscles & endopelvic fascia
  - strong & fast PFM contraction clamp urethra, increasing urethral pressure to prevent UI during abrupt increase intra-abd pressure **DeLancey 1988a**

40%

  - against pubic symphysis, creating mechanical pressure rise DeLancey 1988b
  - stiffness

aims PFMT → SUI

- ↑ PFM strength and/or timing PFM contraction *ICI 2013*
- *Conditions:* require repetitive active exercise *Hall et al 1999*
- ↑ PFM endurance *Dumoulin et al 2011*
- improve extrinsic cm *Ashton-Miller et al 2001*
- positive effect on ucm *Rud et al 1980*
- increase strength peri- and paraurethral muscles *Bø 1995, Berghmans et al 1998, Hay-Smith et al 2001*

assessment: history taking

associated pathology - diabetes, obesity,lower back pain,SDT - sexually transmitted disease, depression, neurological disease, medications

urogynecology -age of sexual initiation,infection, menopause)

anorectal - constipation, hemorrhoids, anal incontinence

surgery? - hysterectomy. prolapses

obstetric history - episiotomy; vaginal delivery, baby weight

urinary behavior

Frequency:

day:_____ night:_____

( ) dysuria ( ) abdominal strength

( ) difficulty to control urine

( ) urgency ( ) pain

( ) burning feeling

urinary incontinence

Start Date:_____

Incontinence ( ) daytime
( ) nighttime

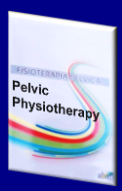
With some effort ( ) urgently ( )

which kind of urinary incontinence ?

What is wrong with you ?? What do you expect from me?

visual analog scale local, personal and social

physical examination shown by movies produced by abafi-HOLLAND 2014



pelvic floor dysfunction should be classified according to "ICS Standartisation"

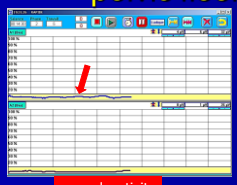
By palpation of the pelvic floor muscles, the contraction and relaxation are qualified:

- Voluntary contraction can be absent, weak, normal or strong, and voluntary relaxation can be absent, partial or complete.
- Involuntary contraction and relaxation is absent or present.
- Based on these signs, pelvic floor muscles can be classified as follows:

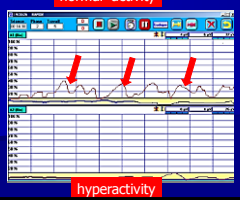
• non-contracting pelvic floor
• non-relaxing pelvic floor
• non-contracting, non-relaxing pelvic floor.

Messelink, Benson and Berghmans ICS Standartisation

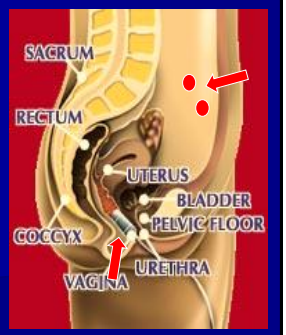
pelvic floor hyperactivity



normal activity



hyperactivity



diagnostic process in physical therapy

CONCLUSION condition PFMF

Overactive	Normal	Coordination disorder	underactive	Non functional

Guidelines on Stress Urinary Incontinence - Royal Dutch Society for Physical Therapy (KNGF) – 2011

working mechanisms PT

- conscious contraction before & during ↑abdominal pressure & continuation contractions as behavior modification to prevent descent PF, the KNACK !!!

Miller 1998

key-word timing

- fast feed forward loop!!!!!!! Pre-contraction!!!!
- functional training!!!!!!

key-word strength

- building up "stiffness" & structural support PF !!!

dose-respons, dosage exercises i.e., frequency, intensity, duration, kind of exercise, motivation, adherence, protocol

Ashton-Miller 2001; Bø 2004

the 4 Fs

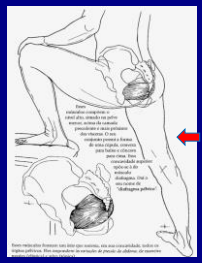
– F = find	▪ Find the pelvic floor
– F = feel	▪ Feel the pelvic floor
– F = force	▪ Force the pelvic floor
– F = follow through.....	▪ Follow trough, keep exercising

find information !

- information anatomy & PFM

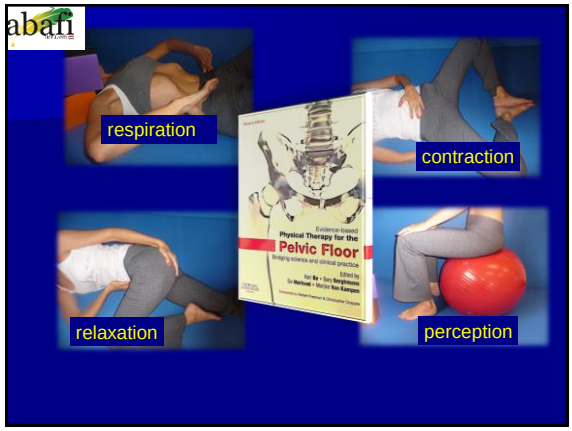
talking about perineum !!!!!

find and feel perineum



how to contract the pelvic floor Imagine that you are tightening your anus as you squeeze the ball in your hand

how to contract the pelvic floor

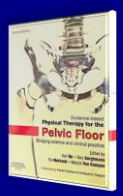


use evidence-based program!!!!!

PFM training – SUI level 1, grade A ICI 2012

Program based on evidence Bø 1990,1999, DiNubile 1991, Mørkved 2002, 2003 , Bø 2004,Bø & Berghmans 2007

- 8-12 MAXIMAL contractions– inward & upward
- 6-8s contraction & relaxation
- 4 fast contractions– 8s of relaxation
- 3 sustained contractions 20s



invasive techniques

to show before the examination and first treatment an anatomical board with the muscles and intern organs localization

Talking about perineum !!!!!

manual therapy

myofacial Training Effects:
- relaxation
- enhanced flexibility
- increase of blood circulation
- pain reduction
- sensory perception
- scar tissue manipulation
- reduction of fibrotic adhensions
- reduction of hypertonicity

GRIESE, Maurenne. Preparing for Birth: Perineal Massage. 2000

CASSAR, Mario-Paul. Manual de massagem terapêutica. São Paulo: Manole, 2001.

BECK-GALLAGHER, Krista. Episiotomy – Is it Necessary? 2000.

vaginal cones

Theory: the cone weight intend to motivate the training so that the women contract firmly with progressive weight.

Use Period (15-20 min) adequate

It can cause ↓ blood supplement↓ O2 consumption, fatigue & muscle sore

Synergist contractions instead of MAPs contractions

Refined protocol if used as BF

Arvonen et al 2001,
Plevnik 1985,
Hay-Smith et al 2001,
ICI 2005

eletrostimulation and SUI

- lack of consistency ES protocols
- insufficient evidence ES > no or placebo treatment
- conclusive evidence is lacking, but PFMT > ES
- insufficient evidence to determine if ES >
- no extra benefit in adding ES to PFMT
- need for more basic research working mechanism ES
- need to determine best ES and outcome measures

ICI 2012

PT indications SUI → biofeedback

UI & dysfunction PF: without awareness
objective biofeedback
restoration awareness PF

* if awareness restored → only PFMT

Berghmans et al 1998

kind of patient population who might benefit from BF

- weak pfm
- unaware of pfm
- needs motivation in the exercises
- women unable to contract their pelvic floor muscles voluntarily.
- patients with structural sphincter defects that can't undergone surgery.

Buckens, T., Latasse, R., Dramaix, N., Wollast, E. (1985). Episiotomy and third degree tears. British Journal of Obstetrics and Gynaecology, 92: 820-3). Laycock J.,Haslam J.,2002; Berghmans B, Bo K.,Morkver S.;van Kampen M.;2007.

types of BF

- EMG-BF
- Manometric BF
- US BF

awareness
automatization

signal
acquisition
dettection-amplification-translation

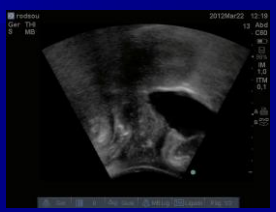
US BF

- the ultrasound image is also able to provide direct feedback to the patient on patterns of muscle activation and assist them in the correct activation of these muscles.

Messelink 1999; Hides et al 2001 ; Stuge et al 2004 ;Thompson et al 2005

US BF

- ultrasound imaging allows physiotherapists to measure properties of muscle (cross - sectional area, thickness, length and displacement) in a reliable, repeatable manner



Hides et al 2006, Sherburn et al 2005, Kristjansson 2004, Young et al 1994 Bo K, Sherburn M and Allen T ,2003.

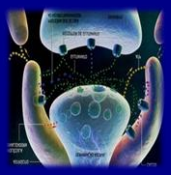
biofeedback through EMG

biofeedback through emg – nowadays it can be as stable as the pressure registration.

it allows the use of small probes, applying biofeedback and electrotherapy at the same time (ideal on dyspareunias)

it doesn´t allow variables of muscle stretching and can be modified according to hormonal impregnation and vaginal opening size.

Seleme,2005

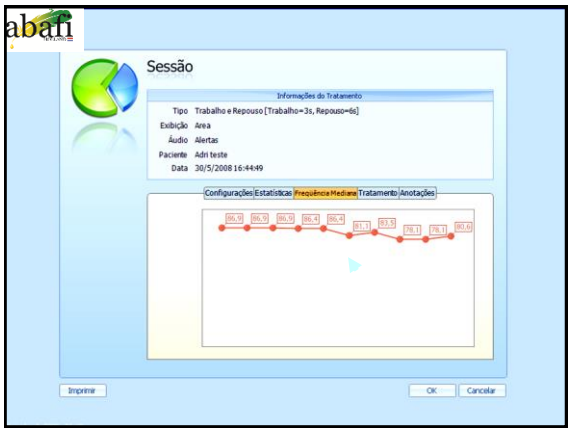


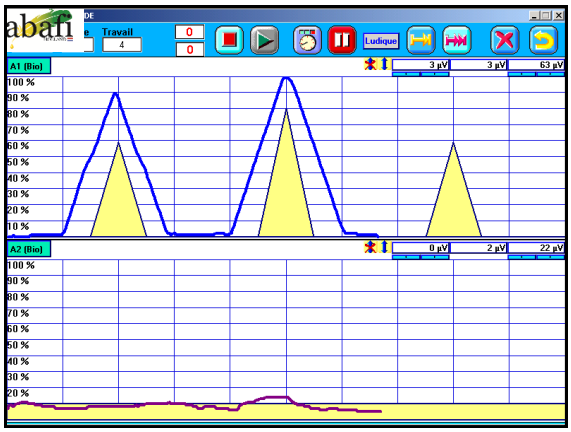
receive the action potential of the motor unit muscle fiber depolarization - contraction - repolarization – rest

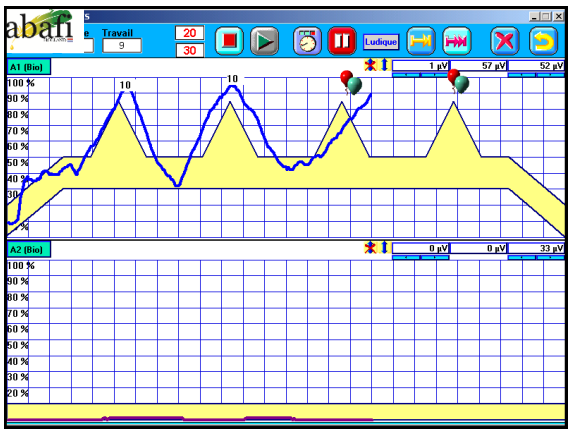
Binder,2002

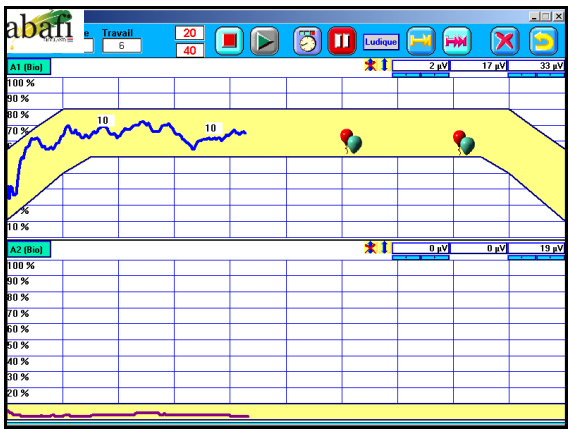
manometric BF

- less accurate than emg
- needs a pressure variation to be registred
- no influence from hormonal changes
- easy to accomodate to the vaginal introitus









advantages to include BF in the treatment

- ✓ no side effects
- ✓ not invasive
- ✓ active participation of the patient
- ✓ motivation in the trainning exercixes
- ✓ the learning process offered by the biofeedback
- ✓ do not limit futur options

conclusions

- In literature protocols of biofeedback showed a wide variation in:
  - Descriptions on patient education
  - Contraction parameters
  - Numbers of training sessions
  - Numbers of repetitions
  - Duration of training
  - Use of accessory muscles
  - Patient positioning, etc

Glazer, H. I. and Laine, C. D. Pelvic Floor Muscle Biofeedback in the Treatment of Urinary Incontinence: a Literature review.Appl.Psychophysiol. Biofeedback 2006; 31(3):187-201).

recomendations

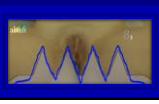
- improve experimental design
- include long term follow-up data
- to use an adequate sample size that allows for meaningful analysis
- better methodological quality
- bf standartization

Glazer, H. I. and Laine, C. D. Pelvic Floor Muscle Biofeedback in the Treatment of Urinary Incontinence: a Literature review.Appl.Psychophysiol. Biofeedback 2006; 31(3):187-201).

PFMT + biofeedback

- wireless BF for functional training
- BF during sporting activities
- mimicking activities where normally UI

wirelless biofeedback



not too much...good contraction...

- Simple exercise asking for bending the knees causes a good PFM contraction

just walking.....

Walking with a bad posture , observe weak motor unit activity of the PFM

Walking with correct posture (strech out) significant > motor unit activity of the PFM

working the pelvic floor nice advice

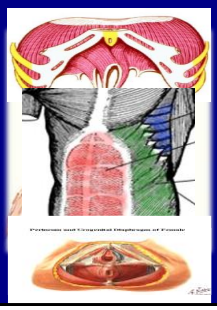
always walk in good posture

coughing causes PFM PRE-contraction

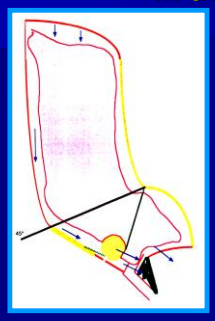
brusque unexpected movement causes PFM PRE-contraction

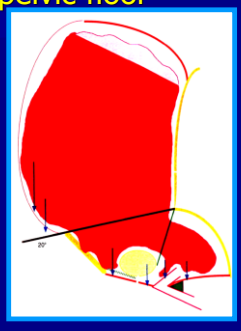
new technology in functional training

the Statics and Dynamics Abdomino-Pelvic

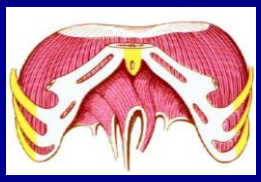


direction of pressure transmitter in the pelvic floor





thoracic diaphragm



Thank you very much !
Maura Seleme

www.abafi.com.br
www.abafiholland.com

Slings for Female Intrinsic Sphincteric Deficiency

Patrick J. Woodman, DO, MS; FACS, FACOG

Associate Clinical Professor Obstetrics & Gynecology
Instructor, Female Pelvic Medicine & Reconstructive Surgery Fellowship
Department of Obstetrics & Gynecology
Indiana University School of Medicine
Associate Professor & Chairman, Specialty Care
Marian University College of Osteopathic Medicine

Conventional Incontinence Procedures

- ~~Needle suspensions~~
- ~~Anterior colporrhaphy~~
- Burch or MMK Colposuspension
- TO Mesh Slings
- RP Mesh Slings
- Fascial sling
- ~~Bulking Agents~~
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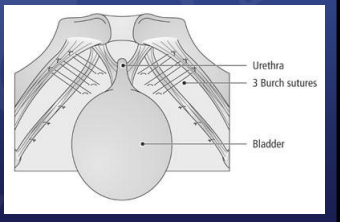
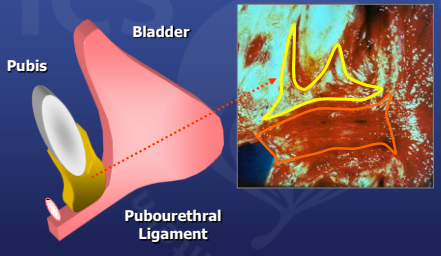


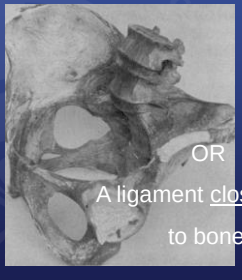
Why do these surgeries not last?



If only attached to soft tissue (ie muscle or "fascia"), failure may be inevitable…

Attach to bone!

so

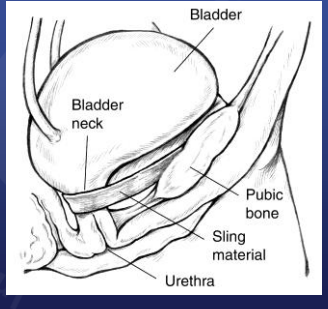


OR

A ligament close to bone!

Suburethral Sling

- Strap of biological or synthetic material placed at the UVJ
- Stabilizes urethra
- Simulates "pubo-urethral ligament"
- Establishes continuity between the urethra and pubic bone



Traditional Suburethral Sling

- Giordano (1907) reported the first urethral sling
- McGuire and Lytton (1978) reported a 80% success rate for the "pubovaginal sling" noting an "intrinsic weakness" in the urethral sphincter in
  - 75% of patients who failed multiple incontinence surgeries had
  - 13% in women with no history of surgery
- Sand (1987) noted a 3-fold increase in Burch failure in a subgroup of patients with MUCP <20cm H_2O
  - Recommend more obstructive procedure

1. McGuire EJ, Lytton B. Pubovaginal sling procedure for stress incontinence. *J Urol*, 1978; 119:82-84.
2. Sand PK, Bowen LW, Panganiban R, Ostergard DR. The low pressure urethra as a factor in failed retropubic urethropexy. Obstet Gynecol 1987;69:399-402.

Contemporary Results Allografts

Author	N	Processing Method	Improved (%)	Follow-up (mos.)	Cure (%)
Elliot	26	SD, + IR	92	15	77
Amundsen	104	FD, - IR	84	19	63
Wright	59	FD, - IR	98	12	NA
Handa	16	FD, - IR	85	12	79
Brown	121	FD, ? IR	83	12	74
Fitzgerald	35	FD, + IR	83	6	69
	361/302		86.5%		70.2%

Contemporary Results Autologous

Author	N	Type of fascia	Success (%)	Follow-up (mos.)	Post-op retention (%)	De novo urgency (%)	Sling erosion (#)
Morgan	247	rectus	88	52	2.4	7.0	0
Chaikin	251	rectus	92	36	2.0	3.0	0
Govier	32	fascia lata	87	14	3.0	9.0	0
Beck	170	fascia lata	92	NR	"High"	<1.0	0
Haab	40	27 fascia lata 13 rectus	86	48	2.7	10.0	0
			90.1%		2.3%	4.5%	0

Burch vs. Sling?

- SISTEr Trial: Multi-center RCT Burch vs. Sling with autologous fascia (N = 655)

  79% F/U at 2y, combo of subjective & objective criteria
  - Sling vs. Burch: overall success 47% vs. 38%** (any leak)
  - Sling vs. Burch: stress success 66% vs. 49%***
  - Sling patients had more UTI, void dysfunction, DOI
- Systematic review / Meta-analysis of 13 RCTs Burch and traditional sling (N = 760)
  - No statistically significant differences b/w traditional slings and other types of sling
  - Due to low numbers, no direct comparison of women with low urethral resistance or intrinsic sphincteric deficiency

1. Albo ME, et al. Burch colposuspension versus fascial sling... *NEJM*, 2007;356(21):2143-55.
2. Rehman H, Bezerra CA, et al. Traditional suburethral sling…*Cochrane Database Syst Rev*, 2011;(1):CD001754.

Burch vs. Sling?

- RCT of women with ISD: "Modified" Burch vs. sub-urethral sling (N=36)
  - Short-term results showed objective and subjective cure rates of 90, 95% for Burch
  - Objective and subjective cure rates for sling 100%
  - Significantly higher post-operative MUCP in sling grp
    - 39.8 ± 23.0 cm H_2O vs. 16.4 ± 8.2 cm H_2O**
  - Elevation of the lateral supporting tissues of an ISD urethra did not improve urethral resistance

1. Sand P, et al. A prospective randomized study comparing modified Burch retropubic urethropexy and suburethral sling for treatment of genuine stress incontinence with low-pressure urethra. *Am J Obstet Gynecol*, 2000;182:30-4.

Conventional Incontinence Procedures

- ~~Needle suspensions~~
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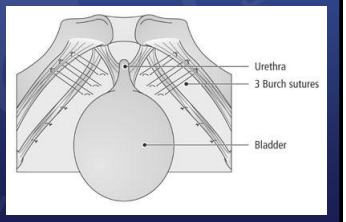
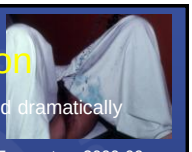


MUS Introduction



- Number of SUI surgeries have increased dramatically since mid-1990s introduction of TVT
  - Reuters Marketscan Commercial Claims & Encounters 2000-09
  - (N = 32.9 Million women aged 18-64) 74 Million person-years
  - 182,110 SUI procedures (246.1/100K person-years)
    - Suburethral sling (198.3/100K person-years) : 37.3% (2000); 89.1% (2009)
    - Burch (25.9/100K person-years): 40.6% (2000); 3.8% (2009)
- Highly successful at treating SUI, can be introduced via a top-down or bottom-up RP approach, or an inside-out or outside-in TO approach (TOMUS, N=597)
  - RP 80.8% objective cure, 62.2% subjective
  - TO 77.7% objective cure, 55.8% subjective

1. Funk MJ, et al. Incidence and time trends... *Obstet Gynecol*, 2012;195:845.
2. Richter HE, et al. Retropubic versus transobturator midurethral slings... *NEJM*, 2010;322: 2066-76.

Traditional Sling vs. MUS?

- Multicenter, RCT of Autologous fascia sling, TVT and Pelvicol sling (N = 72, 79, 50)
  - Pelvicol poor results at 6mo, 1y (73%, 61% improved, 22% dry)
  - At 6mo, improved: AFS 95%, TVT 92% (NS)
  - At 1y, improved: AFS 90%, TVT 93% (NS)
  - At 1y, dry: AFS 48%, TVT 55% (NS)
  - AFS took 20m longer, had higher CISC rates (9.9 vs. 1.5%)
- Systematic review / Meta-analysis of 39 RCTs comparing Burch, AFS sling and MUS
  - Patients undergoing AFS & MUS had similar cure rates*
  - AFS had more LUTS & Higher Re-operation Rate*
  - Retropubic MUS had slightly higher continence rates vs. Burch
  - Retropubic MUS had higher complication rate (bladder perf)

1. Guerrero KL, et al. A randomised controlled trial comparing TVT… *BJOG*, 2010;117:1493-1503.
2. Novara G, et al. Updated systematic review and meta-analysis... *Eur Urol*, 2010;58:218-38.

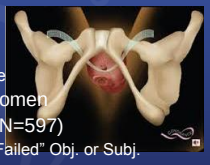
TVT vs. ISD?

- Retrospective sample of a prospective, multicenter cohort, followed-up at 4 years (N=49):
  - 74% completely cured
  - 12% significantly improved
  - 14% not cured: majority >70 yo or MUCP <10cm H_2O
- Some experts advise omitting the ¼ inch gap subscribed when placing the TVT in women with ISD:
  - Tape placed touching urethra (still without tension)
- Retrospective cohort of women with ISD treated with TVT (N=35):
  - Strict definition of ISD: MUCP < 20cm H_2O & VLPP < 60cm H_2O
  - High success rate of 91.4% at 1y
  - 2 of 3 failures had a "fixed urethra"

1. Rezapour M, et al. Tension-Free vaginal tape (TVT) in stress-…. *Int Urogynecol J*, 2001;12:S12-14.
2. Ghezzi F, et al. Tension-free vaginal tape for the treatment of… *Int Urogynecol J*, 2006; 17:335–339.

TOT vs. ISD?

- Retrospective cohort of women undergoing TOT, divided into three treatment groups, F/U at 1 and 2y (N=35):
  - ISD with UH (G1): 96.1% and 87.5%
  - ISD w/o UH (G2): 66.7% and 66.7%
  - UH w/o ISD (G3): 96.6% and 96.4%
  - Lack of UH a "risk factor" for TOT failure



- One-year F/U of TOMUS, RCT of women w/ SUI randomized to TOT or TVT (N=597)
  - Examined a subgroup of women who "Failed" Obj. or Subj. (N=260)
  - Women in lowest Quartile of MUCP (< 45cm H_2O) or VLPP (< 86cm H_2O) had a 2-fold increase OR of failure (OR 1.88, 2.23)

1. Haliloglu B, et al. The role of urethral hypermobility and... *Int Urogynecol J* (2010) 21:173–178.
2. Nager CW, et al. Baseline urodynamic predictors of treatment failure 1 year after mid urethral sling surgery. *J Urol*, 2011;186:597-603.

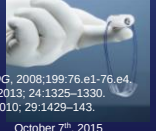
Best MUS for ISD? TVT vs. TOT

- Retrospective cohort of women comparing RP approach (TVT) to the TO approach (Monarc) (N=145):
  (Note: MUCP of < 20cm H2O exclusion for TOT group)
  - Monarc was nearly 6 times more likely to fail at 3 months after surgery in women with borderline MUCP (42 cm H2O or less)
  - Success: (Obj.) RP 97% vs. 91% TO, (Subj.) RP 86% vs. 84% TO
  - Low MUCP: (O) RP 97% vs. 84%** TO, (S) RP 87% vs. 77%***
- Prospective, RCT of women with USI and ISD, assigned to TVT or TOT, and F/U over three years (N=164):
  - Major outcome was recurrent symptomatic SUI requiring surgery
  - TVT 1.4% vs. TOT 20%; RR15.0*** (95% CI 2-113)
  - Overall success rates TVT 83.7% vs. TOT 72%**

1. Miller, et al. Is trans-obturator tape as effective as tension… *Am J Obstet Gynecol*, 2006;195:1799-804.
2. Schierlitz L, et al. Three-year follow-up of Tension-Free Vaginal...*Obstet Gynecol*, 2012;119:321-7.

Best Overall Sling?

- Retrospective cohort of women with USI and ISD placed in one of 3 groups (N=256):
  PVS (N=87), TVT (N=94) and TOT (N=72)
  - ISD Definition < 20cm H_2O MUCP or < 60cm H_2O VLPP
  - 2 Year Cure Rates: 87.2%, 86.9%, 34.9%
  - 7 Year Cure Rates: 59.1%, 55.1%, N/M
- Inelastic RP MUS in women with ISD (N=247)
  - 87.4% subjective improvement, 7.2% retension, 7.7% reintervent
- Retrospective cohort of women with recurrent USI or ISD, treated with an adjustable sling (N=125):
  - 87% cured, 13% not
  - Of those, 7% declined intervention



1. Jeon MJ, et al. Comparison of the treatment outcome of pubovaginal… *AJOG*, 2008;199:76.e1-76.e4.
2. Jijon A, et al. An inelastic retropubic suburethral sling in…*Int Urogynecol J*, 2013; 24:1325–1330.
3. Errando C, et al. A Re-Adjustable sling for female… *Neurourol Urodynam*, 2010; 29:1429–143.

Typical Complications

Complications	PVS (n=87)	TVT (n=94)	TOT (n=72)	P value
Bladder injury	1 (1.2%)	0	0	0.6
De novo urgency	14 (16%)	14 (15%)	13 (18%)	0.9
Voiding dysfunction (one month or longer)	18 (19%)	17 (18%)	8 (11%)	0.75
V.D. Requiring surgery	0	3 (3.1%)	1 (1.4%)	0.26
Recurrent UTI	2 (2.3%)	6 (6.4%)	0	0.06
Mesh Erosion	-	1 (1.1%)	1 (1.4%)	1

1. Jeon MJ, et al. Comparison of the treatment outcome of pubovaginal… *AJOG*, 2008;199:76.e1-76.e4.

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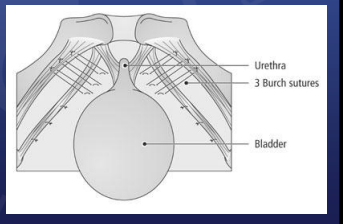

Questions?

References

- McGuire EJ, Lytton B. Pubovaginal sling procedure for stress incontinence. *J Urol*, 1978; 119:82-84.
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- Rezapour M, et al. Tension-Free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD)--a long-term follow-up. *Int Urogynecol J*, 2001;12:S12-14.

References

- Ghezzi F, et al. Tension-free vaginal tape for the treatment of urodynamic stress incontinence with intrinsic sphincteric deficiency. *Int Urogynecol J*, 2006; 17: 335–339.
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- Jijon A, et al. An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency. *Int Urogynecol J*, 2013; 24:1325–1330.
- Errando C, et al. A Re-Adjustable sling for female recurrent stress incontinence and sphincteric deficiency: Outcomes and complications in 125 patients using the Remeex sling system. *Neurourol Urodynam*, 2010; 29:1429–143.

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Notes