

Slings and Things – What’s Holding You Up?

Michael Moen, MD, FACOG, FACS

*Medical Director, Women’s Center for Pelvic Medicine
Edward Hospital, Naperville Illinois*

1

Disclosures

• None

2

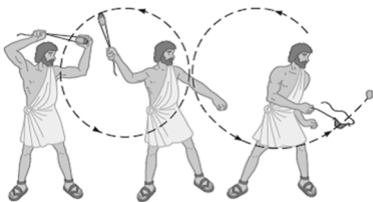


Figure P5.64 The proper use of a sling.

3

Applying slings:

•Applying slings properly depends on the type of injury.



4

Slings and Things

• **Slings - surgery for stress incontinence**

- Pubovaginal slings (bladder neck)
- Midurethral slings - mesh

• **Things - surgery for pelvic organ prolapse**

- Native tissue repairs
- Mesh-augmented repairs
 - Abdominally placed mesh (sacrocolpopexy)
 - Vaginal mesh (vaginal mesh "kits")

5

Learning Objectives

• Understand the historical development of surgical procedures for stress incontinence

• Describe current surgical techniques for treatment stress incontinence

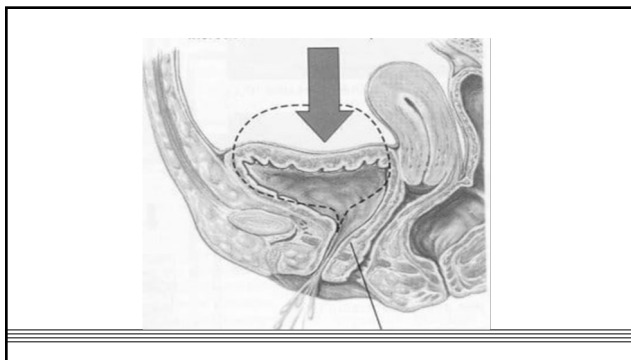
• Discuss the ongoing controversy concerning the use of mesh in urogynecologic surgery

6

**Kelly procedure
(Suburethral Plication) - 1914**

“ This affection is due to the loss of elasticity or normal tone of urethral and vesical sphincter, so well shown by the cystoscopic picture, which in many cases presents a gaping internal sphincter orifice which closes sluggishly as the cystoscope is withdrawn. The point of vantage toward which the operative treatment should be directed is the internal orifice of the urethra and sphincter of the bladder”

7



8

Fig. 2 Kelly operation. Plication of vesical neck.

Technique

Figure 3. The diagrams demonstrate the suture placement. Note that the paramidurethral sutures pass deeply to the anterior aspect of the symphysis pubis, which the needle touches but does not penetrate. No. 1 chromic catgut sutures are used to plicate the pubocervical fascia under the bladder base; care should be taken to avoid over-correction of the cystocele (disturbing the differential support concept).

9

URINARY INCONTINENCE IN WOMEN, WITHOUT MANIFEST INJURY
TO THE BLADDER

A REPORT OF CASES

By HOWARD A. KELLY, M. D., BALTIMORE
Professor of Gynecology, Johns Hopkins University

AND

WILLIAM M. DUMM, M. D., BALTIMORE
Assistant Resident Gynecologist, Johns Hopkins Hospital

• **Kelly 1914: 16 of 20 patients cured (F/U 4 months to 13 years)**

10

Early Sling procedures

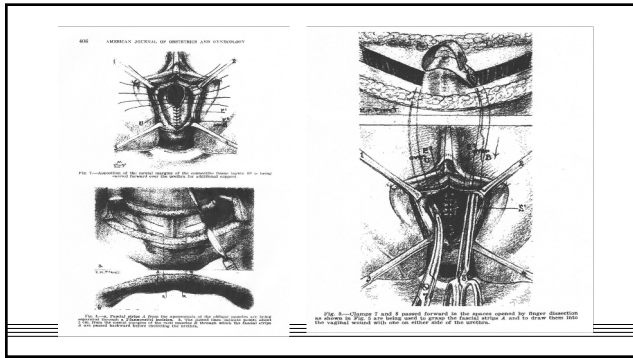
- **Goebell (1910) - pyramidalis muscles**
- **Frangenheim (1914) - pyramidalis muscles attached to strips of overlying fascia**
- **Stoeckel (1917) - Goebell-Frangenheim procedure combined with vaginal plastic operation at bladder neck (i.e. Kelly)**
- **Martius (1929) - bulbocavernosus muscle and surrounding fatty tissue**

11

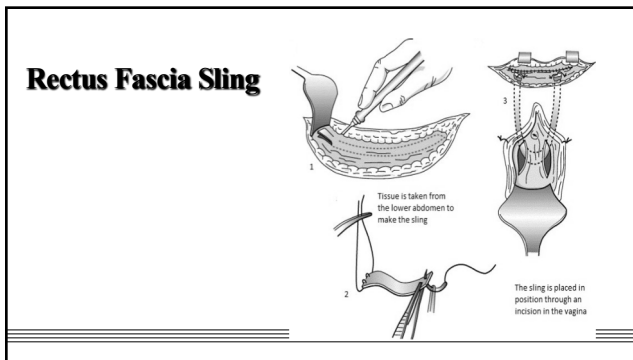
Rectus Fascia Transplantation Sling

- **Aldridge (1942)**
 - *“The new procedure that has been described was devised primarily with the hope of curing post-partum, urinary stress incontinence in women in whom vaginal plastic surgery seemed inadequate.”*
 - *“The disadvantages of the procedure are that it requires a painstaking technique which should not be undertaken by a surgeon who has not acquired a modern conception of the anatomic structures in the anterior vaginal wall about the urethra and bladder.”*

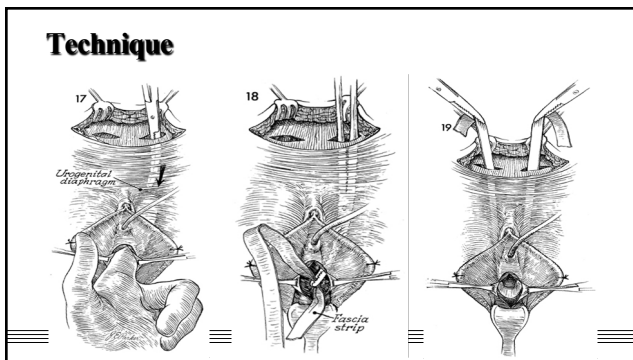
12



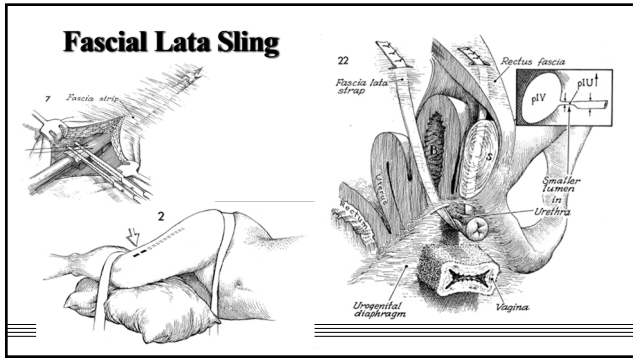
13



14



15



16

Fascial Slings - Key Publications

- **Ridley 1966, Parker 1979, McGuire 1987, Beck 1988, Breen 1997**
- ***In all of these articles, the Fascial Sling is described as a salvage procedure for patients with recurrent stress incontinence***

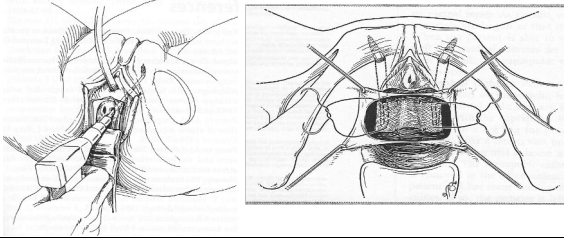
17

Modified Slings – Patch (1990s)

Fig. 15-12 Patch sling using combined needle suspension sling procedure in which a suburethral patch of fascia or synthetic material is suspended to the anterior rectus fascia with permanent suture.

18

Modified Slings – Bone Anchor (1990s)



19

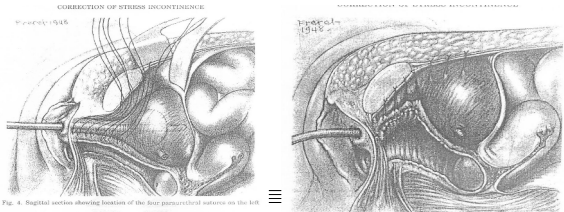
Questions?



20

Retropubic Urethropexy (Vesicourethral Suspension)

• Marshall-Marchetti-Krantz (1949)



21

Burch procedure - 1961

"One day, while we were doing a Marshall-Marchetti-Krantz operation, the sutures in the periosteum continued to pull out and it was necessary to look for another point of attachment. An examination of the field revealed that the intravaginal finger was pushing the anterior vaginal wall up to a level as high as the origin of the levator muscle from the white line of the pelvis. Since the white line is the usually accepted origin of the so-called fascia surrounding the vagina it seemed reasonable and anatomically correct to suture this perivaginal fascia to the white line and the underlying levator muscle with three interrupted sutures on each side. This maneuver produced a most satisfactory restoration of the normal anatomy of the bladder neck and, in addition, a surprising correction of most of the cystocele involving the base of the bladder."

22

Urethrovaginal fixation to Cooper's ligament for
correction of stress incontinence, cystocele,
and prolapse

JOHN C. BURCH, M.D.
Nashville, Tennessee

Y Burch 1961: 53 cases; 100% success

23

Technique

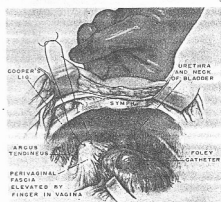


Fig. 1. The suture has been passed through the perivaginal fascia and the wall of the vagina, but not through the mucous membrane. The sutured point is now matched to that point on Cooper's ligament to which it is most easily approximated, and the suture passed through this point and tied.

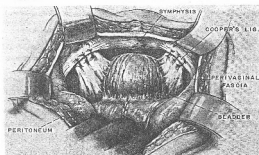
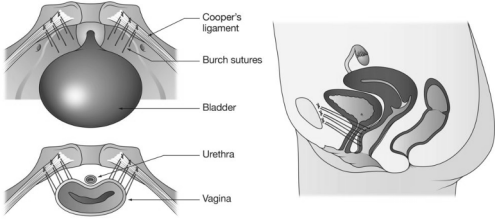


Fig. 2. The lateral ends of the suture have been approximated to Cooper's ligament for a interrupted suture.

24

Modified Burch Procedure



25

Needle Suspension Procedures

- **Pereyra (1959); Stamey (1973); Raz (1981); Gittes (1987); other variations**
- ***“cure of urinary incontinence depends exclusively on raising the internal vesical neck of the bladder upward and forward behind the symphysis pubis, the cystoscope offers the most accurate way of placing the suspending sutures exactly at the bladder neck”***
Stamey 1980

26

Technique

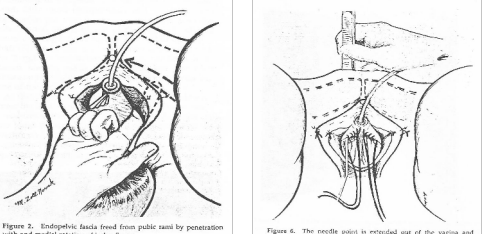
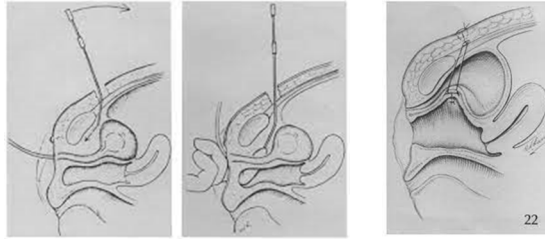


Figure 2. Endopelvic fascia freed from pubic rami by penetration with and medial rotation of index finger.

Figure 3. The rectle point is reticulated out of the vagina and divided with temporary tissue rods.

27

Technique



28

SUI Treatments: Early 1900s to Mid 1990s

- **Pubovaginal slings (1910)**
 - Rectus fascia (1942), Fascia lata (1980s)
 - *Primarily used as salvage operations for recurrence*
- **Kelly suburethral plication (1914)**
 - *Vaginal approach most commonly used by Gynecologists*
- **Retropubic urethropexy (1949)**
 - MMK (1949), Burch procedure (1961)
 - *Abdominal approach used by Gynecologists and Urologists*
- **Needle suspension procedures (1959)**
 - Pereyra (1959); Stamey (1973); Raz (1981); Gittes (1987)
 - *Vaginal approach most commonly used by Urologists*

29

Comparison of procedures

Three surgical procedures for genuine stress incontinence:
Five-year follow-up of a prospective randomized study

Arish Bergman, MD, and Giovanni Ellis, MD
Los Angeles, California

OBJECTIVE: Our purpose was to evaluate and compare the long-term results of the Kelly plication, modified Pereyra needle suspension, and Burch urethropexy for the treatment of stress urinary incontinence in women.

STUDY DESIGN: One hundred twenty-seven consecutive women underwent surgery at the gynecologic oncology division at Women's Hospital, Los Angeles County-University of Southern California Medical Center between January 1986 and June 1987. The only indication for surgery was stress urinary incontinence. Women with previously failed anticholinergic procedures were excluded. Fifty-three patients were premenopausal and 74 postmenopausal. History, physical examination, urodynamic study, cotton swab test, King cytometry, urethral pressure profile at rest and on cough, and anatomically were performed preoperatively. 2 months, 1 year, and 5 years postoperatively. The subjects and surgeons were randomly allocated to one of three surgical procedures: group 1 had anterior suspensory with Kelly plication; group 2 had modified Pereyra needle urethropexy; and group 3 had Burch urethropexy. One hundred seven women were available after 1 year, and 69 were the subjects of the 5-year evaluation. Fisher exact test, χ^2 test, and paired t test were used for statistical analysis.

RESULTS: The results of the 5-year postoperative evaluation had been previously published. The objective success rate for groups 1, 2, and 3 after 5 years was 37%, 45%, and 82%, respectively, and the difference was statistically significant. The drop in the success rate in 4 years was 20%, 22%, and 7% for groups 1, 2, and 3, respectively. Uroynamically all three procedures significantly increased the abdominal pressure transmission to the urethra, when successful. Ninety-one percent of women after the Burch procedure had a negative cotton swab test after 5 years compared with 46% for the Pereyra and 20% for the Kelly procedures.

CONCLUSIONS: In our hands the Burch urethropexy has a higher cure rate that holds over time when compared with the modified Pereyra needle suspension and the Kelly plication. The lower incidence of the positive cotton swab test in women after Burch urethropexy may be proof of a better anatomic suspension of the bladder neck. (Am J Obstet Gynecol. 1993;170:867-71.)

Bergman 1995

- **Kelly plication vs. Needle suspension (Pereyra) vs. Burch procedure**
- **Burch better than Kelly plication and Needle suspension due to better suspension of the bladder neck**

30

QUESTIONS?



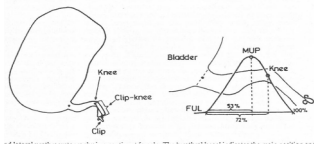
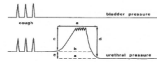
31

Synthetic Midurethral Slings

- Pathophysiology - loss of function of pubourethral ligaments to maintain high-pressure zone at mid-urethra

Comparative urodynamic studies of continent and stress incontinent women in pregnancy and in the puerperium

HERALDIN JOSEFF, M.D.
ULF ULMERTEN, M.D.
Leinfelden, Baden



32

Midurethral Sling - Key Publications

International Urogynecology Journal

Original Article
An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence
U. Chinnai, U. Hildebrandt, P. Johnson, and G. Vignone
Department of Obstetrics and Gynecology, University of Bonn, Bonn, Germany; University of Bonn, Bonn, Germany

International Urogynecology Journal

Original Article
A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence
U. Chinnai, C. Falcone, P. Johnson, M. Jinnai, L. Lamm, C. G. Nishino, and I. Okada
Obstetrics and Gynecology, University of Bonn, Bonn, Germany; Obstetrics and Gynecology, University of Bonn, Bonn, Germany; Obstetrics and Gynecology, University of Bonn, Bonn, Germany

- Original "TVT"
– 1 year data (1996)
– 3 year data (1999)

33

Midurethral Sling - Key Publications

Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary Incontinence

C. G. Nilsson¹, N. Kauv², C. Falckem³, M. Rezapour⁴ and U. Ulmsten⁵
¹Helsinki University Central Hospital, Helsinki, Finland, ²Danderyds Hospital, Karolinska Institutet, Stockholm, ³Uppsala University Hospital, Uppsala, Sweden

Int J Gynaecol Obstet 2008; 102: 100-107
 DOI: 10.1002/ijgo.20424

ORIGINAL ARTICLE

Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence

C. G. Nilsson¹, K. Pahn², M. Rezapour³, C. Falckem⁴

Int J Gynaecol Obstet 2009; 107: 242-249
 DOI: 10.1002/ijgo.20482

ORIGINAL ARTICLE, HISTORY CHOICE

Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence

C. G. Nilsson¹, K. Pahn², R. Aarås³, E. Steier⁴, G. Pahlsson⁵

• Long-term data

- 5 year (2001)
- 11 year (2008)
- 17 year (2013)

34

TVT vs. Burch (2004, 2007)

Medical Journal of Australia and New Zealand 2004; 291: 100-107
 DOI: 10.1002/ajnm.20014

GENERAL OBSTETRICS AND GYNECOLOGY, GYNECOLOGY

A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up

Karen L. Ward, MRCOG, Paul Hilton, MD, FRCOG,* on behalf of the UK & Ireland TVT Trial Group

www.medscape.com
 2004-2007
 www.medscape.com

www.medscape.com
 Urogynaecology

Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up

K. Ward, P. Hilton, on behalf of the UK and Ireland TVT Trial Group*

International Journal of Gynaecology and Obstetrics 2007; 97: 117-124
 DOI: 10.1002/ijgo.20482

Report of Results. Int J Gynaecol Obstet 2007; 97: 117-124

• TVT and Burch equivalent - 2 yrs and 5 yrs

35

Burch vs. Fascial Sling (2007)

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence

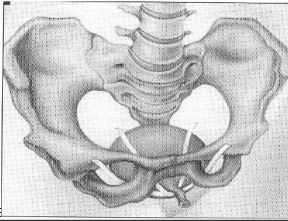
Michael E. Albo, M.D., Holly E. Richter, Ph.D., M.D., Linda Brubaker, M.D., Peggy Norton, M.D., Stephen R. Kraus, M.D., Philippe E. Zimmerman, M.D., Toby C. Chai, M.D., Halima Zyczynski, M.D., Anamias C. Diokno, M.D., Shanon Tennstedt, Ph.D., Charles Nager, M.D., L. Kirby Lloyd, M.D., MaryPat Fitzgerald, M.D., Gary E. Lemack, M.D., Harry W. Johnson, M.D., Wendy Ling, M.D., Veronica Mahlett, M.D., Anne M. Stockdale, Sr. D., Shawn Manefee, M.D., R. Edward Varner, M.D., Kimberly Kenton, M.D., Pam Mitchell, M.D., Larry Sirls, M.D., Kimberly J. Dandano, M.Sc., John W. Kozicki, Ph.D., Leroy M. Nyberg, M.D., Ph.D., and William Steers, M.D., for the Urinary Incontinence Treatment Network*

• Fascial Sling has higher cure rate but also higher morbidity

36

Retropubic vs. Transobturator

• Is orientation of support an issue?



40

RCTs: RP-MUS vs TO-MUS

Transobturator Tape Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence

A Randomized Controlled Trial

Matthew D. Barber, MD, PhD, Susan Klumpp, MD, Miley M. Korman, MD, Mary Kellee R. Puckett, MD, Albert D. Wilson, MD, Sandy Tsamiridis, MD, and Mark J. Gibbons, MD

Effectiveness of Tension-Free Vaginal Tape Compared With Transobturator Tape in Women With Stress Urinary Incontinence and Intrinsic Sphincter Deficiency

A Randomized Controlled Trial

Jan-Martin Brackley, PhD, J. Brian Campbell, MD, Ronald A. Gorman, MD, Christine Murray, MD, Richard Thomas, MD, Allan D. Bump, MD, PhD, PhD, MChD, and Robert Haynes, MD

ORIGINAL ARTICLE

Retropubic versus Transobturator Midurethral Slings for Stress Incontinence

2008 | Volume 16, No. 2 | February 15, 2010 | Pages 161-168

Matthew D. Barber, MD, PhD, Susan Klumpp, MD, Miley M. Korman, MD, Mary Kellee R. Puckett, MD, Albert D. Wilson, MD, Sandy Tsamiridis, MD, and Mark J. Gibbons, MD

Jan-Martin Brackley, PhD, J. Brian Campbell, MD, Ronald A. Gorman, MD, Christine Murray, MD, Richard Thomas, MD, Allan D. Bump, MD, PhD, PhD, MChD, and Robert Haynes, MD

• 2008 (2), 2010
 • $RP \geq TO$ in all studies

41

Ogah 2009

• 62 trials; 7101 pts
 • MUS as effective as traditional slings, open RPU and Lsc RPU, with fewer complications
 • Retropubic route better than obturator

Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women (Review)

Ogah J, Cook JG, Rogerson L



THE COCHRANE COLLABORATION®



WILEY

42

Schimpf 2014

Ÿ MUS = Burch (o)

Ÿ MUS > PVS (s)

Ÿ Retropubic MUS > transobturator (o,s)

Ÿ MUS > Mini (o,s)

RESEARCH www.AJG.org

Sling surgery for stress urinary incontinence in women: a systematic review and meta-analysis

Background: Sling surgery for stress urinary incontinence in women is a common procedure. The aim of this systematic review and meta-analysis was to evaluate the effectiveness and safety of sling surgery compared with other treatments for stress urinary incontinence in women.


Methods: We searched the literature for randomized controlled trials comparing sling surgery with other treatments for stress urinary incontinence in women. The primary outcome was the rate of cure or improvement of stress urinary incontinence at 12 months post-surgery.

Results: We identified 10 randomized controlled trials involving 1,048 women. Sling surgery was compared with placebo (n = 258), sham surgery (n = 258), and other treatments (n = 532). The rate of cure or improvement of stress urinary incontinence at 12 months was significantly higher in the sling surgery group compared with placebo (OR 2.0, 95% CI 1.1-3.7) and sham surgery (OR 2.0, 95% CI 1.1-3.7). There was no significant difference between sling surgery and other treatments.

Conclusion: Sling surgery is an effective treatment for stress urinary incontinence in women compared with placebo and sham surgery. There was no significant difference between sling surgery and other treatments.

43

QUESTIONS?



44

The Mesh Story - terminology

Ÿ 510(k) approval (used for Class 2 devices)

- allows approval of new devices based on being “substantially equivalent” to other devices already available

Ÿ Premarket Approval Application (PMA)

- Used for Class 3 (high-risk) devices; requires clinical trials

Ÿ 522 (studies)

- gives FDA authority to mandate post-market surveillance studies of Class 2 or Class 3 devices

Ÿ Multidistrict Litigation (MDL)

- Used for dangerous drugs, medical devices
- Cases from around the country are transferred to one court

45

Use of mesh in Urogynecologic Surgery

- 1950s - surgical mesh for abdominal hernias
- 1970s – mesh used for sacrocolpopexy
- 1996 – first surgical mesh specifically for SUI
 - ProteGen sling (Gore-tex)
 - Approved based on similarity to 1985 Mersilene hernia mesh
- 1998 – TVT sling (Prolene) approved in U.S.
 - Approved based on similarity to ProteGen sling

46

Use of mesh in Urogynecologic Surgery

- 2001-2002 - first surgical meshes specifically for POP
 - Based on similarity to ProteGen Sling (1996) and Mersilene hernia mesh (1985)
- 2004-2008 - Mesh “Kits” developed and marketed
 - Ultimately, over 100 devices by at least 40 manufacturers
- 2008 - FDA Public Health Notification
 - Over 1,000 reports of (rare) complications related to transvaginal mesh (2005-2008)
- 2011 - FDA Safety Communication
 - Additional 2,874 reports of complications from transvaginal mesh (2008-2011)
 - Complications related to mesh are “not rare” and some are unique to mesh itself

47

Use of mesh in Urogynecologic Surgery

- 2012 - FDA requires postmarket studies (522) for prolapse mesh and single-incision (mini) slings
- Several manufacturers remove products from market
- Precipitous rise in lawsuits begins
 - 2011 - 730; 2012 - 11,798; 2013 - 34,017; 2014 - 32,296
 - By 2019, more than 108,000 lawsuits have alleged that transvaginal mesh causes complications including pain, bleeding, infection, and organ perforation.
 - “Defective vaginal mesh” has caused thousands of women to suffer severe pain and organ damage.
 - Manufacturers misled the FDA, medical community, patients and public by failing to properly test devices, research the risks and warn of the potential complications and injuries.

48

Initially, in 2008, the FDA issued a public health notification on complications associated with transvaginal mesh.

In 2011, the FDA updated its statement and noted that complications associated with transvaginal mesh used to repair prolapse are not rare and that it was continuing to evaluate mesh use for the midurethral sling.

In 2013, the FDA updated its position, noting that "the safety and effectiveness of multi-incision slings is well established in clinical trials that followed patients up to 1 year."

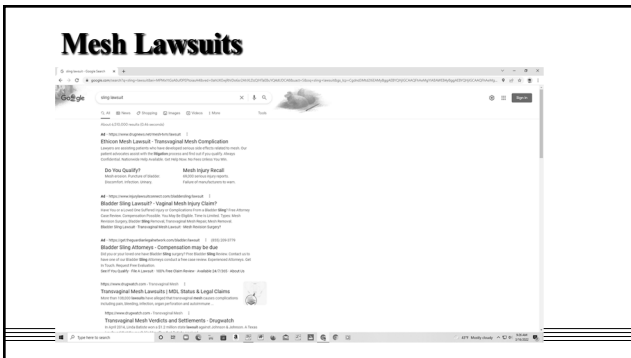
49

Use of mesh in Urogynecologic Surgery

- 2014 - Coloplast settles 400 claims; AMS 20,000; Bard 500
- 2015 - Ethicon settles 4 lawsuits; Boston Scientific settles 3,000 claims; Bard settles another 3,000 claims; Neomedic settles 112 claims
- 2016 - Ethicon settles 3,000 cases
- 2016 - FDA reclassifies mesh for POP as Class 3 (High-risk)
 - Only 2 companies submit PMAs and begin the required clinical studies (Boston Scientific and Coloplast)
- 2019 - FDA determines manufacturers have not demonstrated reasonable assurance of safety and effectiveness and orders companies to stop marketing and sales of transvaginal mesh for POP

50

Mesh Lawsuits



51

Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence

The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.

Jan 2014, Jun 2016, Feb 2018, Dec 2021

- ✔ "Lawyers have publicly advertised their services, targeting women with transvaginal mesh placed for both pelvic organ prolapse and stress urinary incontinence (SUI), and the media has reported on the pelvic organ prolapse mesh litigation. **We are concerned that the multifaceted litigation has resulted in confusion, fear, and an unbalanced negative perception regarding the midurethral sling as a treatment for SUI.** This negative perception of the MUS is not shared by the international medical community and the overwhelming majority of women who have been satisfied with their MUS."
- ✔ **Polypropylene material is safe and effective as a surgical implant**
- ✔ **The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history**
- ✔ **Polypropylene mesh midurethral slings are a standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients**
- ✔ **The FDA has clearly stated that the polypropylene MUS is safe and effective in the treatment of SUI**
- ✔ **The European Commission enquiry on the safety of surgical meshes supports synthetic sling use for SUI**

52

Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence

July 2014

- ✔ Mid-urethral slings are minimally invasive procedures developed in Europe in the 1990s to treat female stress urinary incontinence. They have been shown to be as effective as more invasive traditional surgery with major advantages of shorter operating and admission times, and a quicker return to normal activities together with lower rates of complications. This has resulted in MUS becoming the operation of choice in Europe, Asia, South America, South Africa, Australasia and North America for treatment of SUI with several million procedures performed worldwide.
- ✔ The US Food and Drug Administration (FDA) in the USA released a white paper and safety communications regarding safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. Media attention on this totally distinct and separate issue of mesh use in women has the potential to cause unnecessary confusion and fear in women considering MUS for treatment of stress urinary incontinence. The FDA publications clearly state that MUS (both retropubic and transoburator slings) were not the subject of these safety communications.
- ✔ There is robust evidence to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use.
- ✔ As a result, IUGA supports the use of monofilament polypropylene mid-urethral slings for the surgical treatment of female stress urinary incontinence.

53

Conclusions

- **Concepts concerning stress incontinence and surgical treatments have varied considerably over time**
- **Current options for surgical management include retropubic urethropexy, pubovaginal sling and synthetic midurethral slings**
- **Significant risks are associated with vaginally placed mesh for treating POP, but risks related to synthetic midurethral slings are much lower and the use of MUS for treating SUI is supported by the literature**

54

Thank you!
