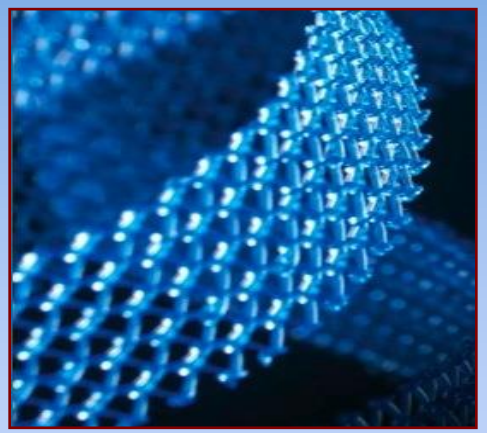
Lothian Urogynaecology Service

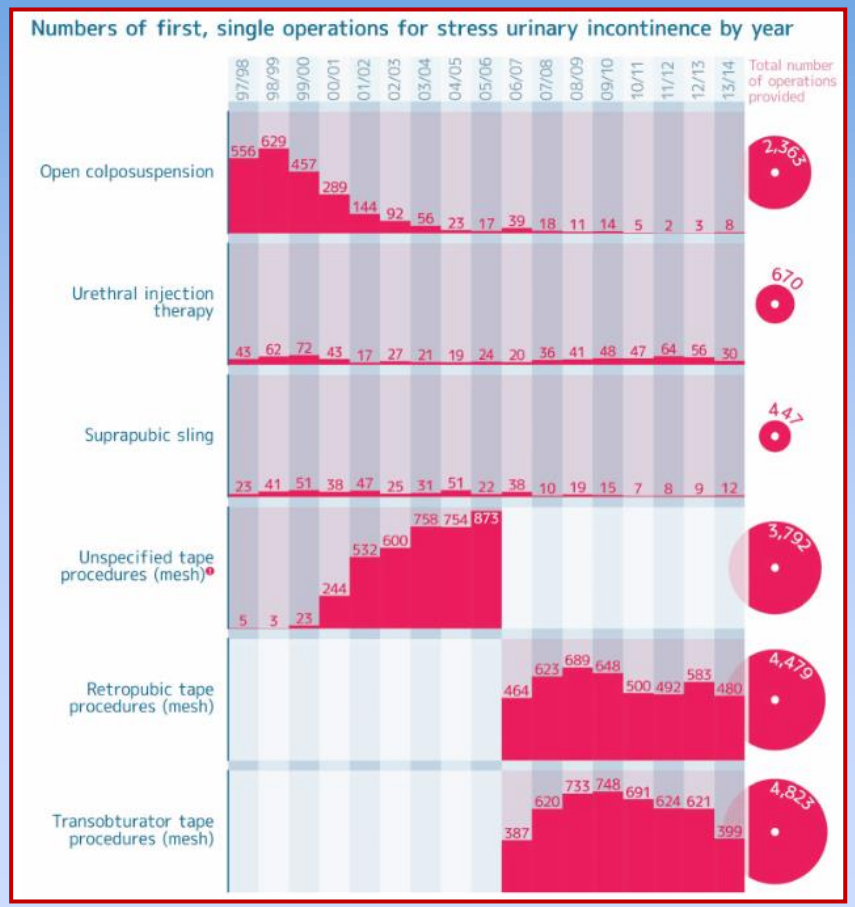
Impact of the Mesh Halt on Management of Pelvic Floor Dysfunction

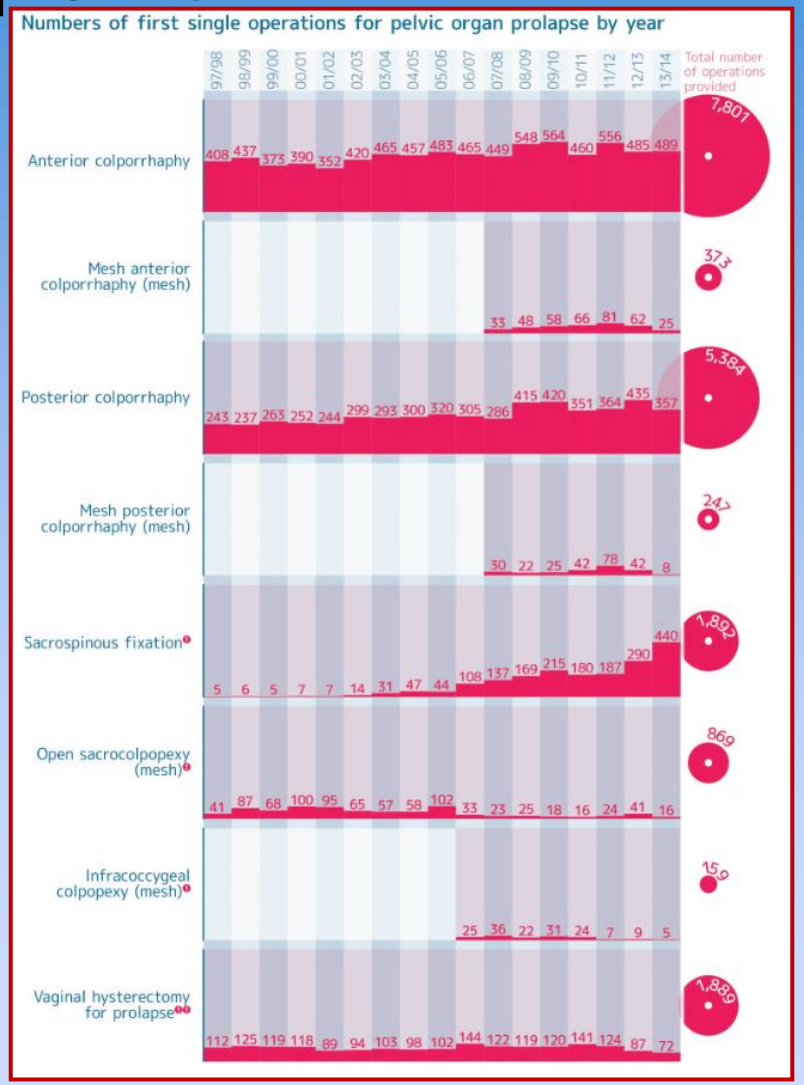


Dr Julia Wilkens FRCOG MD
Consultant Subspecialist
Lead for Urogynaecology in Lothian
SPFN – 14th October 2022

Vaginal mesh for SUI and POP

- First approval of mesh implants
  - SUI 1996 (Boston's ProteGen Sling)
  - POP 2002 - 501(k) procedure





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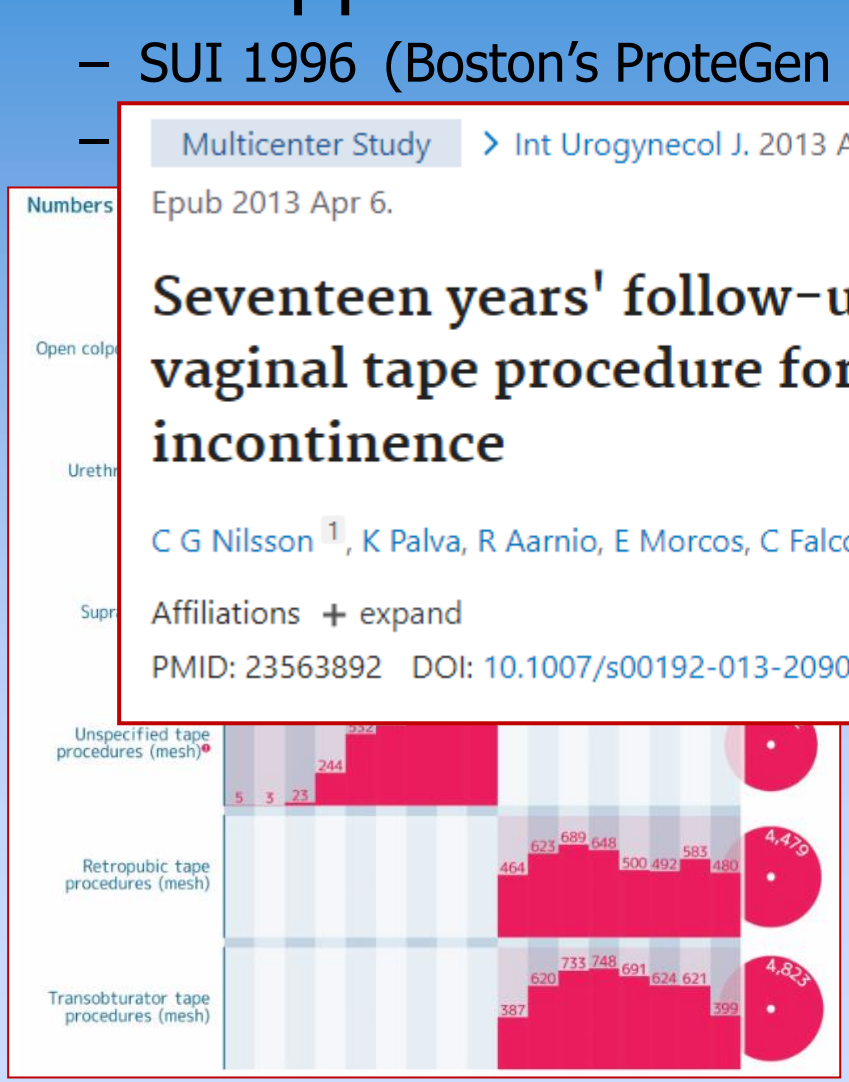


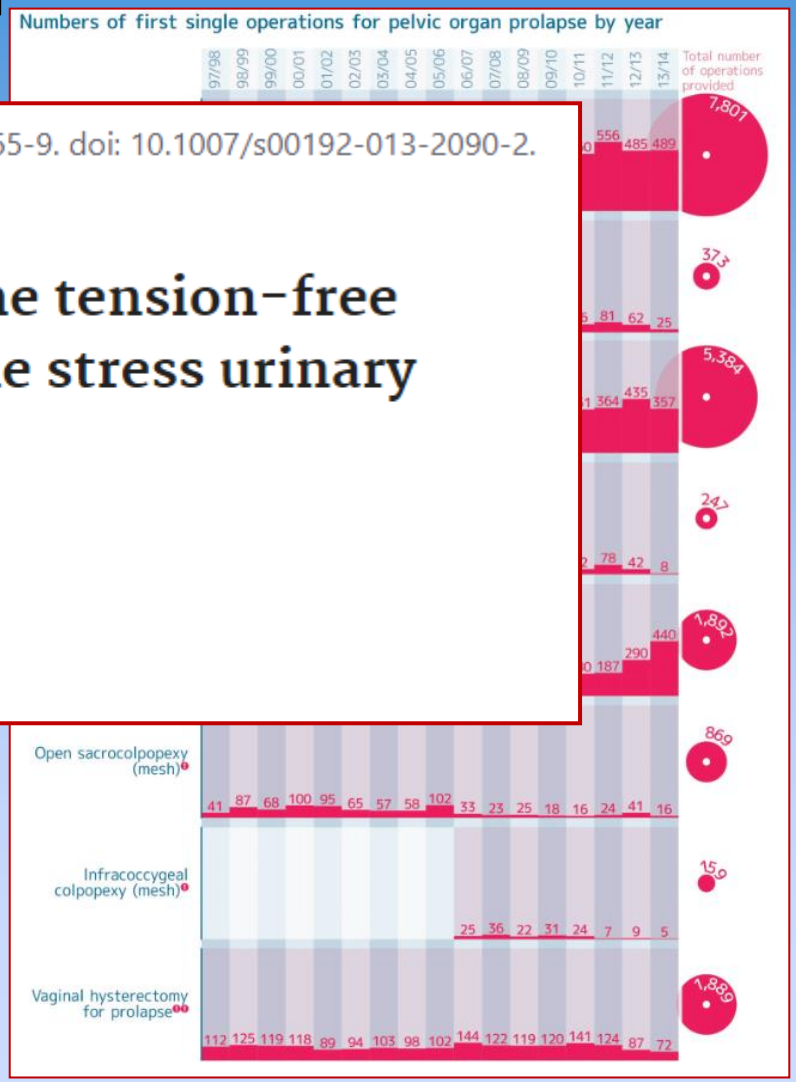
Multicenter Study > Int Urogynecol J. 2013 Aug;24(8):1265-9. doi: 10.1007/s00192-013-2090-2.
Epub 2013 Apr 6.

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

C G Nilsson [1], K Palva, R Aarnio, E Morcos, C Falconer

Affiliations + expand

PMID: 23563892 DOI: 10.1007/s00192-013-2090-2



Suspension of transvaginal mesh June 2014

Publication - Independent report

Transvaginal mesh implants independent review: interim report

Published: **2 October 2015**
Directorate: Chief Operating Officer, NHS Scotland Directorate
Part of: Health and social care
ISBN: **9781785447051**

This interim report outlines the work of the Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP).

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Chapter 9: The Conclusions and recommendations of the Independent Review

No surgical intervention is without risk. This Independent Review has shown that mesh procedures for both SUI and POP carry a risk of complications which in some cases are life changing and cannot be corrected. However for the majority such serious complications do not occur. The aim of our conclusions and recommendations is to minimize and manage that potential risk. Input from clinicians and provision of adequate information will allow patients to make informed choices regarding their treatment.

Halt in use of transvaginal mesh September 2018

News

Halt in use of transvaginal mesh

Published: **12 September 2018 17:12**

Part of: Health and social care

High vigilance measures to be developed.

Health boards have been instructed to completely stop all transvaginal mesh procedures until new protocols are developed and implemented, Health Secretary Jeane Freeman has told the Scottish Parliament.

The routine use of mesh has been suspended in Scotland since 2014, leading to a substantial reduction in the use of mesh products. For example, the number of operations for stress urinary incontinence (SUI) recently was at 5% of the rate before the suspension.

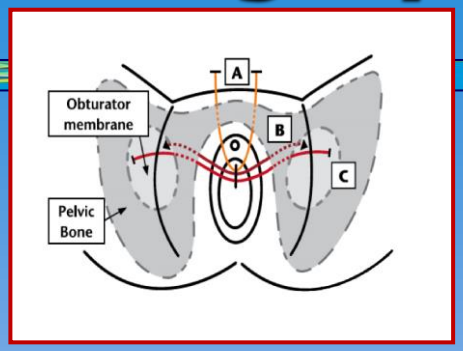
'Immediate' halt on use of mesh implants in Scotland

12 September 2018

Scotland's health boards have been ordered to "immediately" halt the use of vaginal mesh implants in surgery.

The controversial implants were **listed as an underlying cause of death** of a woman in August, sparking calls for an inquiry and an outright ban.

Stress Urinary Incontinence Surgery



- Significant overall reduction
  - Reduced demand
  - Reduced capacity (theatre time / trained surgeons)

SUI Procedures[1]	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Jan - July 2022[3]
Introduction of tension-free vaginal tape[2]	678	655	774	713	301	194	91	93	49				
Introduction of transobturator tape[2]	969	817	771	572	252	46	28	6	*				
Colposuspension of neck of bladder	20	23	17	22	44	66	76	87	103	150	53	31	8
Autologous sling procedures	24	27	12	14	28	69	61	35	41	38	22	16	7
Endoscopic injection of inert substance into outlet of female bladder	85	105	109	80	63	59	74	216	267	243	112	108	54
Other SUI Procedures[1]	*	13	17	34	28	9	*	*	*	0	*	0	0
TOTAL	1776	1640	1700	1435	716	443	330	437	460	431	187	155	69

Stress incontinence (SUI) procedures (2010 – Present) / Source: Public Health Scotland (SMR01)

STRESS URINARY INCONTINENCE SURGERY IN THE UK 2018-2019

2ND NATIONAL REPORT

BSUG AUDIT AND DATABASE COMMITTEE 2020

Figure 1: *The number of SUI procedures added to the BSUG database each year 2008-2019.*

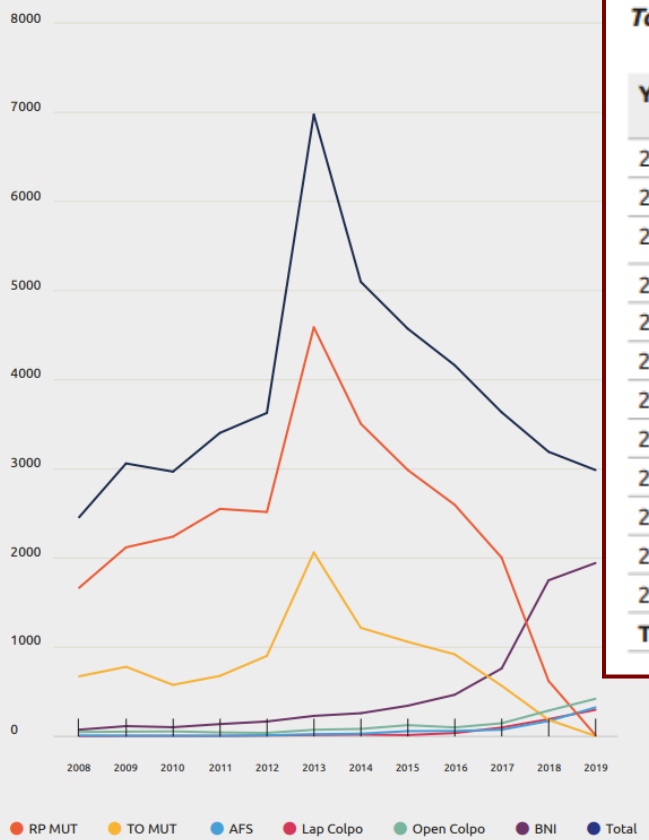
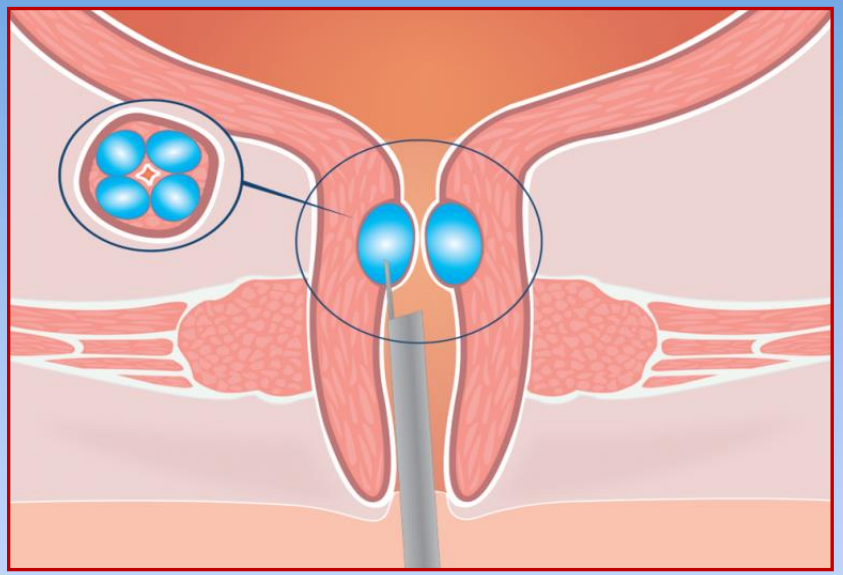


Table 6: *The number of SUI procedures added to the BSUG database each year 2008-2019*

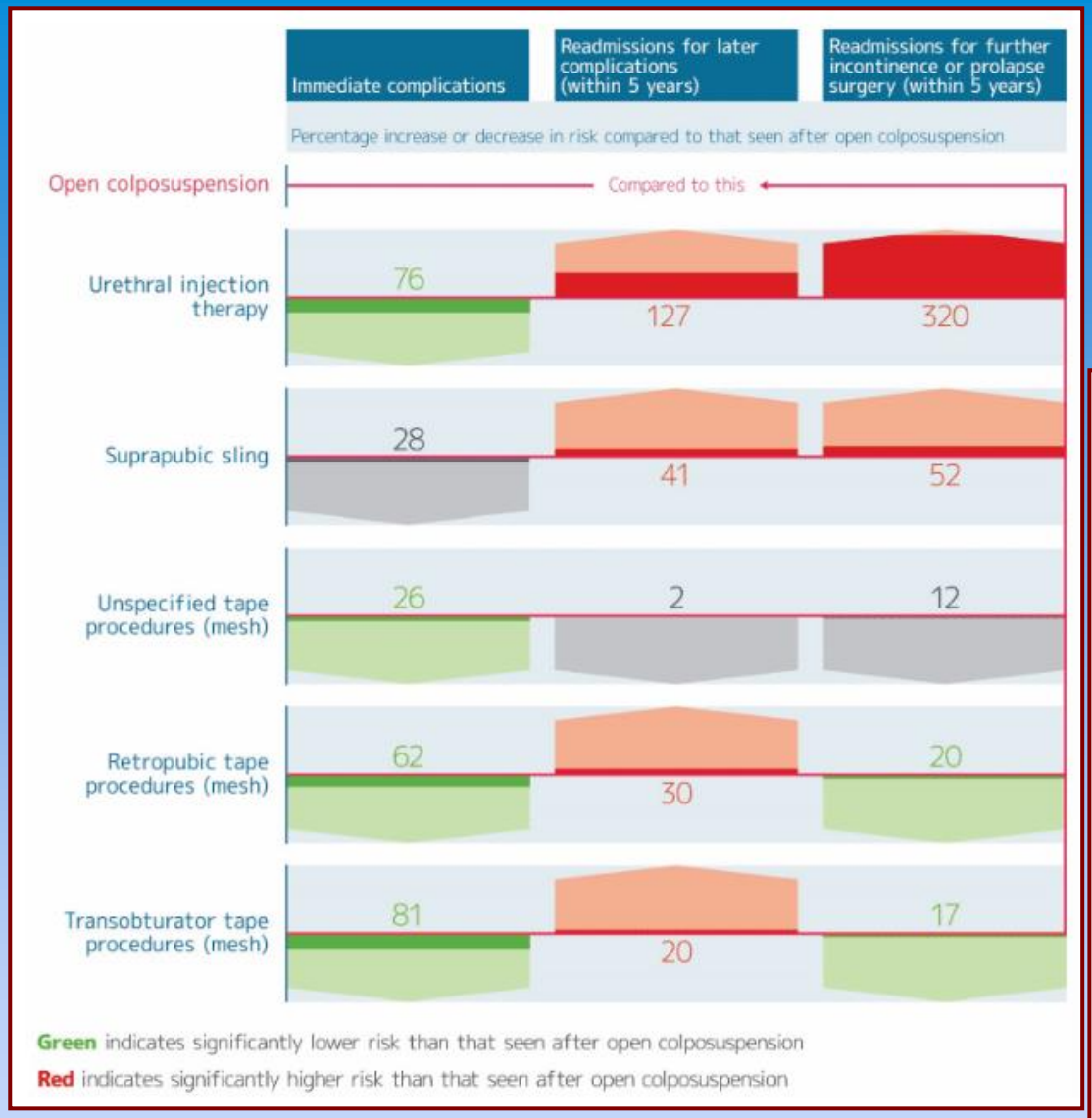
Year	RP MUT	TO MUT	AFS	Lap colpo	Open colpo	BNI	Total
2008	1664	670	6	0	45	71	**2456**
2009	2118	777	3	2	49	111	**3060**
2010	2238	574	3	2	52	99	**2968**
2011	2550	675	2	2	40	134	**3403**
2012	2515	900	8	6	35	163	**3627**
2013	4588	2060	21	12	70	226	**6977**
2014	3506	1215	26	16	80	256	**5099**
2015	2987	1058	55	11	122	340	**4573**
2016	2596	917	57	33	97	463	**4163**
2017	2003	565	71	95	143	758	**3635**
2018	619 (19%)	182 (6%)	168 (5%)	189 (6%)	285 (9%)	1748 (55%)	**3191 (100%)**
2019	5 (0.2%)	0	321 (10.8%)	294 (10%)	418 (14%)	1942 (65%)	**2980 (100%)**
Total	**27389**	**9593**	**741**	**662**	**1436**	**6311**	**46132**

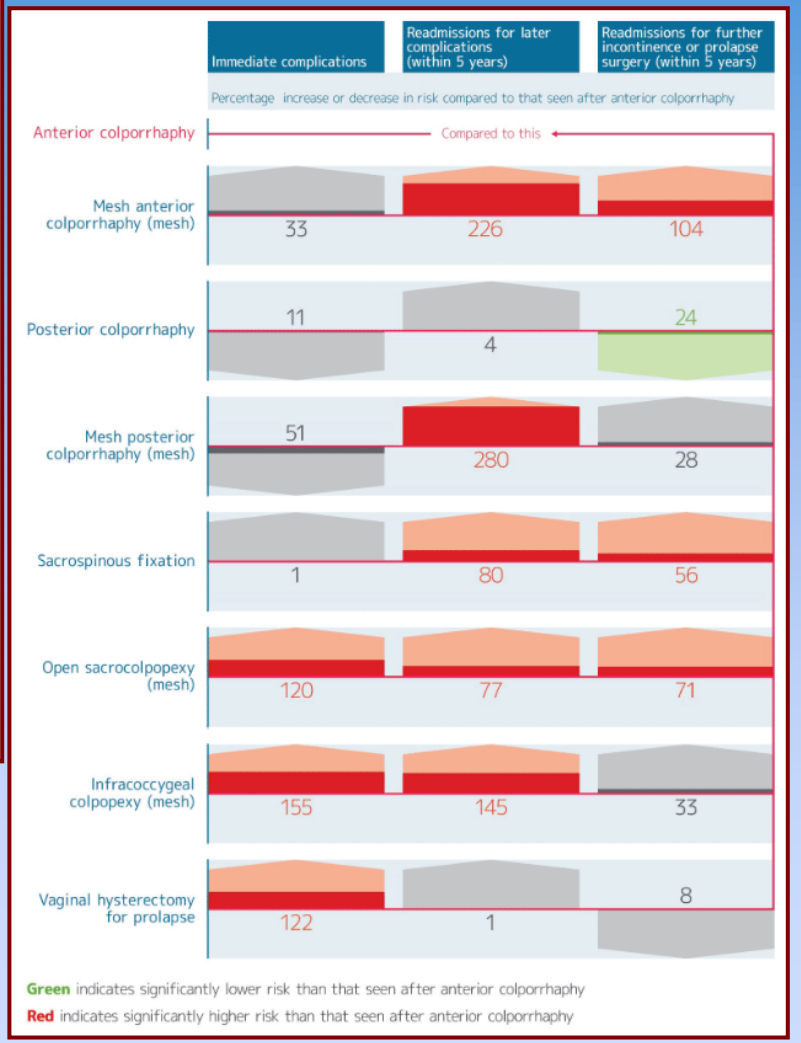
Impact of Mesh Halt Clinical Practice in Urogynaecology

- Management of SUI
  - Focus on conservative management
    - Pelvic floor muscle training
    - Vaginal devices
  - Limited surgical options
    - More invasive
    - Bladder neck injections



- Impact on Surgical Training
  - Learning curves / Opportunities


Immediate complications
Readmissions for later complications (within 5 years)
Readmissions for further incontinence or prolapse surgery (within 5 years)
Percentage increase or decrease in risk compared to that seen after open colposuspension
Open colposuspension
Compared to this
Urethral injection therapy
76
127
320
Suprapubic sling
28
41
52
Unspecified tape procedures (mesh)
26
2
12
Retropubic tape procedures (mesh)
62
30
20
Transobturator tape procedures (mesh)
81
20
17
Green indicates significantly lower risk than that seen after open colposuspension
Red indicates significantly higher risk than that seen after open colposuspension


Immediate complications
Readmissions for later complications (within 5 years)
Readmissions for further incontinence or prolapse surgery (within 5 years)
Percentage increase or decrease in risk compared to that seen after anterior colporrhaphy
Anterior colporrhaphy
Compared to this
Mesh anterior colporrhaphy (mesh)
33
226
104
Posterior colporrhaphy
11
4
24
Mesh posterior colporrhaphy (mesh)
51
280
28
Sacrospinous fixation
1
80
56
Open sacrocolpopexy (mesh)
120
77
71
Infracoccygeal colpopexy (mesh)
155
145
33
Vaginal hysterectomy for prolapse
122
1
8
Green indicates significantly lower risk than that seen after anterior colporrhaphy
Red indicates significantly higher risk than that seen after anterior colporrhaphy

STRESS URINARY INCONTINENCE SURGERY IN THE UK 2008-2017

1ST NATIONAL REPORT

BSUG AUDIT AND DATABASE COMMITTEE 2018

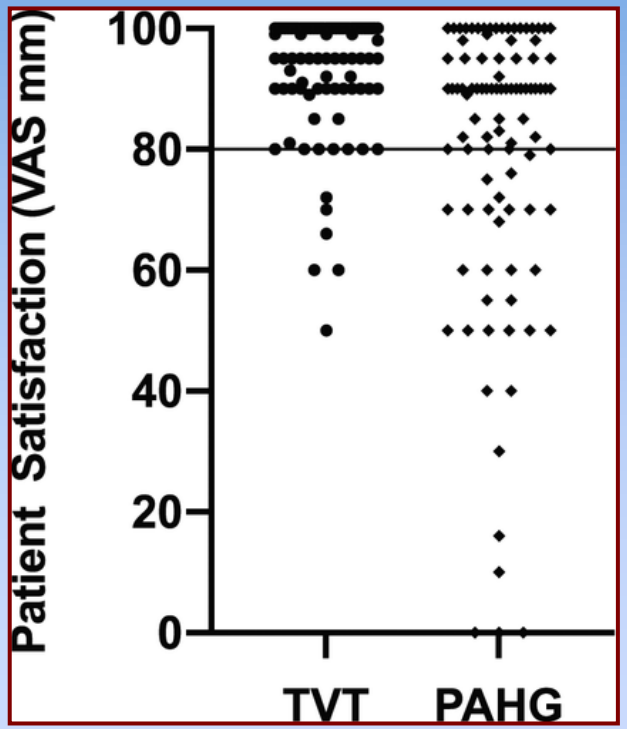
Table 4: *Efficacy and complication rate of sole SUI procedures.*

	RP MUT	TO MUT	BNI	Colpo	Sling
Efficacy for sole continence procedures at varying follow-up intervals					
'Much better' or 'Very much better'	90.3%	91.0%	54.9%	88.5%	85.7%
Complication rate for sole continence procedures at varying follow-up intervals					
Intraoperative	4.6%	1.8%	0.1%	4.5%	5.6%
Postoperative	10.4%	6.7%	2.1%	17.9%	23.9%
Total	**15.0%**	**8.5%**	**2.2%**	**22.4%**	**29.5%**
Risk category	Very common	Common	Common	Very common	Very common

Randomized Controlled Trial > J Urol. 2022 Sep;208(3):658-667.
doi: 10.1097/JU.0000000000002720. Epub 2022 Aug 5.

Tension-Free Vaginal Tape and Polyacrylamide Hydrogel Injection for Primary Stress Urinary Incontinence: 3-Year Followup from a Randomized Clinical Trial

Anna-Maija Itkonen Freitas [1], Camilla Isaksson [1], Päivi Rahkola-Soisalo [1], Sari Tulokas [1], Maarit Mentula [1], Tomi S Mikkola [1]



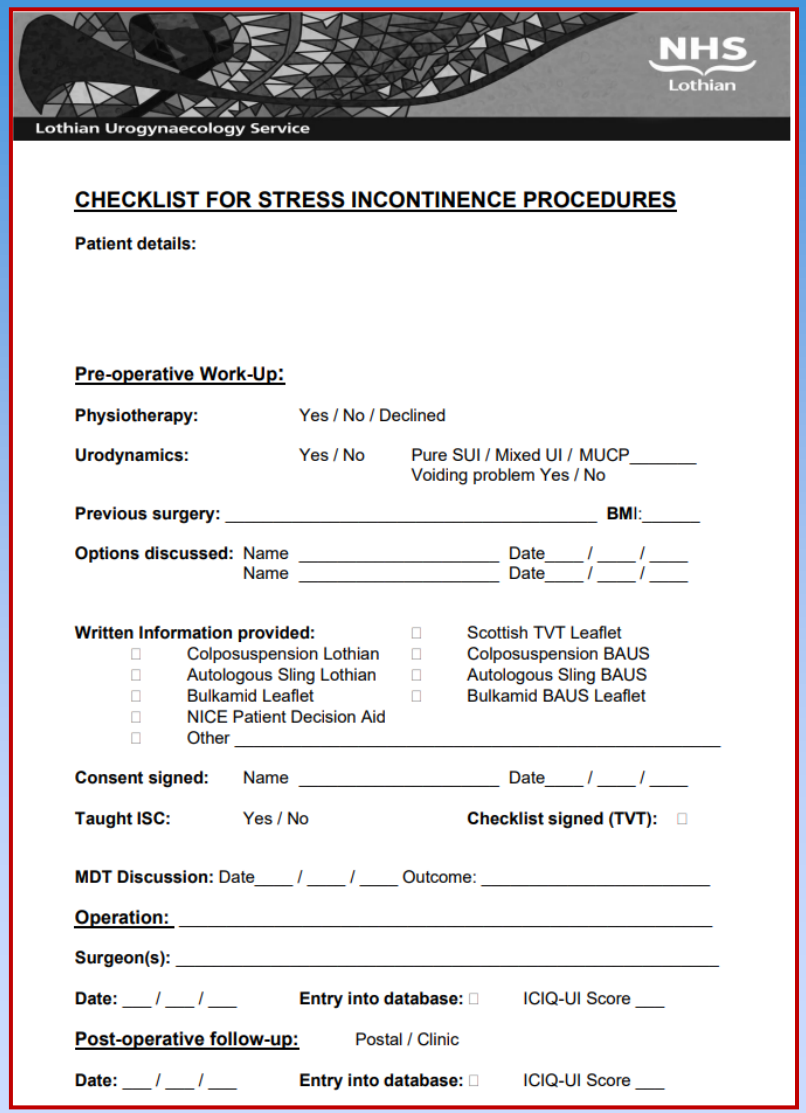
Materials and methods: In this noninferiority trial, 223 women eligible for operative SUI treatment were randomized for TVT (110) or PAHG (113). Primary outcome was patient satisfaction and the noninferiority margin for the difference was 20%. Secondary outcomes were effectiveness and complications.

Results: At 3 years, 188 (84.3%) women attended the followup. The satisfaction score (visual analogue scale 0-100) median was 98.5 (IQR 90-100) in the TVT group and 90.0 (IQR 70-100) in the PAHG group, whereas a score ≥80 was reached in 87 (94.6%) and 65 (67.7%), respectively (difference 26.9%, 95% CI 16.7% to 36.8%). Thus, PAHG did not meet the noninferiority criteria set in our study. The cough stress test was negative in 88 (95.7%) of TVT patients vs 75 (78.1%) of PAHG patients (difference 17.5%, 95% CI 8.6% to 26.9%). Any peri- or postoperative complication before crossover between the groups was detected in 40 (43.5%) women in the TVT group and 23 (24.0%) women in the PAHG group (difference 19.5%, 95% CI 6.8% to 31.4%).

Conclusions: In midterm followup, PAHG did not reach in patient satisfaction the noninferiority set in our study. Furthermore, mid urethral TVT slings show better subjective and objective cure rates than PAHG. However, complications were more often associated with TVT. Since the majority of PAHG treated women were also cured or improved, primary SUI women can be offered PAHG as a safe and durable alternative treatment.

Impact of Mesh Halt Clinical Practice in Urogynaecology

- HIGH VIGILANCE SCRUTINY
  - Case selection / workup
  - Consent procedure
  - MDT discussion
  - Trained operator
  - Follow-up / Audit
  - Database
  - Accountable Officer
  - Report complications



NHS Lothian

Lothian Urogynaecology Service

CHECKLIST FOR STRESS INCONTINENCE PROCEDURES

Patient details:

Pre-operative Work-Up:

Physiotherapy: Yes / No / Declined

Urodynamics: Yes / No Pure SUI / Mixed UI / MUCP_____
Voiding problem Yes / No

Previous surgery: _____ **BMI:**_____

Options discussed: Name _____ Date____ / ____ / ____
Name _____ Date____ / ____ / ____

Written Information provided:
- ☐ Colposuspension Lothian
- ☐ Autologous Sling Lothian
- ☐ Bulkamid Leaflet
- ☐ NICE Patient Decision Aid
- ☐ Other _____
- ☐ Scottish TVT Leaflet
- ☐ Colposuspension BAUS
- ☐ Autologous Sling BAUS
- ☐ Bulkamid BAUS Leaflet

Consent signed: Name _____ Date____ / ____ / ____

Taught ISC: Yes / No **Checklist signed (TVT):** ☐

MDT Discussion: Date____ / ____ / ____ Outcome: _____

Operation: _____

Surgeon(s): _____

Date: ___ / ___ / ___ **Entry into database:** ☐ ICIQ-UI Score ___

Post-operative follow-up: Postal / Clinic

Date: ___ / ___ / ___ **Entry into database:** ☐ ICIQ-UI Score ___

Impact of Mesh Halt on Patients

- Focus on conservative management
  - Better engagement
- Threshold for presentation
- Mesh concerns
- Loss of trust
- Limited choice

It is estimated that 14 million people in the UK have bladder control problems.

Less than half of those will seek help and advice.

More people suffer with bladder problems than with asthma, diabetes and epilepsy put together

Bladder and Bowel Foundation (2014)

Root Cause Analysis

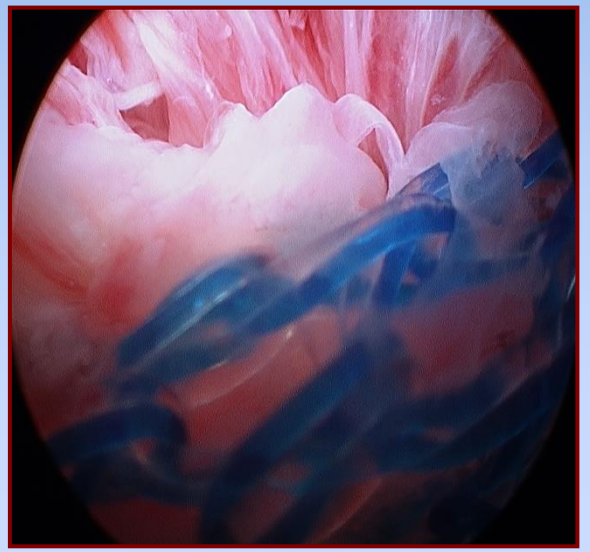
- **Where lies the problem?**
  - Mesh Material
  - Suitability

    (Balance stability / mobility)
  - Application
    - Surgical training
      - Surgical expertise
      - Clinical assessment / Patient selection
      - Awareness of post-operative complications
    - Patient information
    - Appropriate decision making / MDT Involvement

Where are we now?

- Reduced mesh complications
- More patients with unresolved stress incontinence
- Limited choices
  - Increased invasiveness

  or
  - Reduced success rates



What should we aim for?

- **Patient choice** for effective treatment of stress incontinence
  - Option of retropubic TVT
    - Longest experience / Complete removal possible
- **Optimal governance**
  - Continuing "High Vigilance Scrutiny"
  - Awareness of mesh complications
  - Case selection for mesh removals
- Introduction of new procedures / devices only as part of well-designed clinical trials

Table 2: A CLASSIFICATION OF COMPLICATIONS RELATED DIRECTLY TO THE INSERTION OF PROSTHESES (MESHES, IMPLANTS, TAPES) OR GRAFTS IN UROGYNECOLOGICAL SURGERY

CATEGORY

	General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection) D (Abscess)
1	**Vaginal**: no epithelial separation Include prominence (e.g. due to wrinkling or folding), penetration (without separation) or contraction (shrinkage) Grades of mesh contraction (*a*-*e*) from Table 4 is incorporated	1A: Abnormal prosthesis or graft finding on clinical examination	1B: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	1C: Infection (suspected or actual)
2	**Vaginal**: smaller ≤ 1cm exposure	2A: Asymptomatic	2B: Symptomatic	2C: Infection D = Abscess
3	**Vaginal**: larger >1cm exposure, including extrusion	3A: Asymptomatic 1-3A*a* if mesh contraction	3B: Symptomatic 1-3B (*b*-*e*) if mesh contraction	3C: Infection D = Abscess 1-3C (*b*-*e*) if mesh contraction
4	**Urinary Tract** compromise or perforation Include prosthesis (graft) perforation, fistula and calculus	4A: Small intraoperative defect e.g. bladder perforation	4B: Other lower urinary tract complication or urinary retention	4C: Ureteric or upper urinary tract complication
5	**Rectum or Bowel** compromise or perforation Include prosthesis (graft) perforation and fistula	5A: Small intraoperative defect (rectal or bowel)	5B: Rectal injury or compromise	5C: Small or Large bowel injury or compromise D = Abscess
6	**Skin** compromise Include discharge pain lump or sinus tract formation	6A: Asymptomatic, abnormal finding on clinical examination	6B: Symptomatic e.g. discharge, pain or lump	6C: Infection e.g. sinus tract formation D = Abscess
7	**Patient** compromise Include hematoma or systemic compromise	7A: Bleeding complication including haematoma	7B: Major degree of resuscitation or intensive care*	7C: Mortality * *(additional complication - no site applicable - S0)

TIME (clinically diagnosed)

T1: Intraoperative to 48 hours	T2: 48 hours to 6 months	T3: over 6 months

SITE

S1: Vaginal: area of suture line	**S2**: Vaginal: away from from area of suture line	**S3**: Trocar passage Exception: Intra-abdominal (S5)	**S4**: other skin site	**S5**: Intra-abdominal

N.B.
1. Multiple complications may occur in the same patient. There may be early and late complications in the same patient. i.e. All complications to be listed. Tables of complications may often be procedure specific.
2. The highest final category for any single complication should be used if there is a change within time. (patient 888)
3. Urinary tract infections and functional issues (apart from 4B) have not been included.

IUGA ICS international urogynecological association

CODE

☐☐☐ - T ☐ - S ☐

PRIMUM NON NOCERE

"A good surgeon knows when not to operate"

Victor Bonney 1937

Thank You