

# DISCLOSURES No financial

# OBJECTIVE

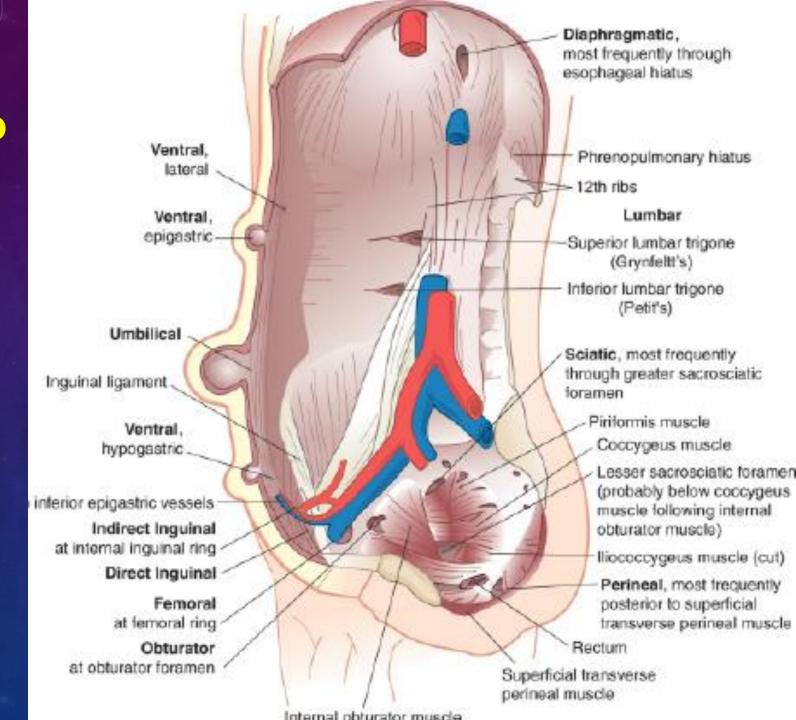
- Mesh overview
- Indications
- Vaginal mesh
- ACC/Medsafe data

# HEY DOC... I HAVE A HERNIA



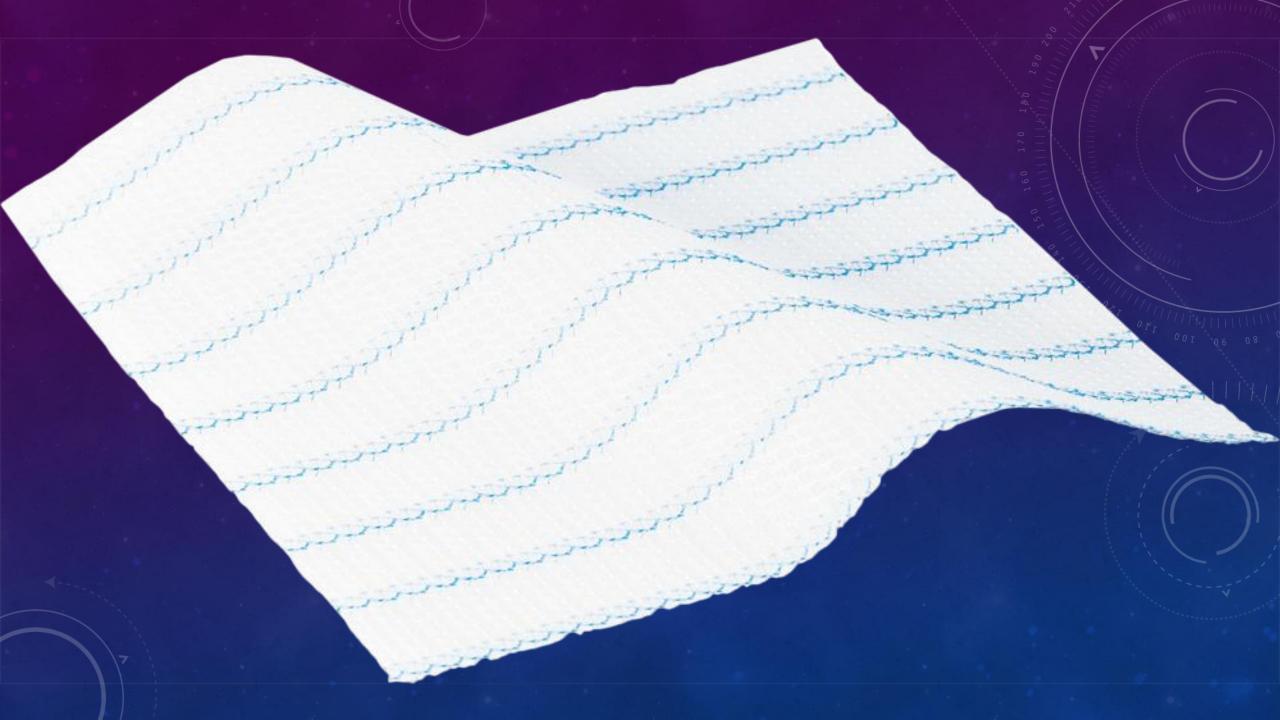
# What is a hernia?

Why do we fix them?





Staubitz J 2017





# THE IDEAL MESH

Strong

Cheap

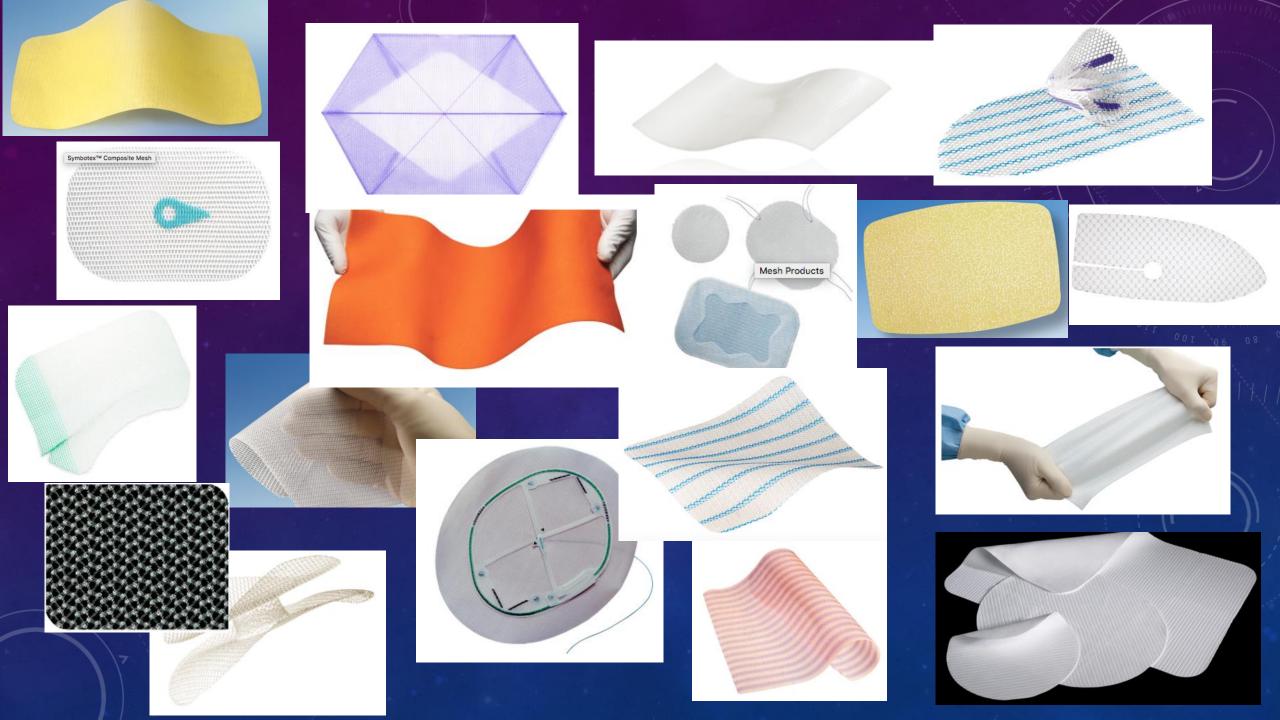
Easy to handle

Resistant to infection

Stable

Inert

Nonallergenic



# TYPE OF MESH

- Synthetic, non composite
  - Permeant
    - Polyester, (PE), Polypropylene (PP), expanded polytetrafluoroethylene (ePTFE)
  - Absorbable
    - Polygycolic acid, Polyglactin 910 (Vicryl)
- Composite
- Biologic dermis, submucosa, small intestine, pericardium
  - Human
  - Animal (bovine or porcine)

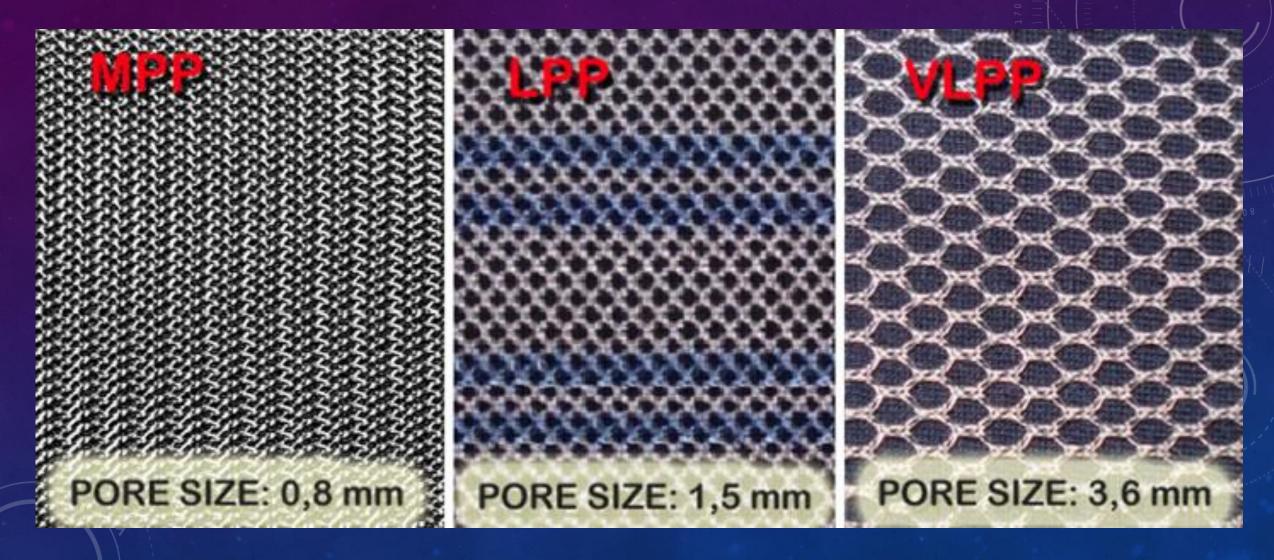








# **PORE SIZE**



# WEIGHT







# FILAMENT STRUCTURE













Feedback

#### Surgical mesh - Wikipedia

https://en.wikipedia.org/wiki/Surgical\_mesh •

**Surgical mesh** is a loosely woven sheet which is used as either a permanent or temporary support for organs and other tissues during **surgery**. **Surgical mesh** is created from both inorganic and biological materials and is used in a variety of surgeries.

Medical Uses · Pelvic surgery · Biocompatibility · PVDF (nanofibrous mesh)

#### Medsafe removes surgical meshes from supply in New Zealand | Stuff ...

https://www.stuff.co.nz/.../medsafe-removes-surgical-meshes-from-supply-in-new-zeal... ▼
Dec 11, 2017 - Surgical mesh used for some gynaecological procedures will be removed from New Zealand's supply by January 4, Medsafe has announced.

#### Patients who say surgical mesh has made their lives a 'living hell ...

https://www.stuff.co.nz/.../patients-who-say-surgical-mesh-has-made-their-lives-a-livin... ▼ Jun 4, 2017 - Blucher is one of an untold number of women in New Zealand who have suffered catastrophic injuries from the insertion of **surgical mesh** to ...

#### Urogynaecological Surgical Mesh Implants - Medsafe

www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp ▼
Jun 28, 2018 - Surgical mesh is in use for urogynaecological surgery including repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Surgery is used to treat pelvic organ prolapse when other non-invasive treatments have been found to be not suitable or have failed.

#### Surgical mesh registry on way, no temporary ban | RNZ

https://www.radionz.co.nz/.../surgical-mesh-registry-on-way-no-temporary-ban ▼
Aug 7, 2018 - Surgical mesh advocacy group, Mesh Down Under, is claiming a partial victory in its campaign against the harm caused by the medical ...

national

Using surgical mesh for hernias 'safe and effective', surgeon says •

Cate Broughton • 10:23, Oct 06 2017











# Risks trom surgical mesh in hernia repair too high, Canadian surgeon says

Cate Broughton • 18:07, Jan 14 2018















# Mesh Down under

Dedicated to support and information sharing for New Zealanders injured by surgical mesh.

www.meshdownunder.co.nz

















CASES WE HANDLE ABOUT ATTORNEYS VICTORIES FAQS

#### **HERNIA MESH LAWYER**

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**ABOUT** 

**DEFECTIVE HERNIA MESH** 

**NEWS** 

**GET IN TOUCH** 

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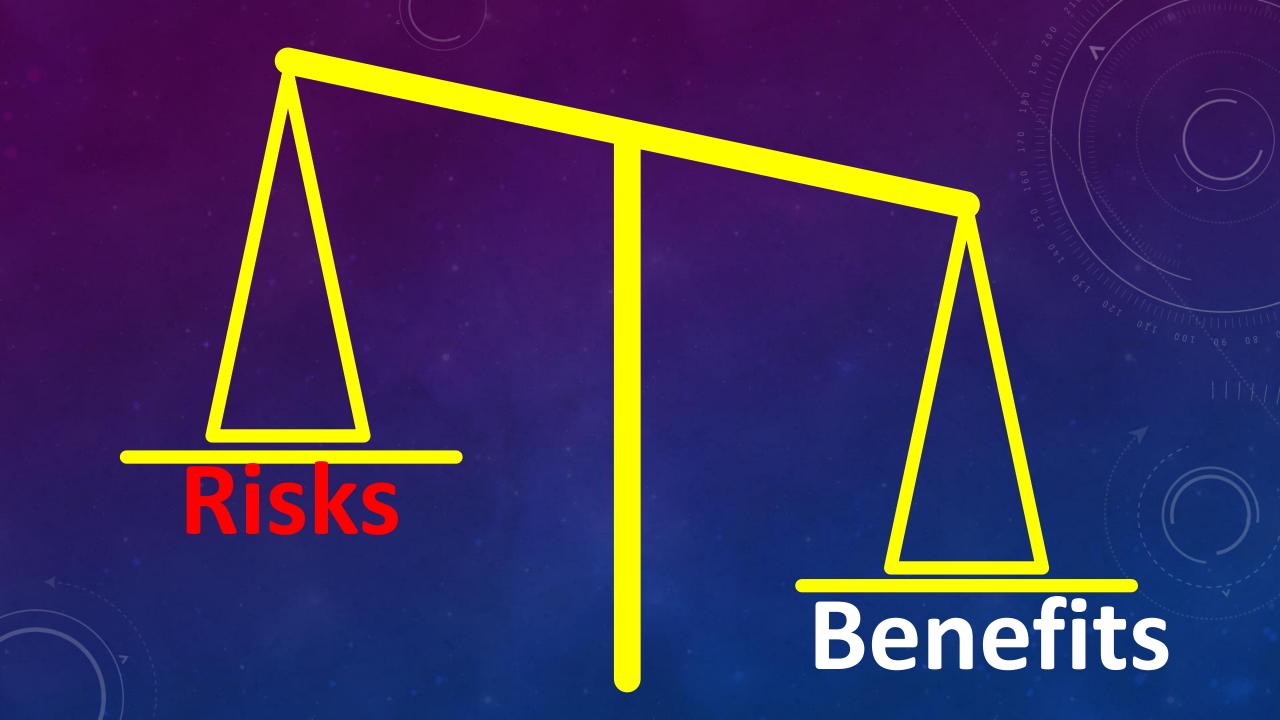


# Bard® Mesh PerFix®Plug, Medium Monofilament Knitted Polypropylene

hernia MESH LAWSUIT

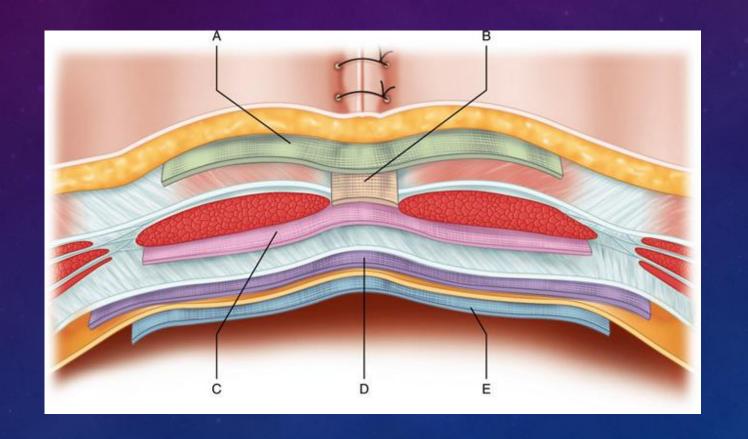
#### AVOID HERNIA MESH LAWYERS WHO ARE ONE TRICK PONIES

Some hernia mesh attorneys are best described as one trick ponies. This means that these mesh law firms or attorneys will only handle a limited amount Ethicon Psylomesh lawsuits in Federal Court or perhaps a couple of Atrium C-QUR lawsuits. Most hernia mesh victims do not know what type of hernia re





# INCISIONAL HERNIA







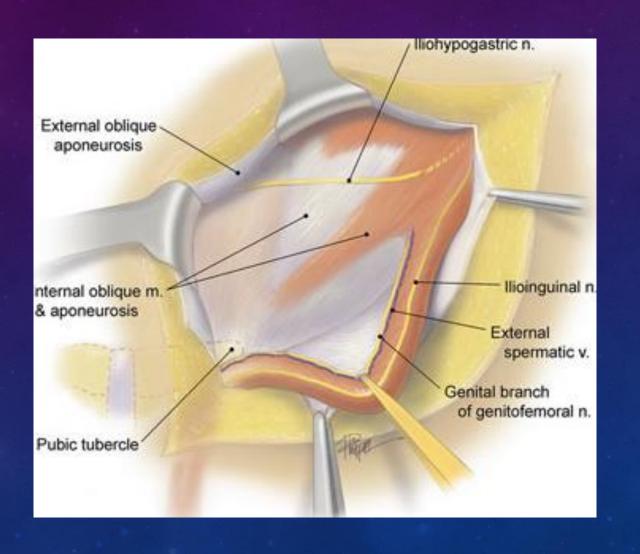
#### ORIGINAL SCIENTIFIC REPORT

# Suture Versus Mesh Repair in Primary and Incisional Ventral Hernias: A Systematic Review and Meta-Analysis

Tim Mathes<sup>1</sup> · Maren Walgenbach<sup>1</sup> · Robert Siegel<sup>2</sup>

- 10 RCTs 1215 patients
- Recurrence lower with mesh (24% to 7%, RR 0.36)
- Complication rate not different (pain, infection)

# INGUINAL HERNIA



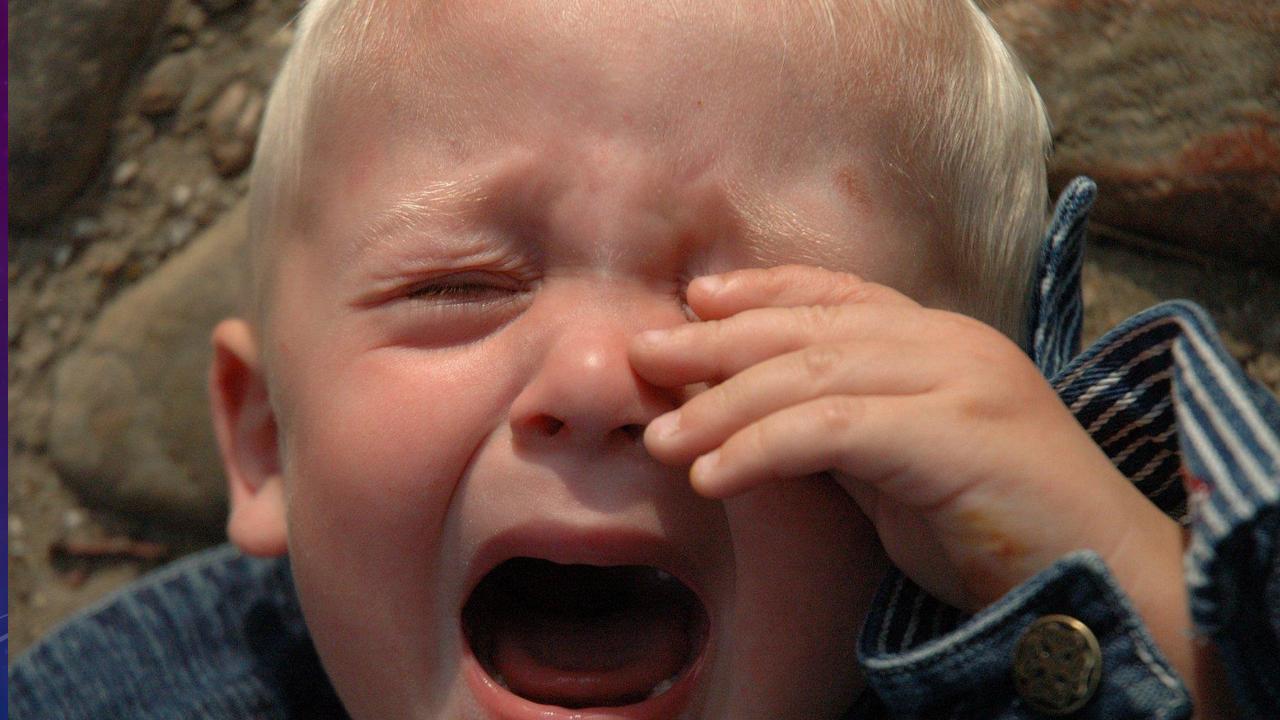
#### **Cochrane Database of Systematic Reviews**

# Mesh versus non-mesh for inguinal and femoral hernia repair

Cochrane Systematic Review - Intervention | Version published: 13 September 2018 see what's new

• Recurrence (RR 0.46) • • neurovascular and visceral injuries (RR 0.61) • **urinary retention (RR 0.53)**  4min 22second faster, and 0.6 days shorter stay • Wound infection (RR 1.29) Cochrane library 2018

Novitsky 2014



Chronic pain after mesh versus nonmesh repair of inguinal hernias: A systematic review and a network meta-analysis of randomized controlled trials \*,\*\*

Stina Öberg<sup>a,\*</sup>, Kristoffer Andresen<sup>a</sup>, Tobias W. Klausen<sup>b</sup>, Jacob Rosenberg<sup>a</sup>

g magazina	Shouldice		Lichtenstein			Risk Ratio		Risk Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI		M-H, Random, 95% CI	
2002 - Nordin et al	9	148	8	148	85.3%	1.13 [0.45, 2.84]			
2007 - Karakayali et al	1	42	3	49	14.7%	0.39 [0.04, 3.60]		•	
Total (95% CI)		190		197	100.0%	0.96 [0.41, 2.26]			
Total events	10		11						
Heterogeneity: Tau2 = 0.	00; Chi2=	0.75, 0	f = 1 (P =	0.39); P	= 0%		0.01	01 10	100
Test for overall effect: Z = 0.09 (P = 0.93)							0.01	Favours Shouldice Favours Lichten	100 stein

	Other non-	mesh	Lichtenstein		Risk Difference			Risk Difference	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI		M-H, Random, 95% CI	
2012 - Szopinski et al	5	105	3	103	10.9%	0.02 [-0.03, 0.07]		<u>+</u>	
2015 - Palermo et al	0	100	0	100	78.8%	0.00 [-0.02, 0.02]			
2015 - Youssef et al	4	71	3	72	5.9%	0.01 [-0.06, 0.09]		+	
2016 - Olasehinde et al	1	34	1	33	4.4%	-0.00 [-0.08, 0.08]			
Total (95% CI)		310		308	100.0%	0.00 [-0.01, 0.02]		•	
Total events	10		7					20	
Heterogeneity: Tau* = 0.0	0; Chi* = 1.13	3, df = 3	P = 0.77);	I* = 0%			-	15 15	7.4
Test for overall effect: Z = 0.32 (P = 0.75)								-0.5 0 0.5 Favours other non-mesh Favours Lichtenstein	- 3

# Mesh abdominal wall hernia surgery is safe and effective—the harm New Zealand media has done

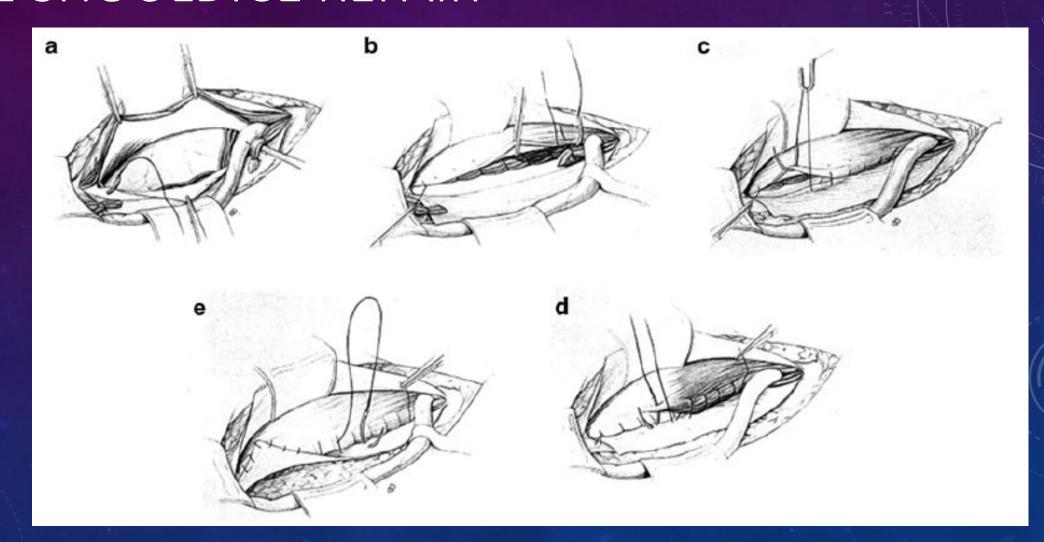
Steven Kelly



# Mesh abdominal wall hernia surgery is safe and effective the harm New Zealand media has done: response to Dr Steven Kelly's article

**Robert Bendavid** 

# THE SHOULDICE REPAIR



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Shouldice technique is better than other open techniques, not using mesh

- Main results:
  - 16 trials: 1121 mesh repair and 1608 non-mesh
  - Recurrence rate higher with Shouldice repair but lower than other non-mesh technique
  - No difference in chronic pain, complication, and operative stay.
  - Longer operating time with Shouldice repair



# Surgical Techniques for Parastomal Hernia Repair

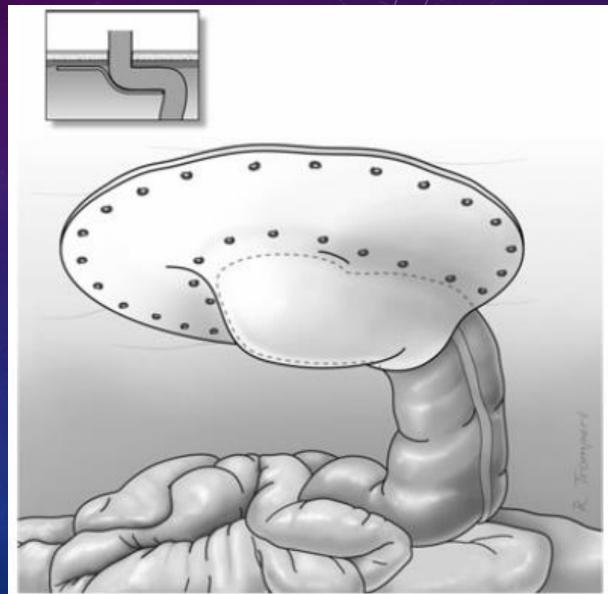
## A Systematic Review of the Literature

Birgitta M.E. Hansson, MD,\* Nicholas J. Slater, MD,† Arjan Schouten van der Velden, MD, PhD,\* Hans M.M. Groenewoud, MSc,‡ Otmar R. Buyne, MD, PhD,† Ignace H.J.T. de Hingh, MD, PhD,§ and Rob P. Bleichrodt, MD, PhD†

- Non-mesh repair- 69% recurrence
- Mesh repair- similar recurrence 6.9-17%
- Laparoscopic Sugarbaker technique has lower recurrence than keyhole technique
- Infection rate low 3%

# Keyhole

# Sugarbaker



## PREVENT-Trial: Prophylactic Mesh to Prevent Parastomal Hernia

Patient undergoing Elective End Colostomy Formation (n=150)

RANDOMIZATION

Routine End Colostomy Formation End Colostomy w/ Parastomal Mesh



24.2% Parastomal Hernia

4.5%

Mesh Infection

0%

Brandsma et al. Ann Surg. July 2016.



### PROPHYLACTIC MESH IN PREVENTING PARASTOMAL HERNIA

- RRESTO systematic review 2017
  - 8 RCTs 410 patients
  - Reduction in hernia rate in RCTs
  - No difference in postop complication (stoma necrosis, fistula, stricture, infection, mortality
- Cochrane review in 2018
  - 10 RCT, 844 patients
  - Reduce hernia rate (22 vs 41%)
  - No difference in LOS, need for re-operation, infection

# Analysis I.6. Comparison I Prosthetic mesh placement for the prevention of parastomal herniation, Outcome 6 Stoma-related infection.

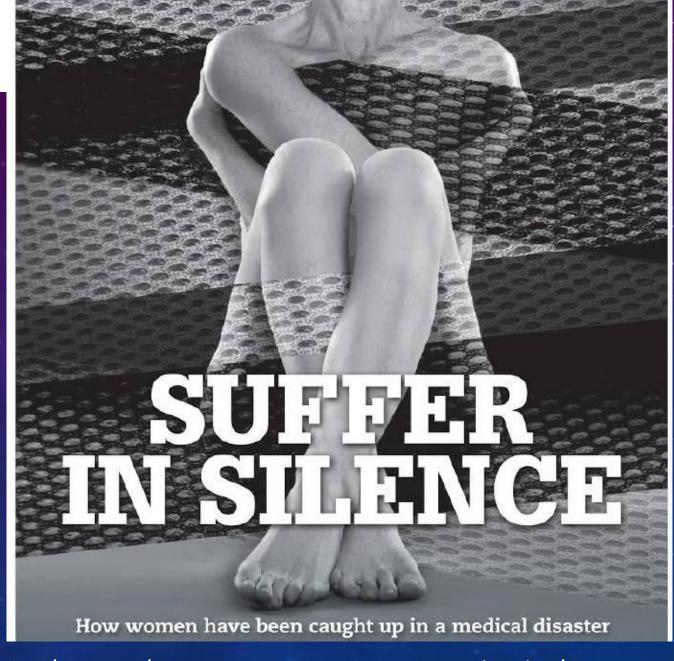
Review: Prosthetic mesh placement for the prevention of parastomal hemiation

Comparison: I Prosthetic mesh placement for the prevention of parastomal herniation

Outcome: 6 Stoma-related infection

Study or subgroup	Mesh n/N	No Mesh n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% Cl
Brandsma 2017	1/72	3/78		38.7 %	0.36 [ 0.04, 3.39 ]
Fleshman 2013	1/58	2/55		27.6 %	0.47 [ 0.04, 5.08 ]
Lopez-Cano 2012	0/19	0/17			Not estimable
L pez-Cano 2016	2/24	0/28		6.2 %	5.80 [ 0.29, 115.21 ]
Serra-Aracil 2009	1/27	1/27		13.4 %	1.00 [ 0.07, 15.18 ]
Vierimaa 2015	1/35	1/32		14.0 %	0.91 [ 0.06, 14.02 ]
Total (95% CI)	235	237	+	100.0 %	0.89 [ 0.32, 2.50 ]
Total events: 6 (Mesh), 7 (N	o Mesh)				
Heterogeneity: Chi² = 2.41,	df = 4 (P = 0.66); I	2 =0.0%			
Test for overall effect: $Z = 0$	.21 (P = 0.83)				
Test for subgroup difference	s: Not applicable				
			0.01 0.1 1 10 100		





https://www.theherald.com.au/story/4472081/senate-approves-inquiry-into-mesh-video/

# VAGINAL MESH

- Stress urinary incontinence
- Pelvic organ prolapse

# STRESS URINARY INCONTINENCE

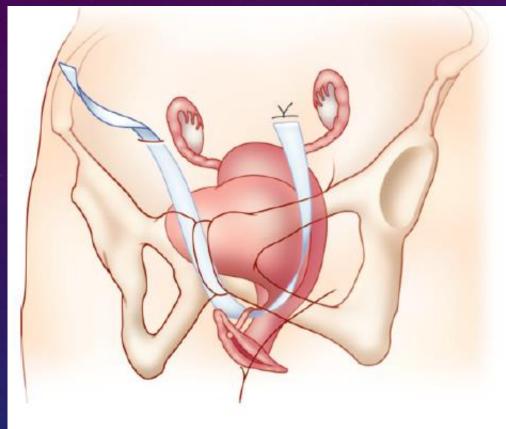
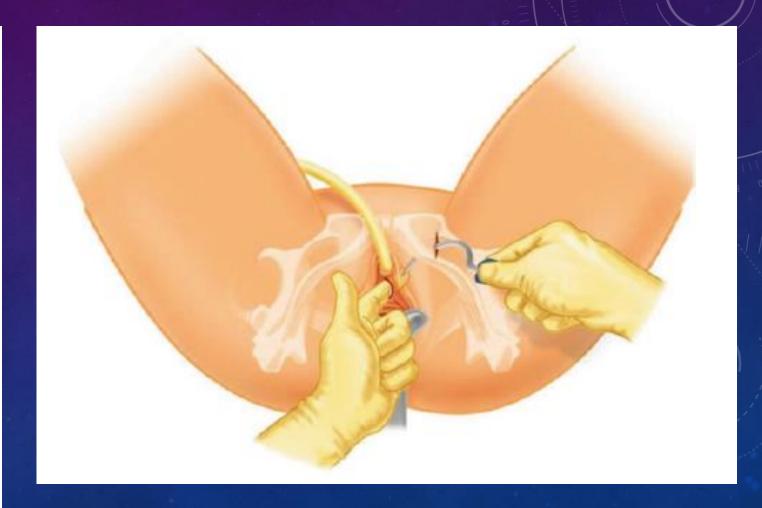
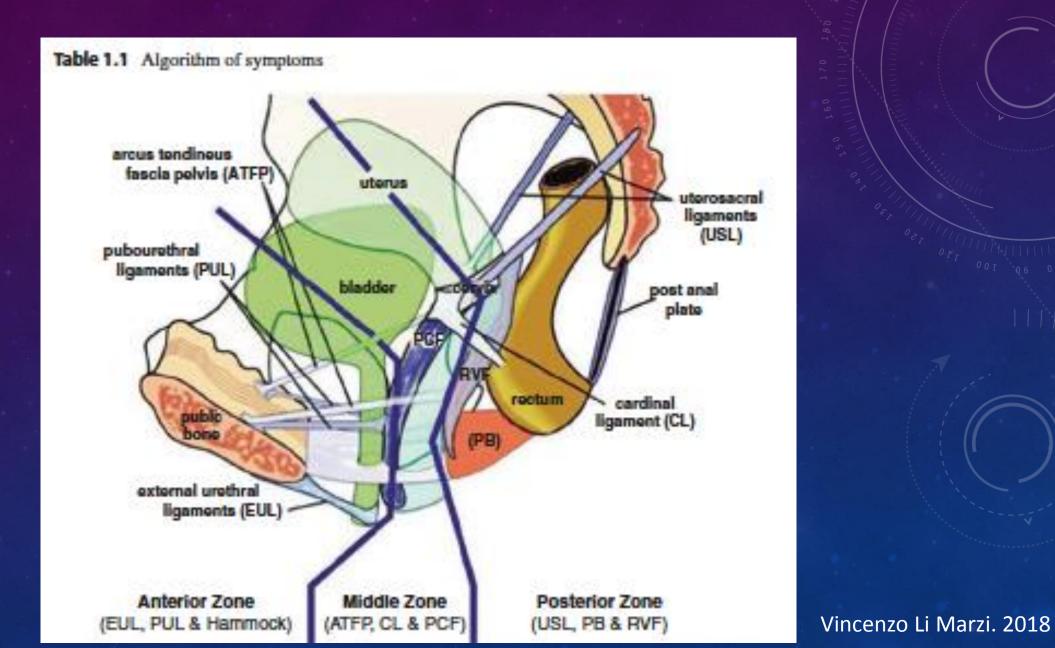


Fig. 3.1 Position of the retropubic tension-free vaginal tape



# PELVIC ORGAN PROLAPSE



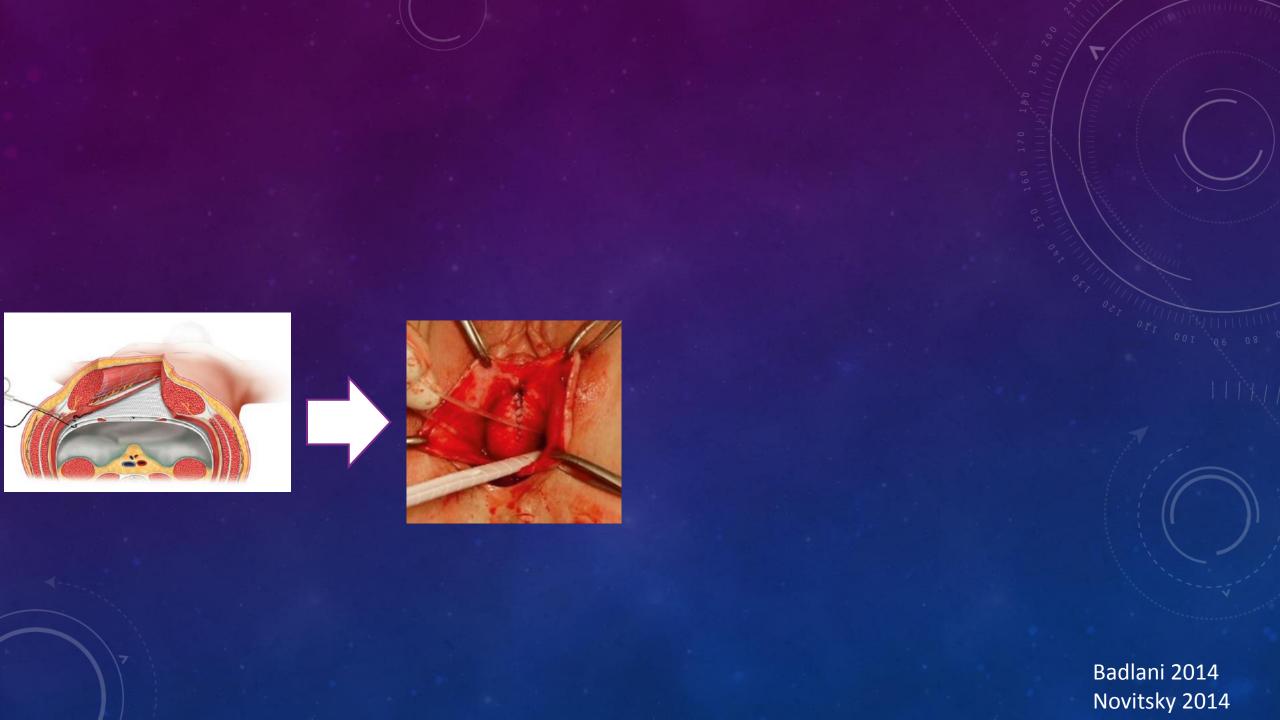
Restore anatomy

Sexual function

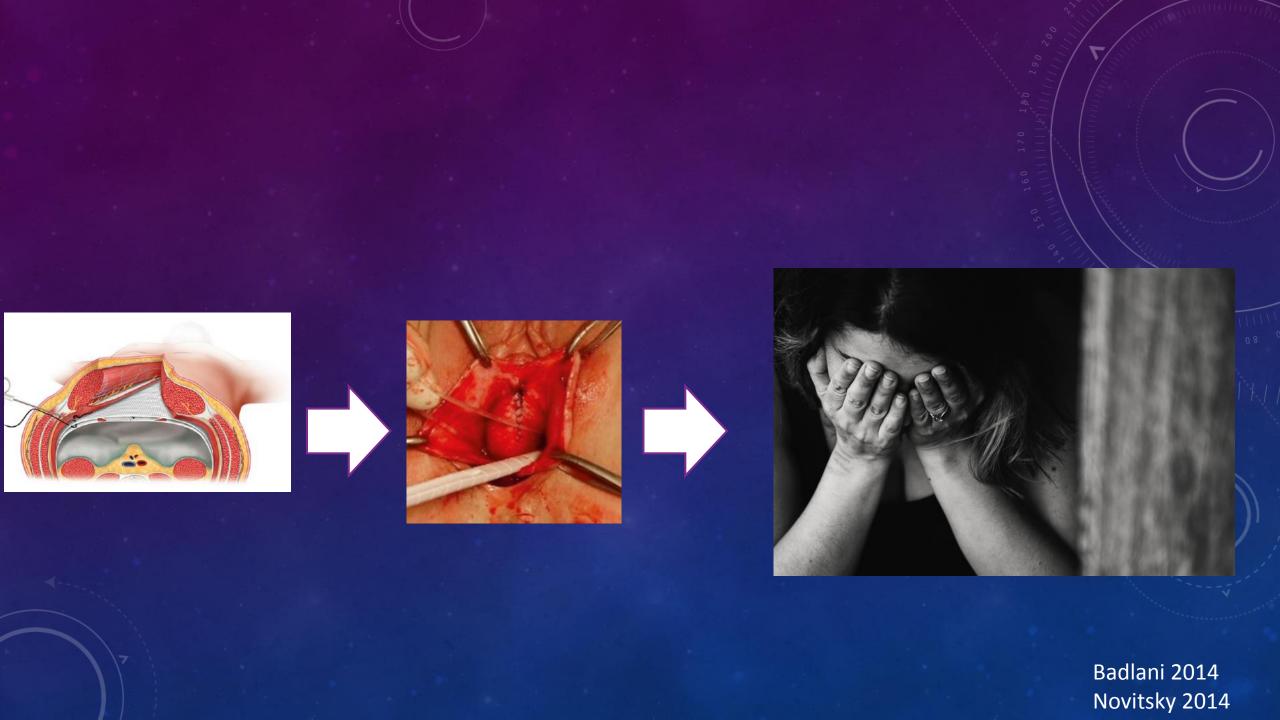
Goal

Urinary symptoms

Bowel symptoms









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Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse

- Awareness of prolapse less in the mesh group (RR = 0.66)
- More in the mesh group require repeat surgery for the combined outcome of prolapse, stress incontinence, or mesh exposure (RR 2.40)

Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT)

Cathryn MA Glazener, Suzanne Breeman, Andrew Elders, Christine Hemming, Kevin G Cooper, Robert M Freeman, Anthony RB Smith, Fiona Reid, Suzanne Hagen, Isobel Montgomery, Mary Kilonzo, Dwayne Boyers, Alison McDonald, Gladys McPherson, Graeme MacLennan, John Norrie (for the PROSPECT study group)\*

- Vaginal mesh or graft did not improve outcome :
  - Symptomatic prolapse
  - QoL
  - Adverse effect (infection, urinary retention, pain)
  - All other short term outcomes
- 12% cumulative synthetic mesh related complications
  - 11% removal





Review – Incontinence

Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence



ed for the treatment of SUI and POP, with in Association of Urology 2016), the European of surgical meshes (SCENIHR 2015), other ind national recommendations.

the use of nonautologous durable materials in surgery has well-established benefits but significant risks, which are specific to the condition and location they are used for. Various graft-related complications have been described—such as infection, chronic pain including dyspareunia, exposure in the vagina, shrinkage, erosion into other organs of xenografts, synthetic PP tapes (used in SUI), and meshes (used in POP)—which differ from the complications seen with abdominal herniae. *Conclusions:* When considering surgery for SUI, it is essential to evaluate the available options, which may include synthetic midurethral slings (MUSs) using PP tapes, bulking agents, colposuspension, and autologous sling surgery. The use of synthetic MUSs for

The use of synthetic MUSs for surgical treatment of SUI in both male and female patients has good efficacy and acceptable morbidity. Synthetic mesh for POP should be used only in complex cases with recurrent prolapse in the same compartment and restricted to those surgeons with appropriate training who are working in multidisciplinary referral centres.

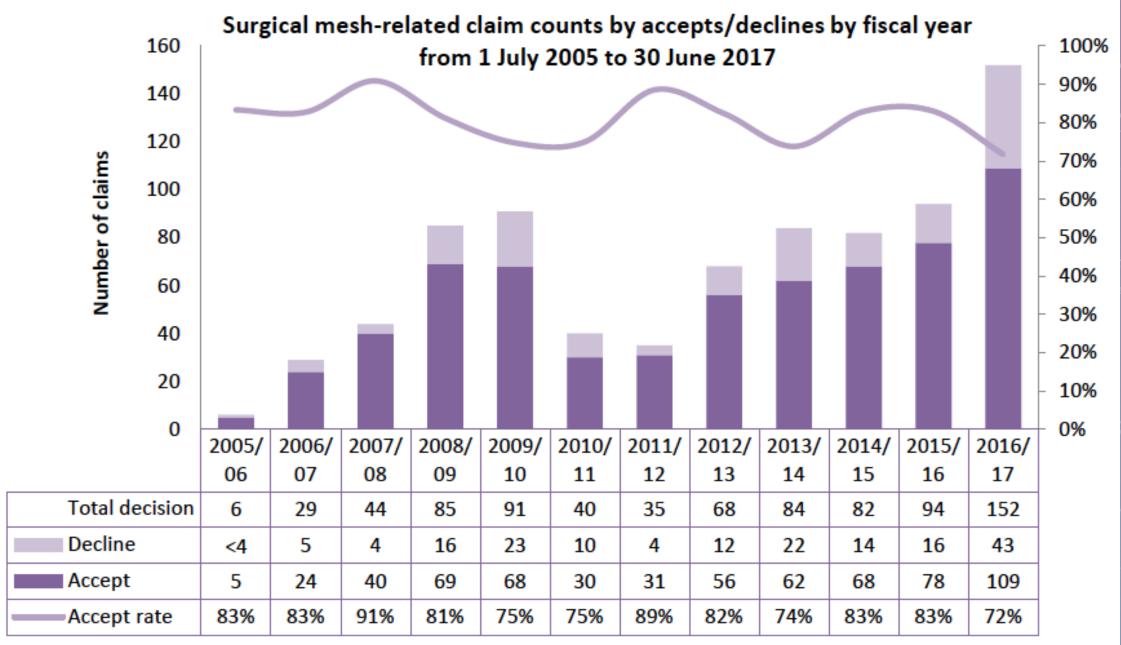
ceptable ecurrent ropriate

of stress ernative treating referral

eserved.

# ACC Treatment Injury Claims Surgical Mesh-Related Claim Data From 1 July 2005 to 30 June 2017 (12 fiscal years)

Figure 2: Number of surgical mesh-related claims accepted and declined by fiscal year



Note: Claim counts fewer than four (n=1, 2 or 3) are presented as "<4"

### 8. What are the costs related to surgical mesh-related claims?

Figure 25: Cash costs paid on accepted surgical mesh-related claims by payment type



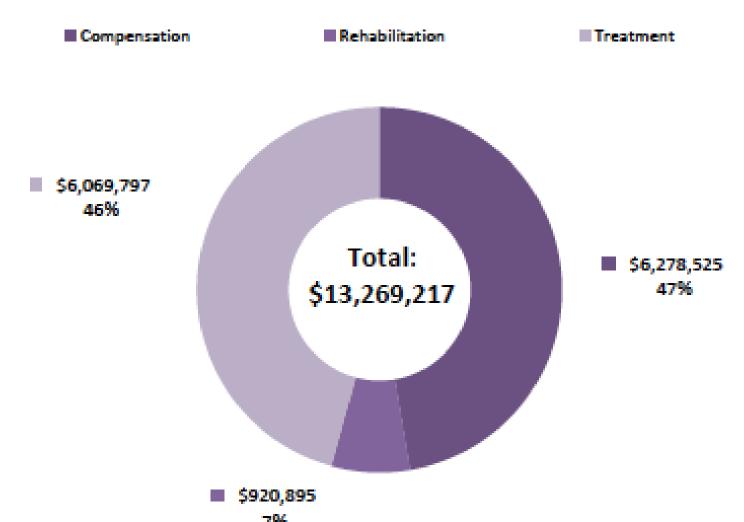


Figure 3: Number of surgical mesh-related claims accepted and declined by treatment event (surgery type groups)

Surgical mesh-related claim counts by accepts/declines by surgery type groups from 1 July 2005 to 30 June 2017

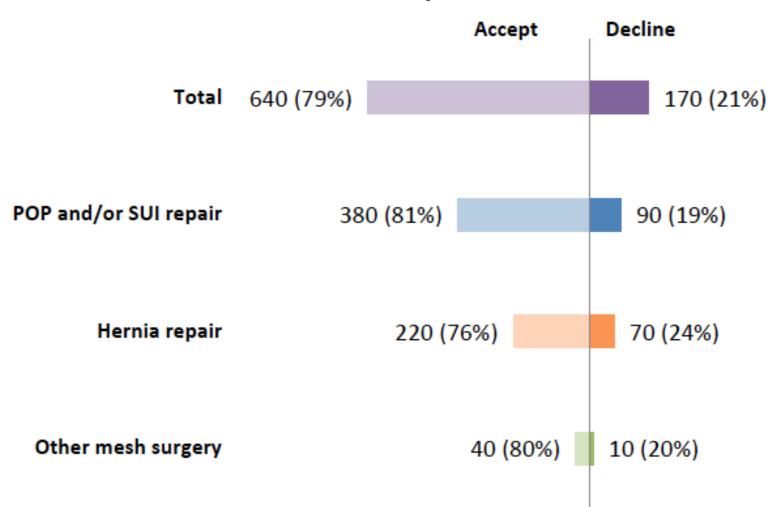


Table 6: Number of surgical mesh-related claims by surgery type groups by primary injury/symptom

### Surgical mesh-related claim counts by surgery type groups by primary and secondary injury/symptom from 1 July 2005 to 30 June 2017

							_		
POP and/or SUI repair			Hernia repair		Other mesh surgery				
Primary injury/symptom	n	%	Primary injury/symptom	n	%	Primary injury/symptom	n	%	
Mesh erosion	307	65%	Infection	140	48%	Infection	15	30%	
Pain	27	6%	Hernia	44	15%	Mesh erosion	7	14%	
Infection	23	5%	Pain	16	6%	Nerve injury	5	10%	
Nerve injury	17	4%	Nerve injury	14	5%	Fistula - other	5	10%	
Haematoma - bruising	14	3%	Haematoma - bruising	12	4%	Hernia	5	10%	
Perineal injury	13	3%	Seroma	11	4%	Other 9 injuries/symptoms	13	26%	
Sexual dysfunction	10	2%	Mesh erosion	10	3%				
Scarring	9	2%	Mesh migration	10	3%				
Urinary tract injury	9	2%	Gastrointestinal injury	5	2%				
Urinary Incontinence	5	1%	Hydrocele	5	2%				
Mesh migration	5	1%	Bowel injury	5	2%				
Mark and antique		10/	0.1 43	10	C0/				

### 7. What device types relate to the surgical mesh-related claims?

Table 9: Number of surgical mesh-related claims for POP and/or SUI repairs and hernia repairs by device types

Surgical mesh-related claim counts by surgery type groups by device type											
from 1 July 2005 to 30 June 2017											
POP and/or SUI repair			Hern	ia repair		All mesh surgery					
Device type	n	%	Device type	n	%	Device type	n	96			
TVT/TVT-O	96	20%	Prolene	57	20%	TVT/TVT-O	96	12%			
Monarc	51	11%	Parietex	22	8%	Prolene	72	9%			
Gynecare Prolift	50	11%	C-Qur	16	6%	Monarc	52	6%			
Gynecare	37	8%	Surgipro	9	3%	Gynecare Prolift	50	6%			
Apogee	32	7%	Prolite	9	3%	Gynecare	37	5%			
Perigee	26	6%	Marlex	8	3%	Apogee	32	4%			
SPARC	12	3%	Proceed	6	2%	Perigee	27	3%			
Caldera Ascend	8	2%	Atrium	5	2%	Parietex	23	3%			
Prolene	8	2%	Ultrapro	4	1%	C-Qur	16	296			
IVS	7	1%	Permacol	4	1%	Surgipro	14	2%			
Uphold	7	1%	3DMax	<4	-%	Marlex	13	2%			
Recto-Swing	7	1%	Vipro	<4	-%	SPARC	12	1%			
Y-Mesh	6	1%	Dualmesh	<4	-%	Prolite	11	1%			
Cysto Swing	5	1%	GoreTex	<4	-%	IVS	8	196			
Gynecare Elevate	4	1%	Physiomesh	<4	-%	Ultrapro	8	1%			

# ADVERSE REACTION TO MEDSAFE

	Total mesh sale	Adverse reaction	% of AE
Stress urinary incontinence	41432	187	0.4%
Pelvic organ prolapse	6713	254	3.7%
Hernia	61610	394	0.6%



### Safety Information

**Surgical Mesh Implants** 

Regulatory action on surgical mesh products 31 January 2018

- Followed Australian TGA stance:
  - All surgical mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation will no longer be supplied
  - One single incision mini-sling for the treatment of stress urinary incontinence is no longer supplied in NZ
- Medsafe will continue to monitor the use of surgical mesh products

# MY TWO CENTS

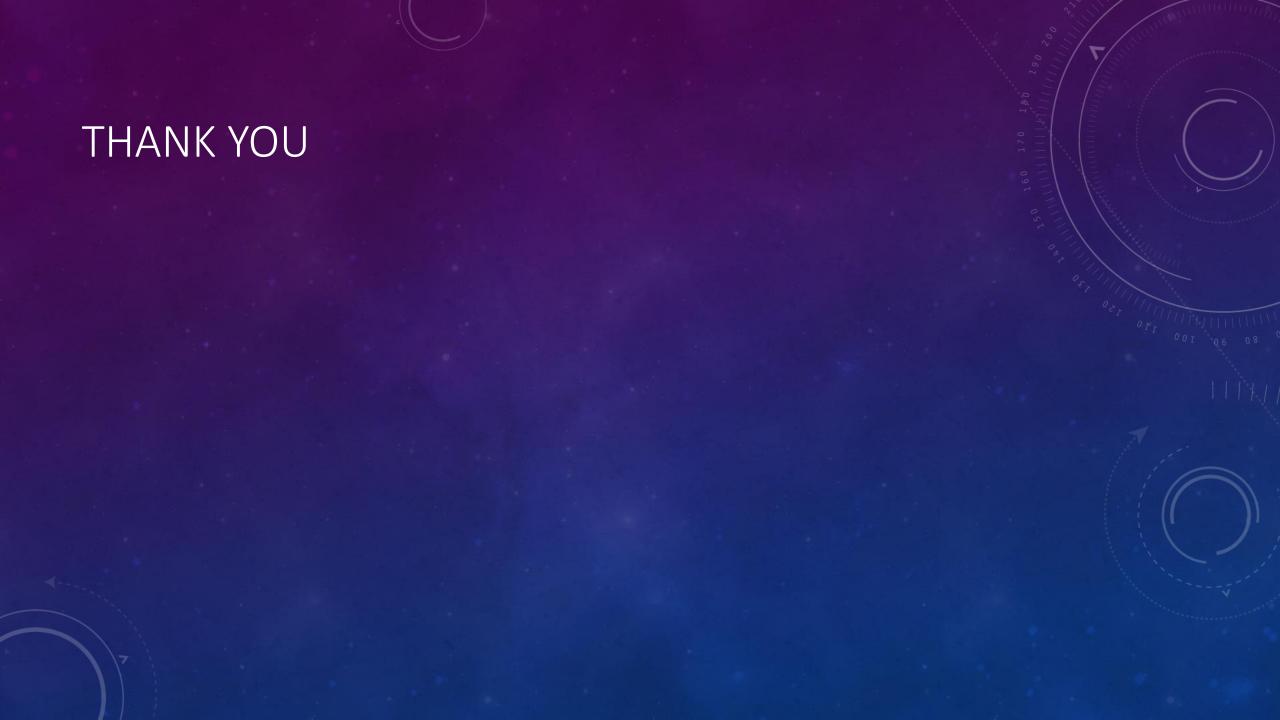
- Mesh can be problematic, but is safe in the appropriate setting
- Registry is probably a good idea
- Adequate training is required

## SO BACK TO MY PATIENT

- " you should have a repair"
- " an inguinal hernia repair with mesh"
- " this repair offers the best outcome in my hands"
- "chronic pain rate up to 10%, but no difference whether mesh is used or not"
- "very small risk of infection and other complications"

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- Huw G Jones. Prosthetic mesh placement for the prevention of parastomal herniation. Cochrane Systematic Review Intervention Version published: 20 July 2018 Pianka F. Prophylactic mesh placement for the PREvention of paraSTOmal hernias: The PRESTO systematic review and meta-analysis. PLoS One. 2017 Feb 9;12(2):e0171548



### Summary table of devices supplied in New Zealand.

Table 1: Summary of devices supplied in New Zealand for the period 1 Jan 2005 to 31 December 2017

Product Grouping	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total Units
Urinary Incontinence Products (male)	0	0	0	24	37	40	40	56	60	2	29	39	7	334
Urinary Incontinence Products (female)	1314	1533	1721	1625	1844	1833	1761	1924	2131	1612	1291	1137	823	20549
Pelvic Organ Prolapse Products	557	591	568	842	1011	755	679	597	377	267	205	159	105	6713
Hernia products in relation to groin, ventral repairs	3756	4212	3460	2780	2661	2467	2805	3860	3911	4155	8494	8669	10380	61610
Total	5627	6336	5749	5271	5553	5095	5285	6437	6479	6036	10019	10004	11315	89206