
1937

How do we react on the FDA-report on alloplastic materials ?

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Urogynecologic Surgical Mesh:

Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse

July 2011


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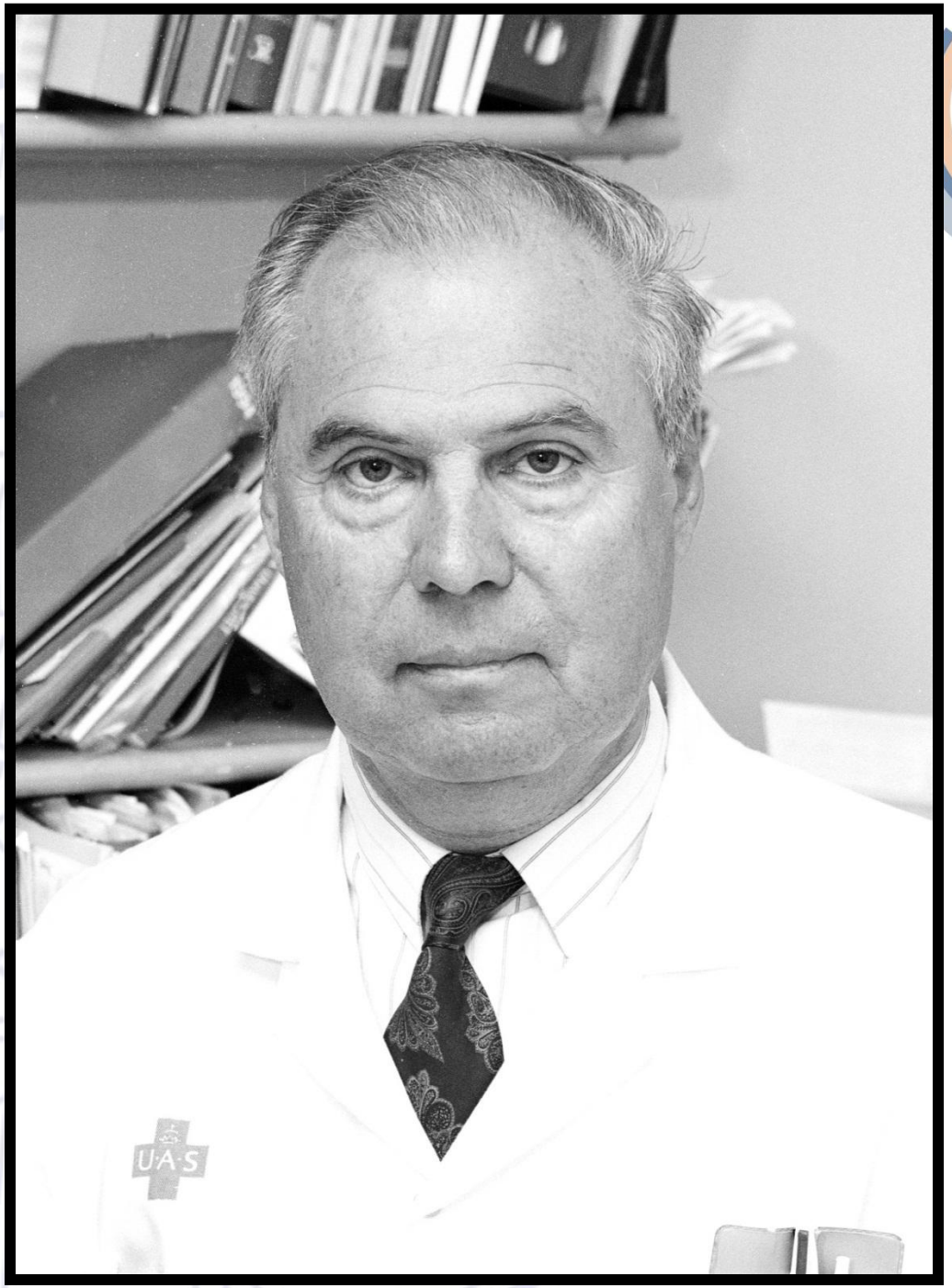
I understood from my good friend Metil Itil that medicolegal problems are important in Turkey - as they are in Germany



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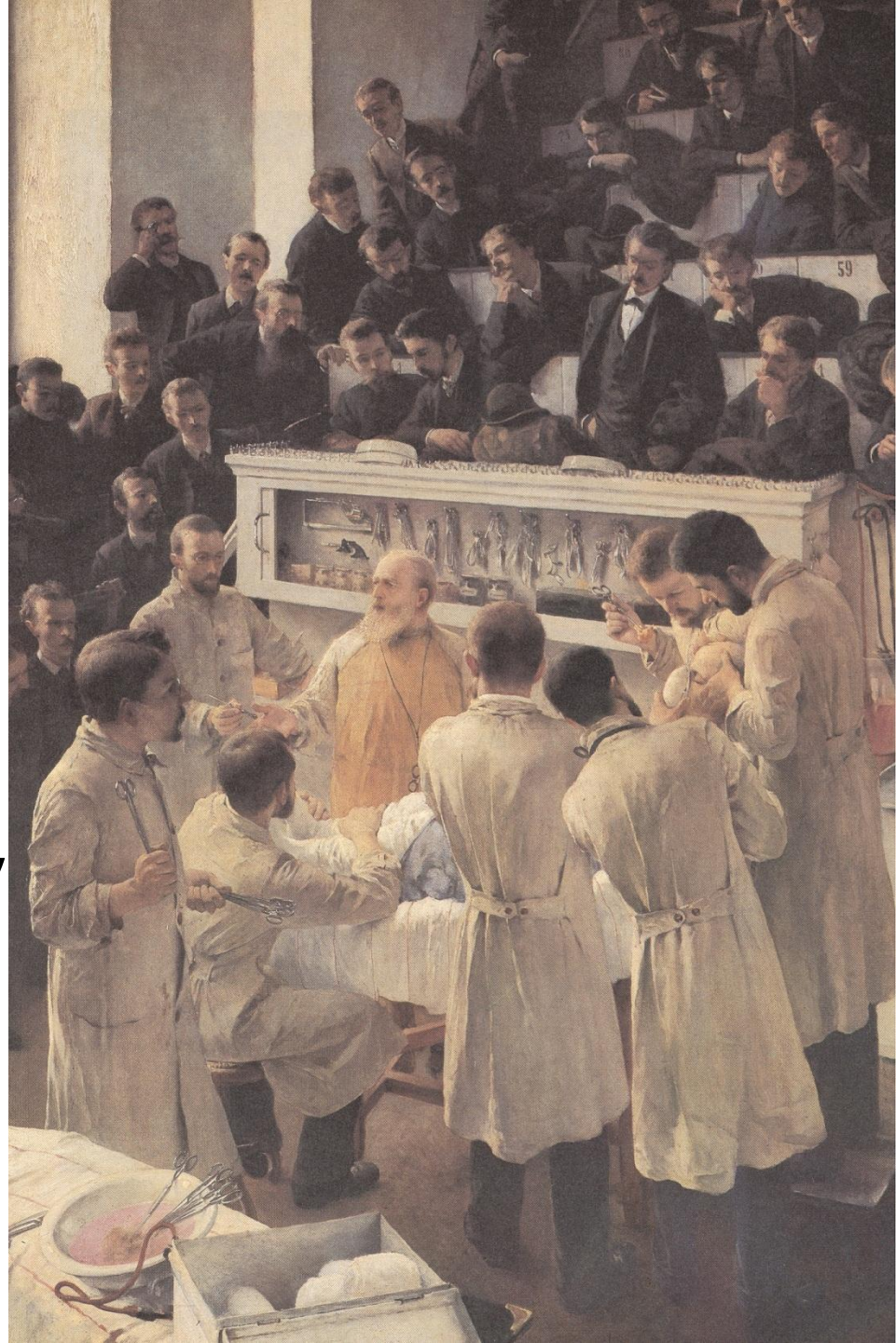
There is no condition or disease that cannot be made worse by surgery !

aim of old surgeons:

- patient should survive
- patient should not have an infection
- patient should not be worse than before surgery



What are the expectations of our patients?

Robinson et al (Kings College Hospital London)2013

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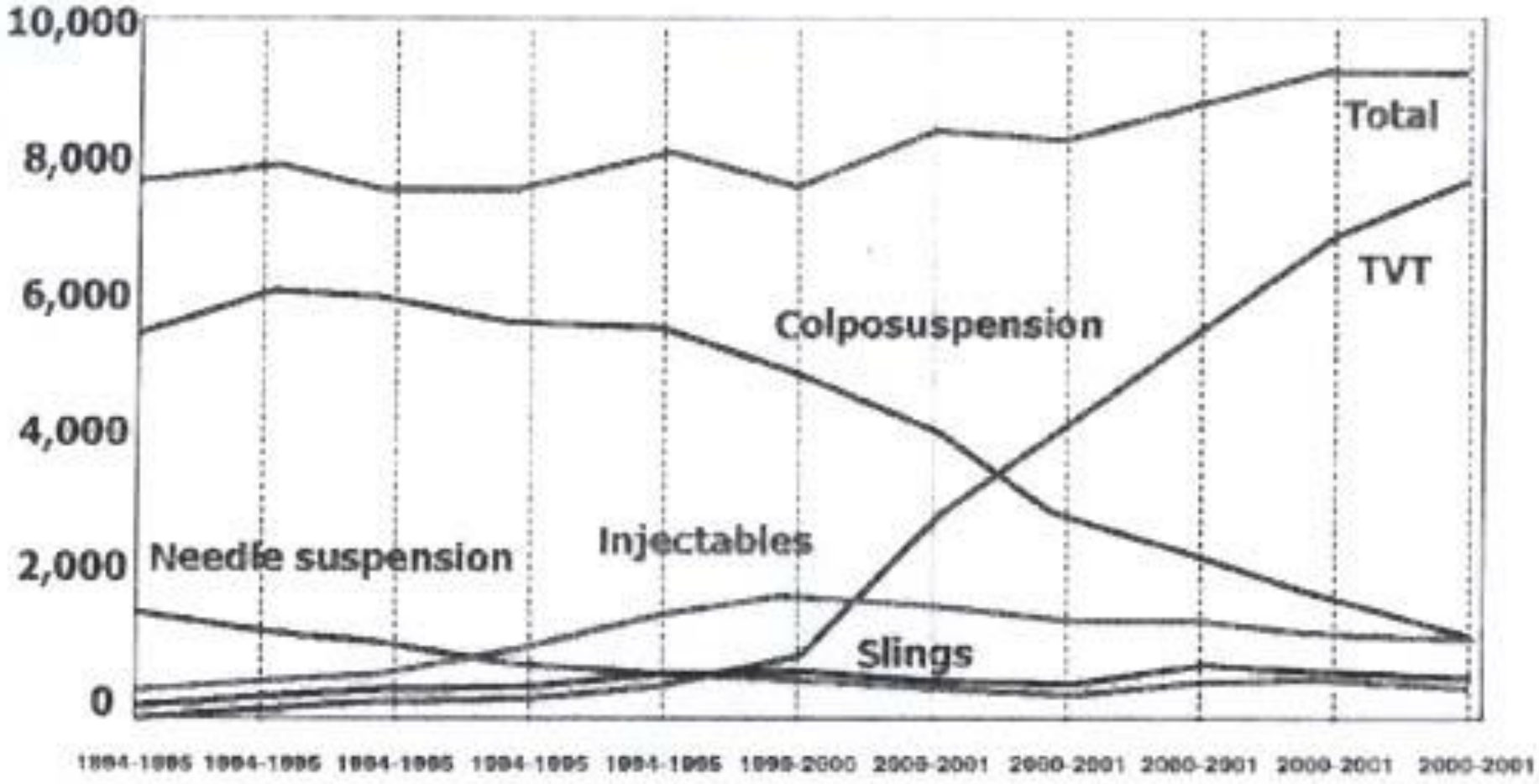
57 % are happy with a 60% improvement without side effects

38 % accept a minor procedure with a 85 % success rate and a 2% risk of side effects (e.g. self catheterisation)

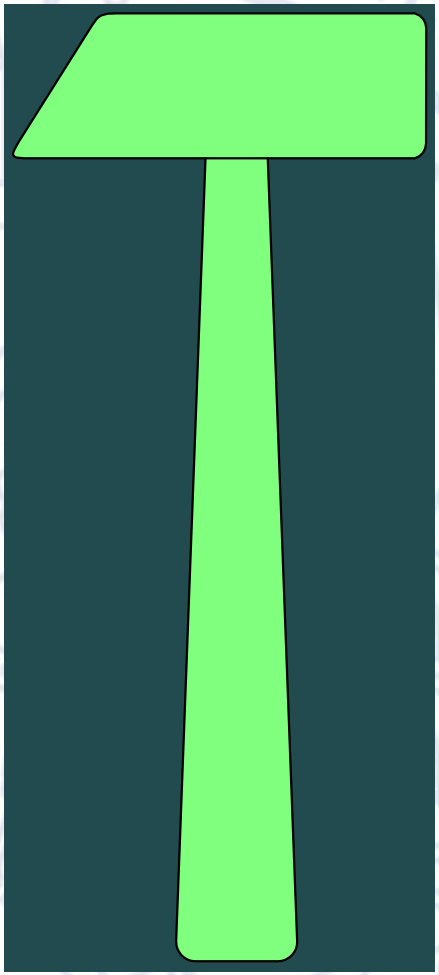
23 % accept a major operation with a 85 % success rate and a 2% risk of side effects (e.g. self catheterisation)

A woman’s estimated lifetime risk of POP is 30-50 percent, with 2 percent of women becoming symptomatic. Symptomatic POP can be managed conservatively with either pelvic floor muscle exercises or vaginal inserts to support the prolapsing tissue (pessaries). Surgical correction is also an option, although not all women will have long-term improvement in symptoms from traditional surgical correction without mesh . In total, women have an estimated 11 percent lifetime incidence of surgery to repair POP or SUI .

Hospital episode statistics 1994-2005



Department of Health – Hospital Episode Statistics
Ward & Hilton, ICS 2006



If You have a new hammer,
every problem looks like a nail !

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danger
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How t
doctor
Elizabeth V

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Richard Smith
editor
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BMJ 2003;326:12

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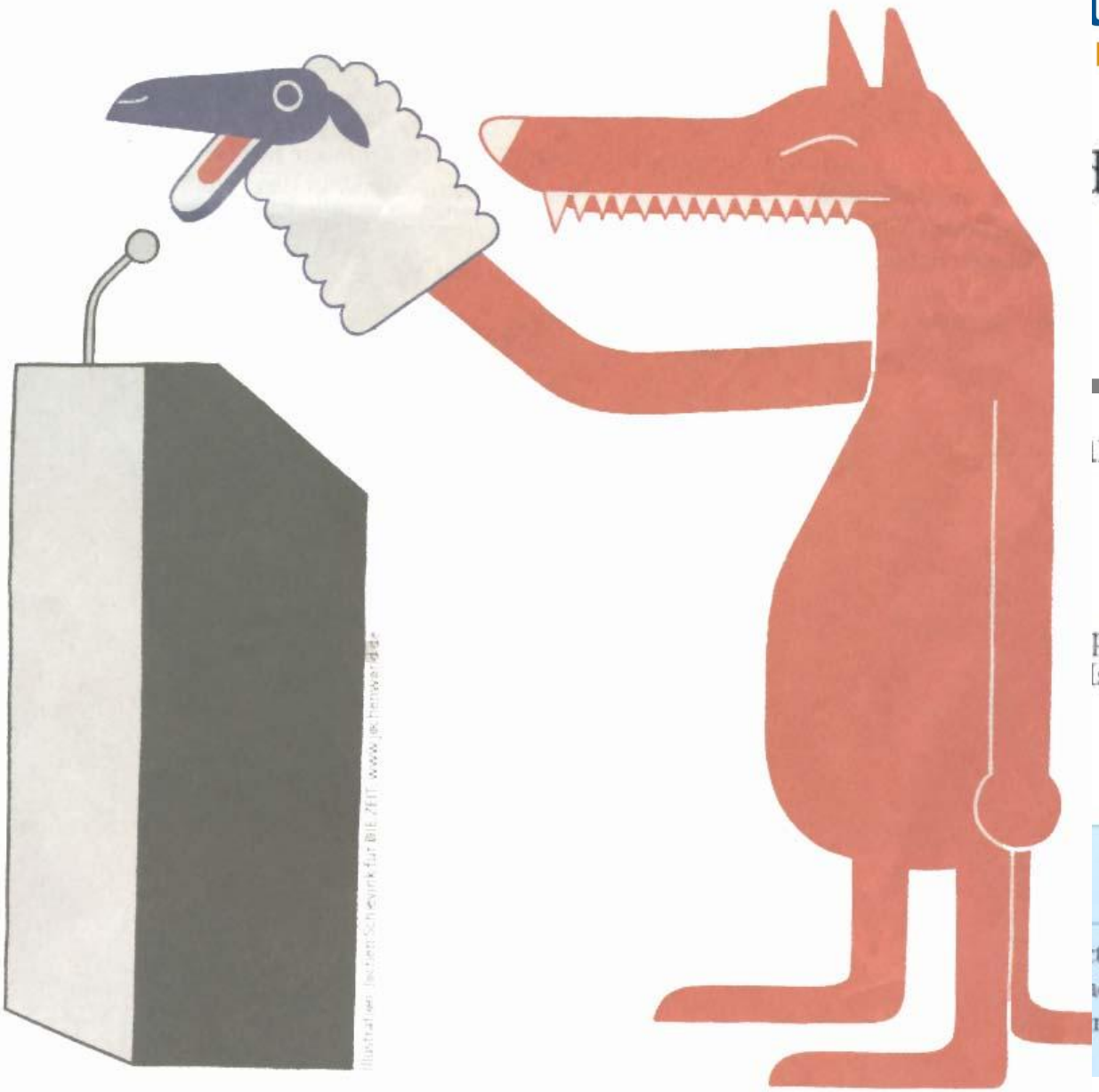


38th ANNUAL MEETING
Dublin, Ireland
May 28 - June 1, 2013
IUGA
DUBLIN 2013
CFI
12 papers and posters discussing products taken from the market at that time !

> 5 000 000 implanted worldwide

- TVT (Gynecare)
- LIFT™ (Cousin Biotech)
- Serasis™ (Serag Wiessner)
- Obtape™ (Mentor)
- Uretex™ (Sofradim)
- Monarc™ (AMS)
- T-Sling™ (Herniamesh)
- Stratasis™ (Cook)
- Uratape™ (Porges)
- I.STOP™ (CL Medical)
- Lynx™ (Boston Scientific)
- Veritas™ Collagen Matrix
- Synovis
- DynaMesh (FEG-textile)
- MiniArc (AMS)
- Adjust,Surgimesh,Aspira,Ophira, Gynemesh, Elevate….

- Sabre™ (Mentor)
- IVS™ (Tyco)
- SPARC™ (AMS)
- PelviLace™ (Mentor)
- Tordynex™ (Tulip)
- Pro Surg-Biosling™
- Remeex™ (Neomedic)
- Safyre™ (Promedon)
- TOB™ (Porgès)
- Swing-band™ (Text.HI-TEC)
- Obtryx™ (Boston Scientific)
- Emerald™ (Gallini)
- TVT-O (Gynecare)
- TVT-Secur (Gynecare)
- MiniArc Pro (AMS)

The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications

An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

many of the „new“ slings and meshes did not have to provide any data, because they fulfilled the 510(k) conditions - apparently not !

W.Edwards Deming 1900-1993

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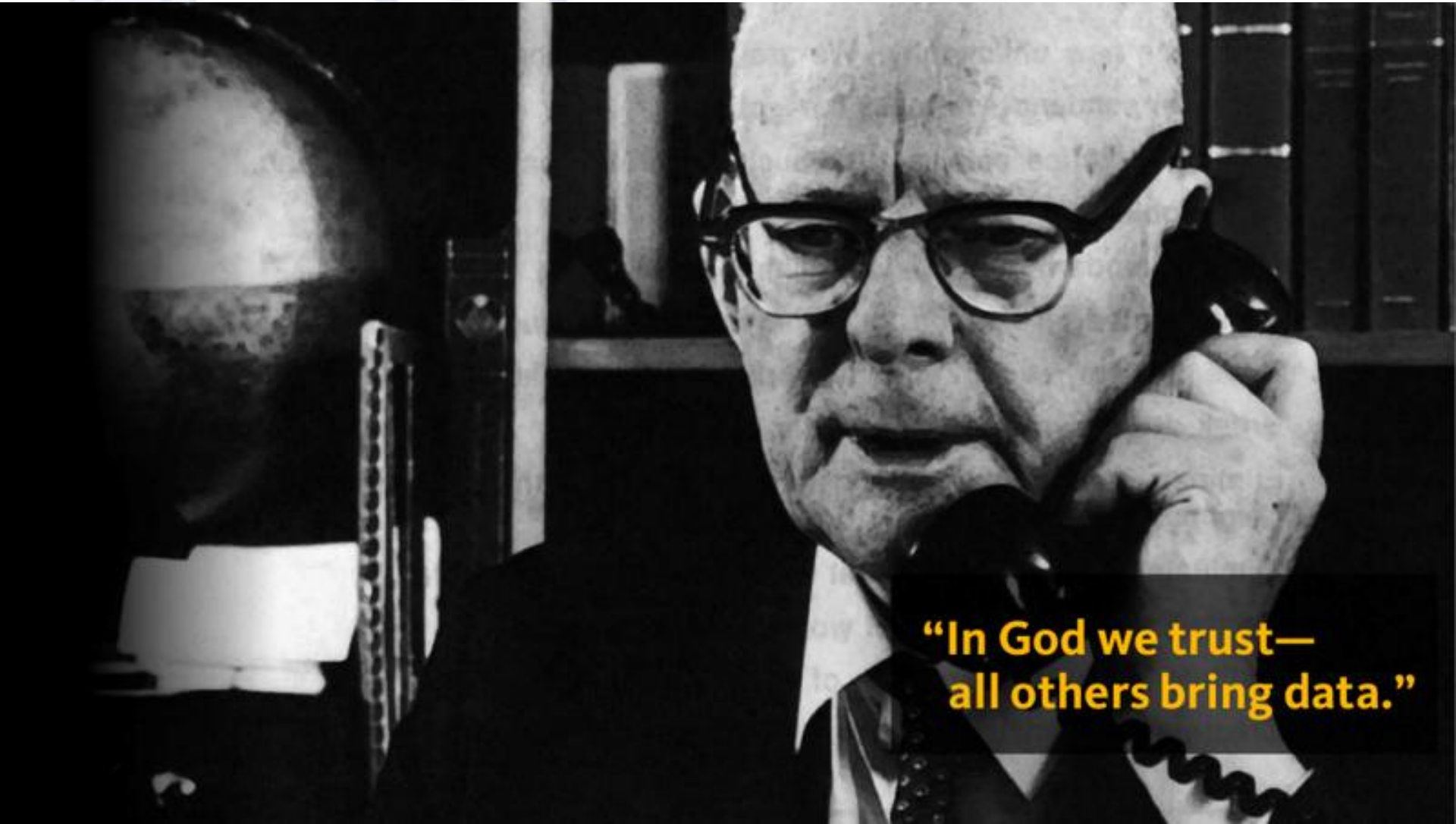

Table 2: A CLASSIFICATION OF COMPLICATIONS RELATED DIRECTLY TO THE INSERTION OF PROSTHESES (MESHES, IMPLANTS, TAPES) OR GRAFTS IN UROGYNECOLOGICAL SURGERY

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	**T2**: up to 24 hours post - op	**T3**: 24 hours to 2 weeks post – op	**T4**: 2 weeks to usual post - op review (6 to 12 weeks)	**T5**: Post - op review to 12 months	**T6**:1 - 3 yrs post - op	**T7**: >3yrs post - op

SITE

S1: Vaginal: area of suture line	**S2**: Vaginal: away from from area of suture line	**S3**: Vaginal Vault	**S4**: Trocar passage Exception: Intra-abdominal (S7)	**S5**: Trocar entry / exit	**S6**: other skin site	**S7**: 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 ☐

Peter K. Sand, Evanston Continence Centre, Evanston. Illinois. U.S.A.

Obstetrics & Gynecology:
August 2010 - Volume 116 - Issue 2, Part 1 - pp 293-303
doi: 10.1097/AOG.0b013e3181e7d7f8
Original Research

Vaginal Mesh for Prolapse: A Randomized Controlled Trial

Iglesia, Cheryl B. MD; Sokol, Andrew I. MD; Sokol, Eric R. MD; Kudish, Bela I. MD; Gutman, Robert E. MD; Peterson, Joanna L. RN; Shott, Susan PhD

Cochrane

Abstract

OBJECTIVE: To present 3-m
a double-blind, multicenter ra
controlled trial comparing trac
prolapse surgery without mes
surgery with mesh.

METHODS: Women with pelv
quantification prolapse stage
randomized to vaginal colpop
mesh or traditional vaginal co
mesh. The primary outcome
objective treatment success (
prolapse quantification stage
months. Secondary outcome
included quality-of-life variable
complication rates.

RESULTS: Sixty-five women were recruited
from January 2007 to August 2009, when the

CONCLUSION: At 3 months, there is a high vaginal mesh erosion rate (15.6%) with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs.

CLINICAL TRIAL REGISTRATION: Clinicaltrials.gov, www.clinicaltrials.gov, NCT00475540.

LEVEL OF EVIDENCE: I

NIHILISM

Believing in nothing can be exhausting.

500 reoperations after alloplastic slings/meshes

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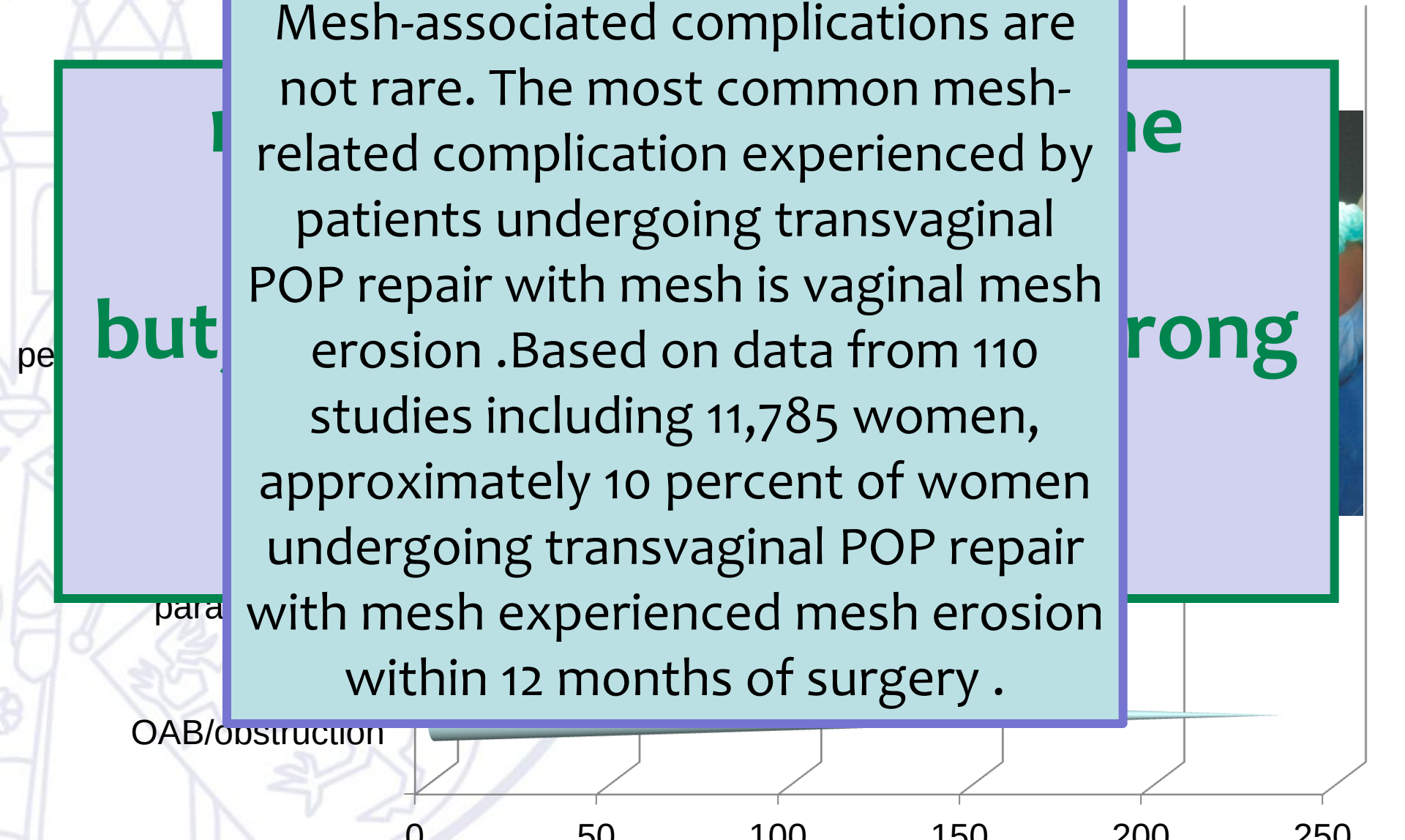
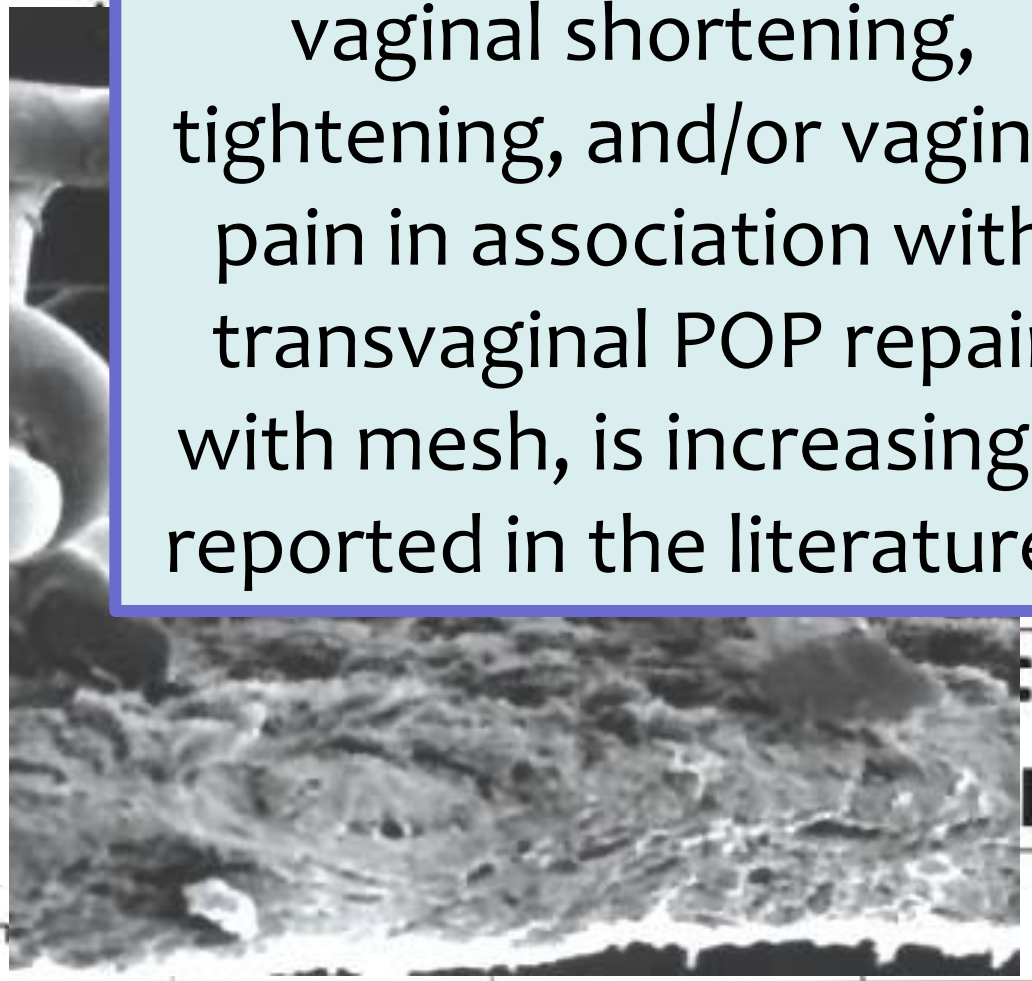
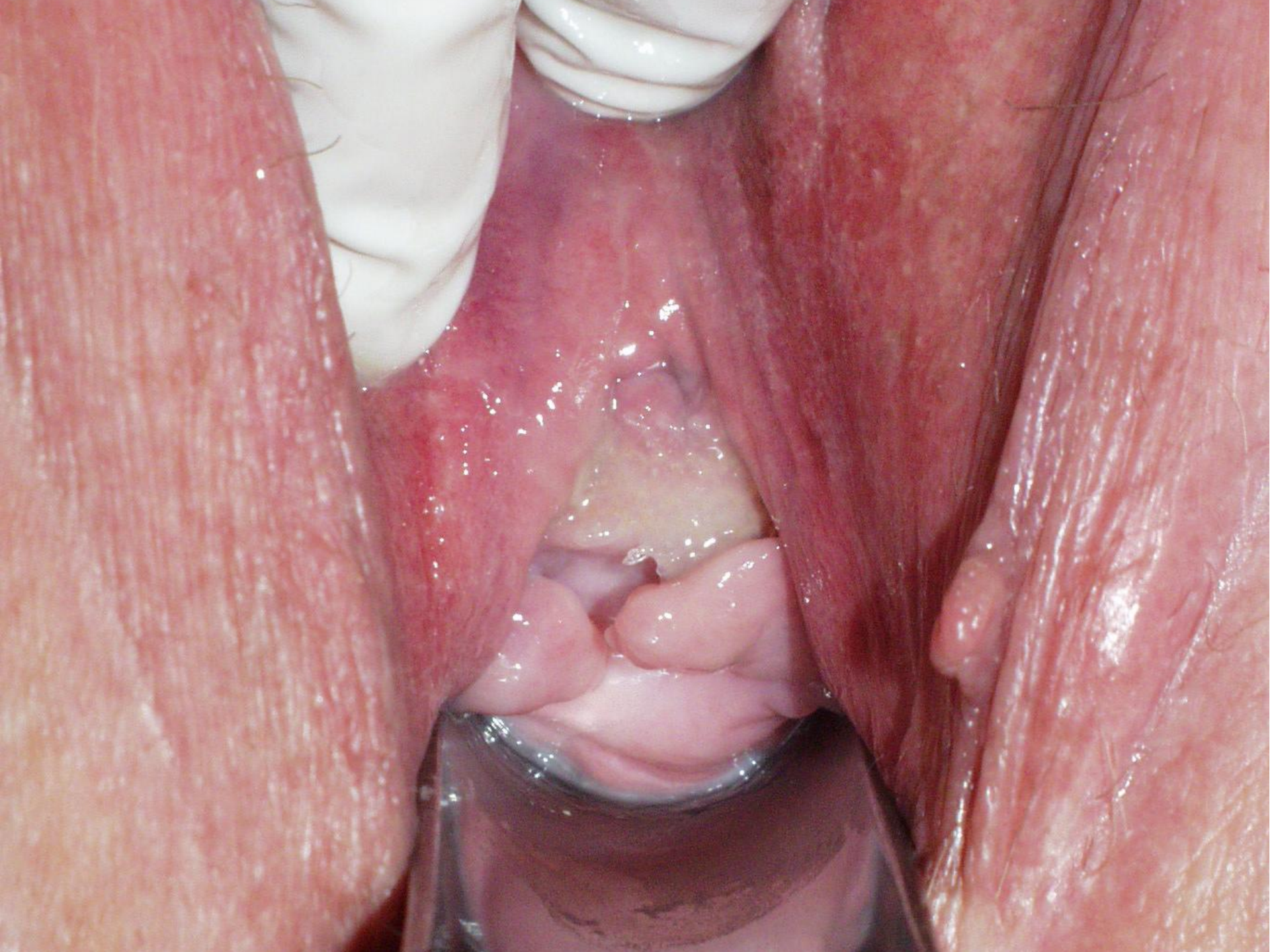
Mesh-associated complications are not rare. The most common mesh-related complication experienced by patients undergoing transvaginal POP repair with mesh is vaginal mesh erosion .Based on data from 110 studies including 11,785 women, approximately 10 percent of women undergoing transvaginal POP repair with mesh experienced mesh erosion within 12 months of surgery .



		Deteriorated	Non Deteriorated	Total	Percentage of degradation
PolyPropylene	LDPPMF	6	22	28	21,43%
	HDPPMF	11	12	23	47,83%
	PPMonofilament	17	34	51	33,33%
	NKNW	8	0	8	100%
	PPMultifilament	3	1	4	75%
	Comp				
	Tota				
Polyester	P				

Mesh contraction, causing vaginal shortening, tightening, and/or vaginal pain in association with transvaginal POP repair with mesh, is increasingly reported in the literature .





mesh erosions

metaanalysis: 54 studies; 7054 women

up to 12 % mesh erosions after abdominal colposacropexy

up to 21 % mesh erosions after vaginal mesh insertion

Int Urogynecol J 2010;21:1413-31

symptoms of defect healing

asymptomatic

Int Urogynecol J (2012) 23:127–129
DOI 10.1007/s00192-011-1498-9

CASE REPORT

Partner dyspareunia—a report of six cases

Eckhard Petri · Kiran Ashok

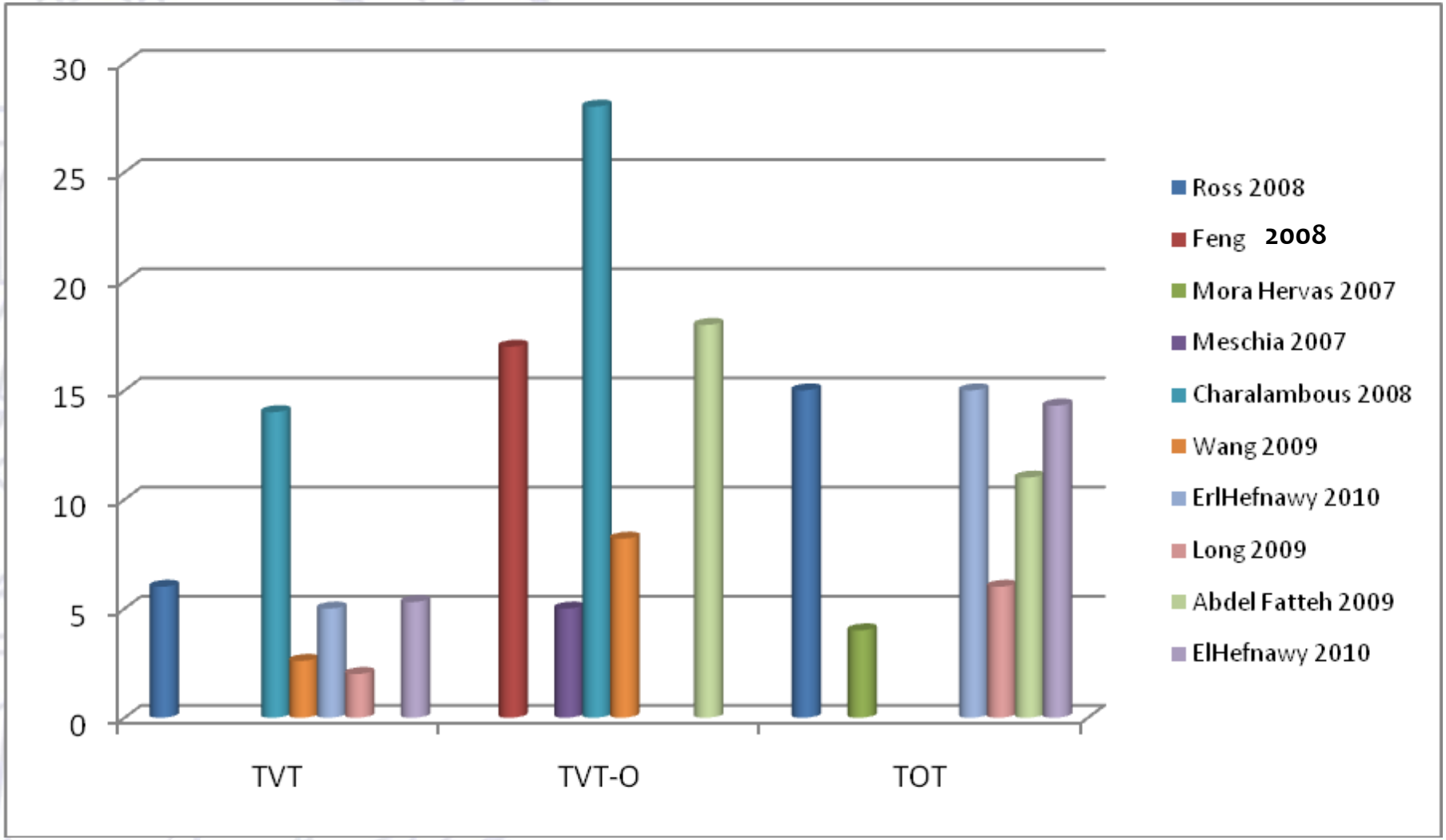
Outsch !

dyspareunia/hispareunia after meshes

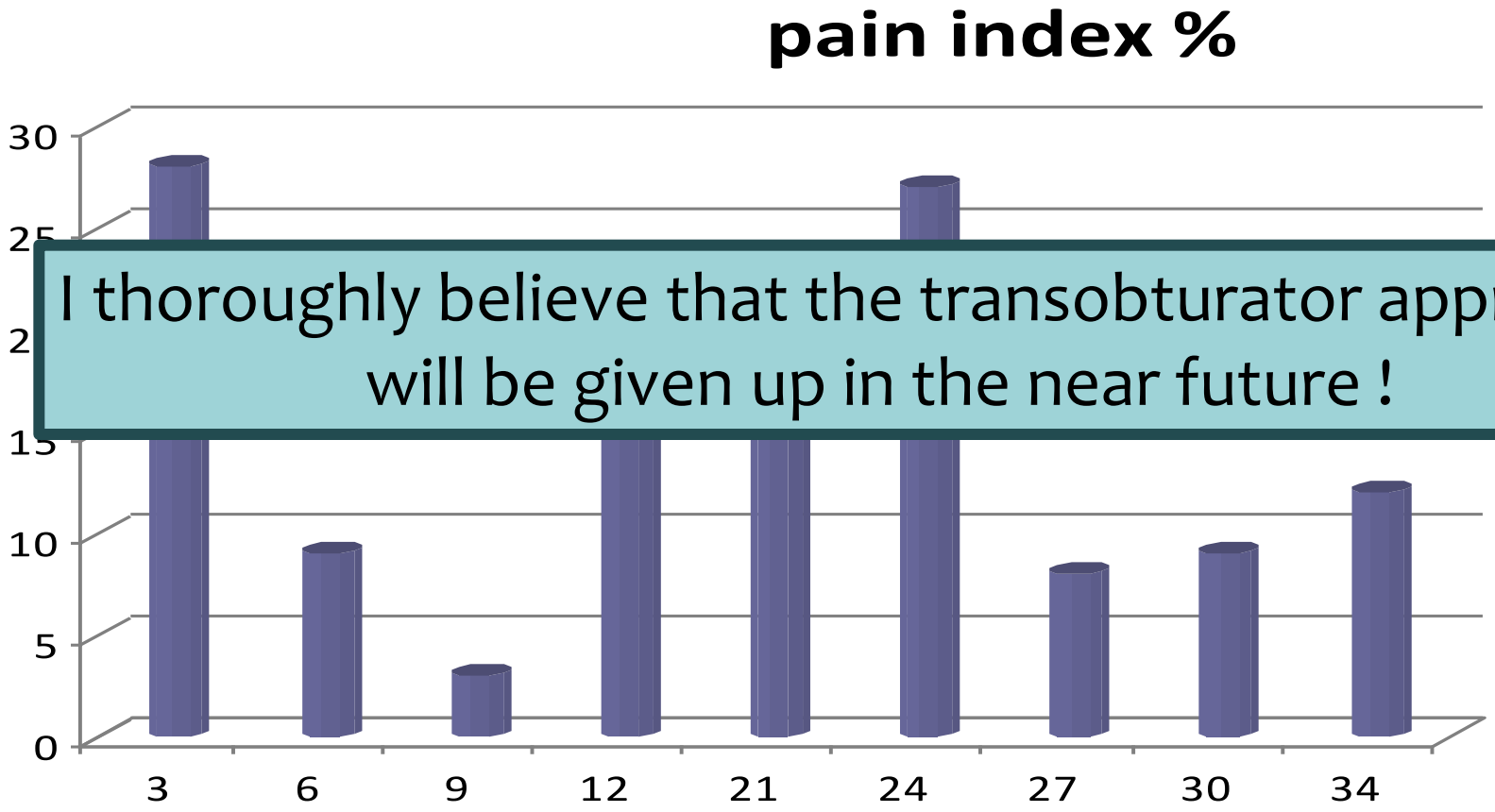
Withagen	2011	294	20/71 (28%)	12	PP
Maher	2011	55	3/21 (14%)	24	
Long	2011	60 (Perigee™)	10/60 (16%)	6	
		48 (Prolift™)	12/48 (25%)	6	
Milani	2011	127	1/43 (2%)	12	
Sergent	2011	101	4/52 (8%)	57	
Sayer	2011	110	2/32 (6%)	24	
Jacquetin	2010	90	5/35 (14%)	3	
Moore	2010	87	6/65 (9%)	24	
Fayyad	2010	36	7/16 (43%)	24	
Feiner	2010	117	4/50 (8%)	12	
Wetta	2009	50		12	
Milina	2009	46	2/11 (18%)	1	
Altman	2009	69		12	
Su	2009	33		6	
Lowman	2008	57	6/35 (17%)	12	
Hinoul	2008	48	3/20 (15%)	12	
Sentilhes	2008	83	6/37 (16%)	1	
de Tayrac	2007	143	10/78 (12.8%)	10	Coated PP

No

pain after transobturator approach

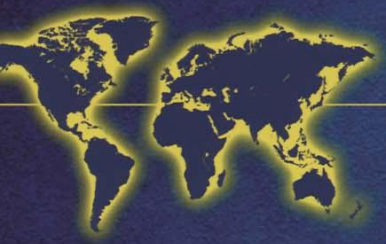


pain does not disappear after 4 weeks, even not after 4 months !



I thoroughly believe that the transobturator approach will be given up in the near future !

ubmit manuscripts: http://www.editorialmanager.com/iujo/



International Urogynecology Journal

Volume 22 Number 5 May 2011

Universitätsmedizin GREIFSWALD

Int Urogynecol J (2011) 22:505–506
DOI 10.1007/s00192-011-1407-2

EDITORIAL

To mesh or not to mesh? That is the question

Steven Swift

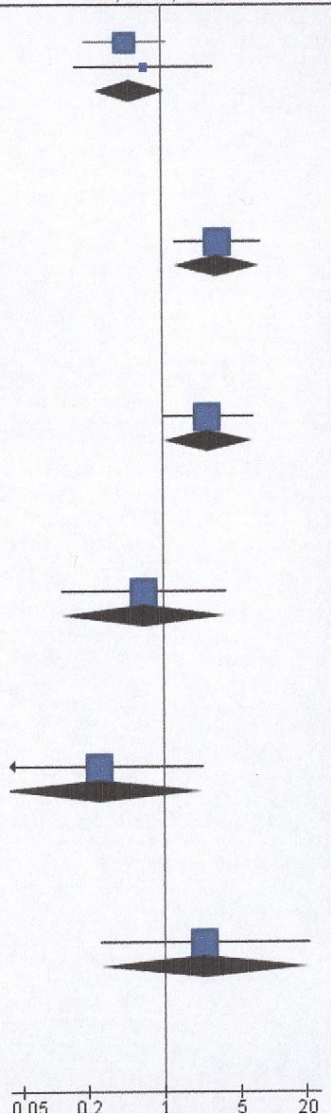
So, how do we answer the question; to mesh or not to mesh? I strongly believe that both approaches are adequate and serve our patients well.

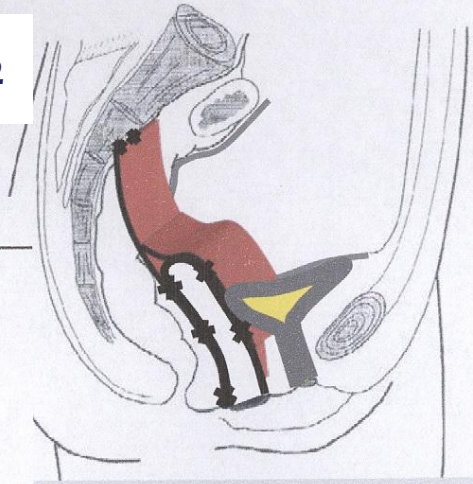
Springer

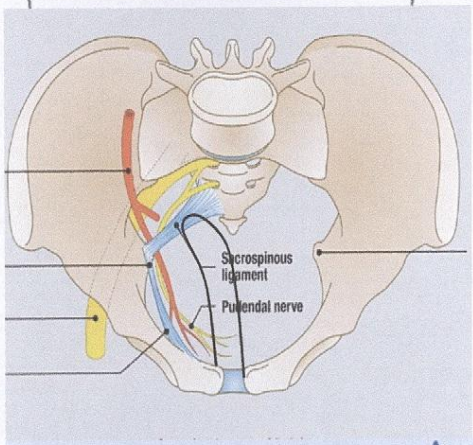
apical prolapse - symptoms

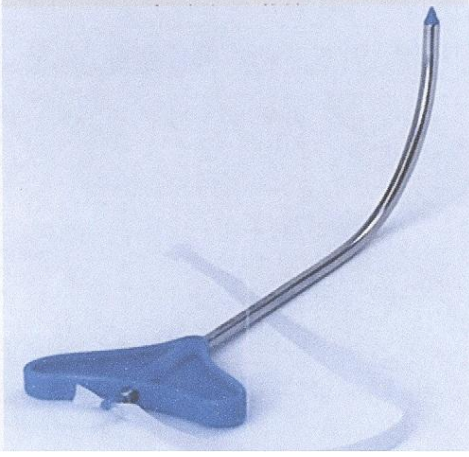
K.Baessler 2012

Study or Subgroup	Method A Events	Method A Total	Method B Events	Method B Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.1.1 abdominal sacral colpopexy vs vaginal sacrospinous colpopexy						
Benson 1996	6	38	14	42	76.3%	0.47 [0.20, 1.11]
Maher 2004	3	46	4	43	23.7%	0.70 [0.17, 2.95]
Subtotal (95% CI)		84		85	100.0%	0.53 [0.25, 1.09]
Total events	9		18			
Heterogeneity: Chi² = 0.21, df = 1 (P = 0.65); I² = 0%						
Test for overall effect: Z = 1.72 (P = 0.09)						
1.1.2 abdominal sacro-hysteropexy versus vaginal hysterectomy plus anterior and/or posterior colporrhaphy at 1 year						
Roovers 2004	16	41	5	41	100.0%	3.20 [1.29, 7.92]
Subtotal (95% CI)		41		41	100.0%	3.20 [1.29, 7.92]
Total events	16		5			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.52 (P = 0.01)						
1.1.3 abdominal sacro-hysteropexy versus vaginal hysterectomy plus anterior and/or posterior colporrhaphy at 8 years						
Roovers 2004	13	42	5	42	100.0%	2.60 [1.02, 6.65]
Subtotal (95% CI)		42		42	100.0%	2.60 [1.02, 6.65]
Total events	13		5			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.00 (P = 0.05)						
1.1.4 vaginal sacrospinous colpopexy vs posterior intravaginal slingplasty						
Meschia 2004a	2	33	3	33	100.0%	0.67 [0.12, 3.73]
Subtotal (95% CI)		33		33	100.0%	0.67 [0.12, 3.73]
Total events	2		3			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.46 (P = 0.64)						
1.1.5 laparoscopic sacral colpopexy vs total vaginal polypropylene mesh						
Maher 2011 NEW	1	53	4	55	100.0%	0.26 [0.03, 2.25]
Subtotal (95% CI)		53		55	100.0%	0.26 [0.03, 2.25]
Total events	1		4			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.23 (P = 0.22)						
1.1.6 uterosacral colpopexy vs vaginal polypropylene mesh						
Iglesia 2010 NEW	3	33	1	26	100.0%	2.36 [0.26, 21.42]
Subtotal (95% CI)		33		26	100.0%	2.36 [0.26, 21.42]
Total events	3		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.76 (P = 0.44)						









Posterior compartment

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Posterior repair with autologous tissue without insertion of a mesh has a success rate of 86% and remains a good option in the primary situation (LOE 1b).

Actually there is no reason to use non-absorbable meshes *routinely* in primary vaginal prolapse surgery in the posterior compartment, taking in account the higher complication rates (LOE 2).

Be aware of complications !

at an averge the anatomical success rate is 10% higher with the use of synthetical mesh, but, complication rates with dyspareunia, mesh erosions and mesh contraction with pain has to be taken in account (LOE 2).

AWMF-guidelines-registry **Nr. 015/006**

U.S. Food and Drug Administration

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News & Events

FDA NEWS RELEASE

For Immediate Release: July 13, 2011
Media Inquiries: Karen Riley, 301-796-4674, karen.riley@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA: Surgical placement of mesh to repair pelvic organ prolapse poses risks
Agency says other options may expose women to less risk than transvaginal procedure

The U.S. Food and Drug Administration today issued an updated safety communication warning health care providers and patients that surgical placement of mesh through the vagina to repair pelvic organ prolapse may expose patients to greater risk than other surgical options.

reduction of recurrencies with meshes of app. 10%

same incidence of reoperations – complications !

patient satisfaction identical – no advantage with meshes !

In October 2008, the FDA issued a Public Health Notification (PHN) to inform clinicians and patients of adverse events related to urogynecologic use of surgical mesh, and to provide recommendations on how to mitigate risks and how to counsel patients. Following the PHN, the FDA continued to monitor the outcomes of urogynecologic use of surgical mesh. A search of the FDA's Manufacturer and User Device Experience (MAUDE) database from the last 3 years (January 1, 2008 - December 31, 2010), identified 2,874 Medical Device Reports (MDRs) for urogynecologic surgical meshes, including reports of injury, death, and malfunctions. Among the 2,874 reports, 1,503 were associated with pelvic organ prolapse (POP) repairs, and 1,371 were associated with stress urinary incontinence (SUI) repairs.

Physicians should:

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.

Physicians should:

- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).

COMPLICATIONS FROM GYNECARE PROLIFT AND BARD AVAULTA MESH PRODUCTS

If you have had a **Gynecare Prolift** prolene mesh or **Bard Avaulta** mesh product placed in your body for pelvic floor repair or urinary incontinence, and have suffered complications, you may have a viable product liability claim against the manufacturers of those products. Ethicon, which is a division of Johnson & Johnson manufacturers the Gynecare Prolift and C.R. Bard, Inc. manufactures the Bard Avaulta. The known complications include, but are not limited to, mesh erosion, mesh shrinkage, infection, granuloma formation, dyspareunia (pain with sexual relations) and neuropathic pain. The failure of the Gynecare Prolift and Bard Avaulta mesh products can lead to the need for multiple operations to remove the mesh, and can result in additional severe injuries such as scar tissue, neuropathic pain and urinary problems. These problems have recently been recognized by the FDA in Public Health Notifications issued in October 2008 and February 2009, in which over 1000 reports and complaints regarding mesh products were lodged.

We are currently litigating against Ethicon and Johnson & Johnson, and are expanding our litigation against C.R. Bard. If you believe that you have been seriously injured due to these products, and you are interested in learning more about how we can help, please provide the following information:

First Name: Last Name:

Address:

City: State: Choose One Zip:

E-mail: Phone:

Date of Initial Implant Surgery: (format: mm/dd/yyyy)

Name of Product(s) initially implanted:

Date of First Complications: (format: mm/dd/yyyy)

Explanation of Complications (please be detailed):

Send Info

DISCLAIMER: This does not constitute legal advice. By providing the requested information you are not entering into an attorney-client relationship with this law firm. Only a written retainer agreement between you and our law firm can create such a relationship.

"The doctor is in court on Tuesdays and Wednesdays."

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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

the reaction is very variable in different countries

- **in the USA meshes for prolapse repair nearly completely disappeared**
- **in Germany apparently only few surgeons care**
- **there are even new developments and products without data !**

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S W A L D

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- lon

RECOMMENDATION:

It is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk. The Safety Communication provides updated recommendations for health care providers and patients and updates the FDA's activities involving surgical mesh for the transvaginal repair of POP.

own concept

- primary prolapse : native tissue repair
- total prolapse : sacrospinous fixation
- recurrent prolapse : abdominal sacrocolpopexy
- paravaginal defect: colposuspension
- multiple recurrencies : **mesh**

TAJEV

April 30th - May 4th, 2014

Titanic Deluxe Hotel, Belek - Antalya

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