Pelvic Mesh Complications

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PELVIC MESH COMPLICATIONS

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Grandmother living in agonising pain from mesh 'life sentence' calls for apology

0

Stuff

Monday 15 October 2018, 10:39 AM

Trella Fuatai

POLITICS

Surgical mesh: A decade of damage

Auckland woman dead after two years of pain from surgical mesh

Cate Broughton - 05:00, Oct 07 2018

Surgical mesh data not stacking up?

RNZ/CGP CONFERENCE

SHARE

Nurse calls on GPs to be the 'heroes' in helping women injured by mesh

'I just want this stuff out of me': Surgical mesh a silent killer of Kiwi women

Megan Gattey - 21:29, Dec 06 2017

Calls for NZ to follow Australian senate surgical mesh report, which says use it as 'last resort'

Mesh destroys 'intimacy in marriage' but Kiwi victim cannot sue

Cate Broughton - 05:00, Dec 08 2018

Questions raised over whether Kiwi surgeons have enough experience and skill for transvaginal mesh implants

Cate Broughton - 05:00, Oct 01 2018

Hernia mesh complication 'like torture' for Christchurch grandfather

Botched surgeries lead to two-decade fight with ACC

Cate Broughton - 17:20, Jan 23 2019

Hundreds keen to share experiences of surgical mesh misery

Katie Stephenson
kstephenson@nzdoctor.co.nz
Thursday 17 Janu

JANUARY 31, 2019

Surgeons Call for Closer Surveillance of Mesh After Implantation

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

Cate Broughton - 05:00, Jan 16 2018

- "The **biggest medical scandal** for Australian women **since thalidomide** in the 1950s and 1960s, when kids were born without arms and legs" (Senator Hinch, 2017)
- "The story is **hair raising**, offering lessons for the entire medical community, manufacturers, and regulators" (J. Gornall, BMJ Oct 2018).
- "The post-marketing assessment of vaginal mesh has been a **shameful** episode in the history of implantable devices" (BMJ Editorial, Oct 2018)
- "The risks were known, not insignificant, and on the respondents' own admission, could cause significant and serious harm if they eventuated," (Judge Katzmann, JnJAustralian Class Action, Nov 2019).
- "Twenty years after mesh started to be used in the pelvis we still don't know its long term risks or complication rate" (BaronessCumberlege,2020)

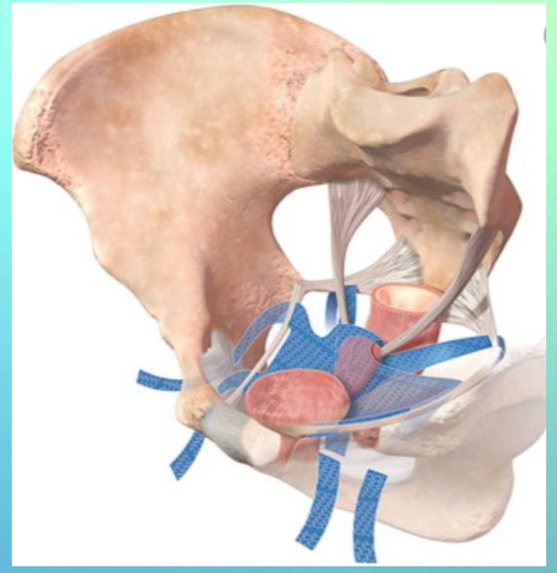
PELVIC MESH

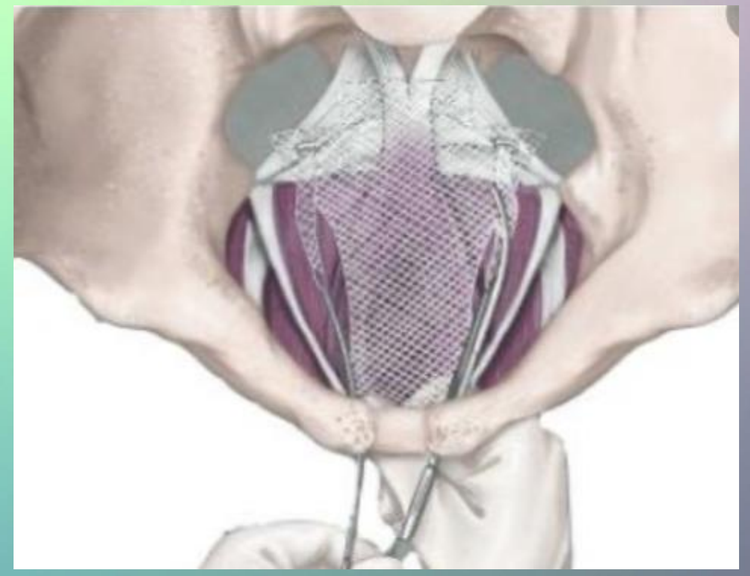
Background

★ 1 in 4 women will have a pelvic floor disorder
★ lifetime risk of surgery for POP is 11% by age 80

POP - vaginal surgery

- Ant/post compartment prolapse repair using native tissue has recurrence rates of up to 25%
  - polypropylene mesh had been used since for inguinal hernias since 1988 (Lichenstein repair) and abdominal hernias since 1950
  - 2002 - pelvic mesh kit (prorepair) was introduced - safety extrapolated from use in hernias for vaginal repair
  - success described by Nieminem et at 2010 - 3 year follow up data



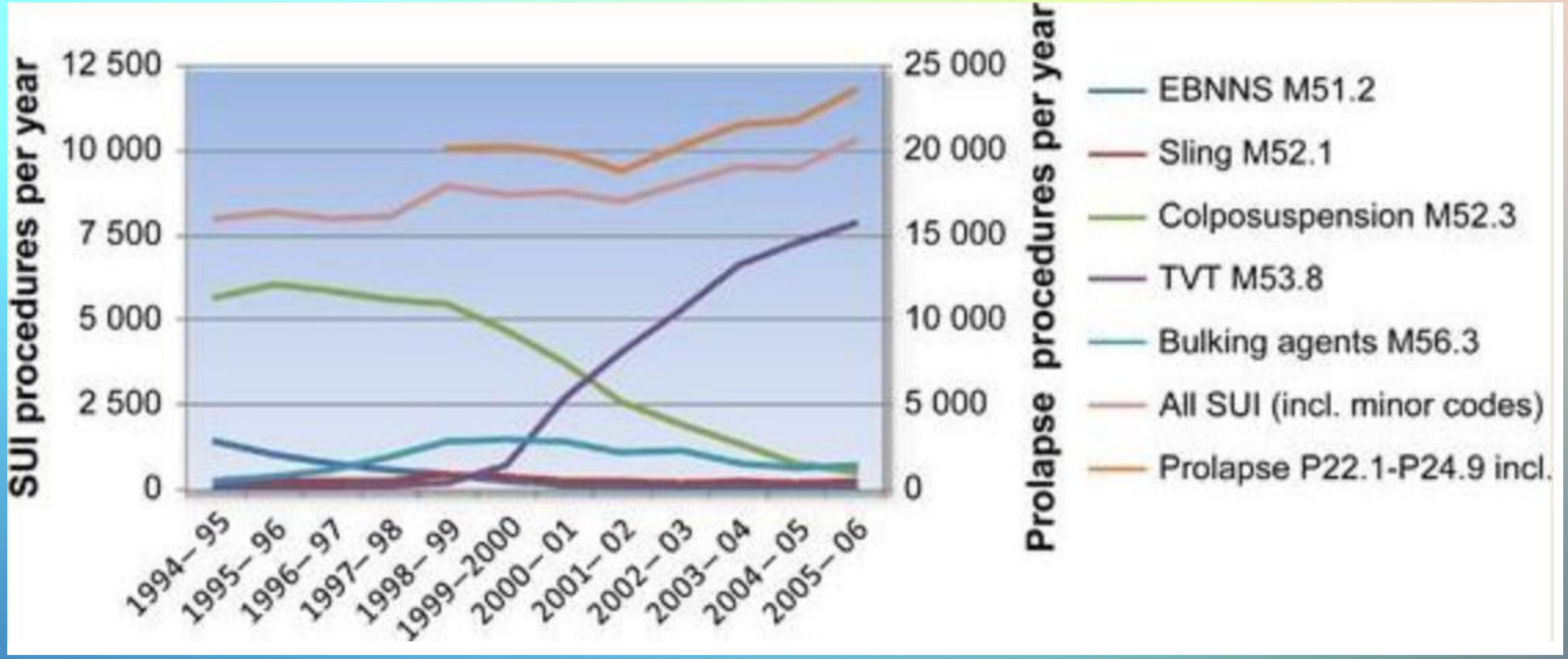


SUI

Introduced 1998. Prev option - colposuspension - major surgery, 1-2 nights in hospital at least.

TVT 1998 - turned into daycase procedure, minimally invasive operation, massive uptake

Ward and Hilton 2002 described cure rate but only 6mo complication rate



FDA - POP

2008 - In the FDA warning, Dr Schulz states:

"Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI. ... The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia."

2011 - FDA provided an updated communication about serious complications associated with transvaginal placement of surgical mesh used to treat POP. Panel recommend SUI mesh remains classified as class II (low to moderate risk) but POP mesh as class III (high risk)

2013 the FDA issued: 95 postmarket study orders to 34 manufacturers of urogynecologic surgical mesh for POP; and 14 postmarket study orders to seven manufacturers of mini-slings for SUI.

2014 - 2018 - FDA investigates post market studies

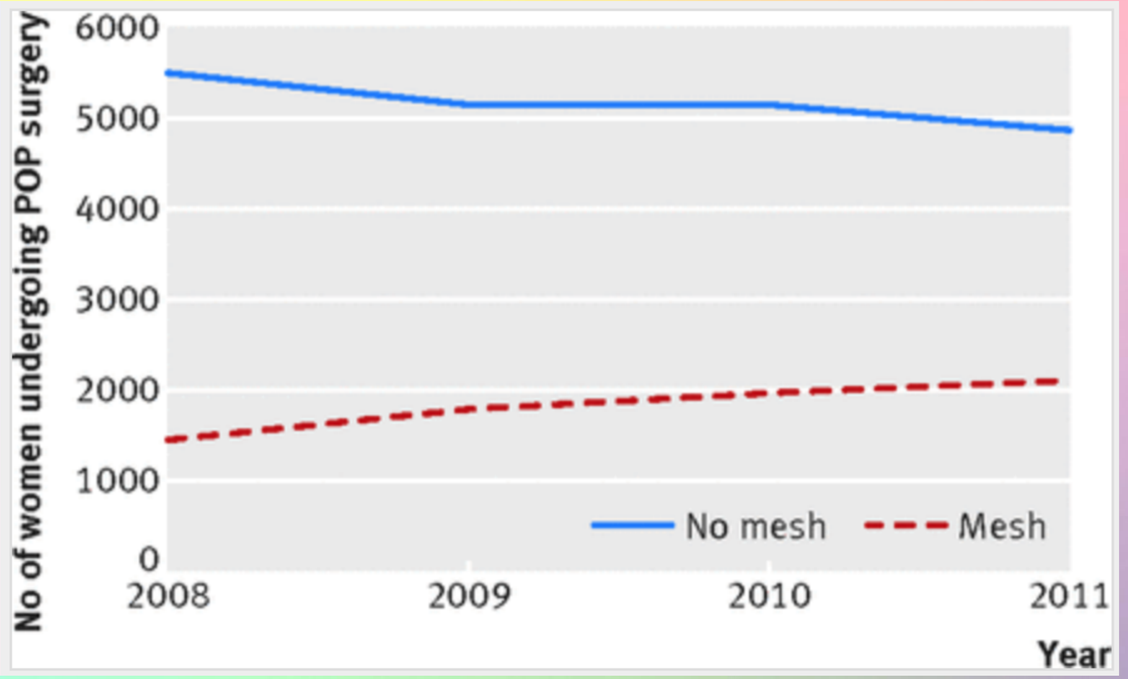
2018 - FDA orders rectocoele mesh repair to stop being used

2019 - FDA orders cystocoele mesh repair to stop being used

Despite high vigilance for POP - SUI - 250,000 synthetic MUS inserted in US in 2010

Common Problems with Mesh for POP Reported to FDA, 2005 to 2010

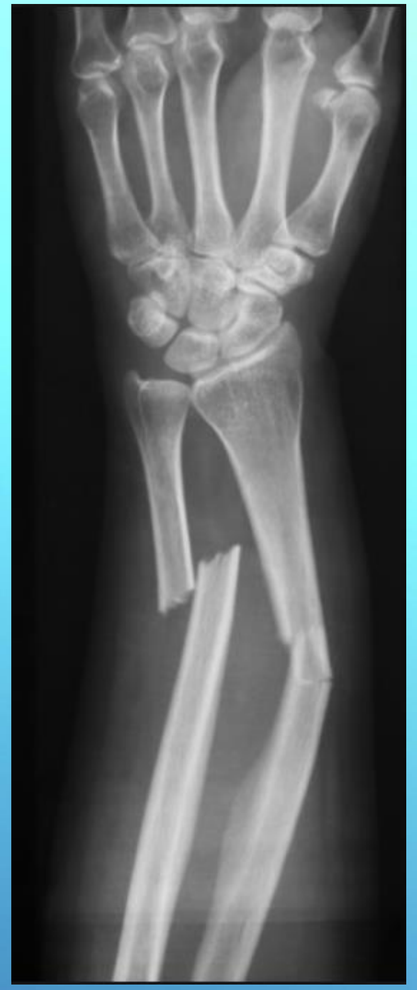
COMPLICATIONS	NUMBER OF REPORTS
Erosion	528
Pain	472
Infection	253
Bleeding	124
Dyspareunia (painful sex)	108
Organ perforation	88
Urinary problems	80
Vaginal scarring	43
Neuro-muscular problems	38
Recurrence	32



Data from NYC - Chughtai et al 2015

"We found that since the release of the FDA warning in 2008, mesh use continued to increase in POP repairs from 21% in 2008 to 30% in 2011"

MY ARM HURTS.....



- It’s all in your head
- Its normal to have pain after surgery. Wait another 6 months
- Your scan is normal
- I can’t see anything wrong on examination
- You just don’t want to go back to work
- She’s just crazy/depressed/anxious
- You will just have to learn to live with it
- Ive never heard of that before
- You consented to the operation
- Mesh doesn’t cause pain/ that shouldn’t hurt
- Its just menopause
- Have you tried losing weight

EMERGING PROBLEMS - POP

- Cochrane review of POP 2013 - only 500 patients, no inferiority to non mesh but complications/safety or morbidity not looked at, but limited metanalysis:

  - New SUI more common with mesh POP ant repair than native tissue

  - Mesh contraction (leading to pain/tightening) reported 2013 to FDA

<u>Longer term</u>

At least 1 in 4 women with pelvic mesh suffer complication, increases with time.

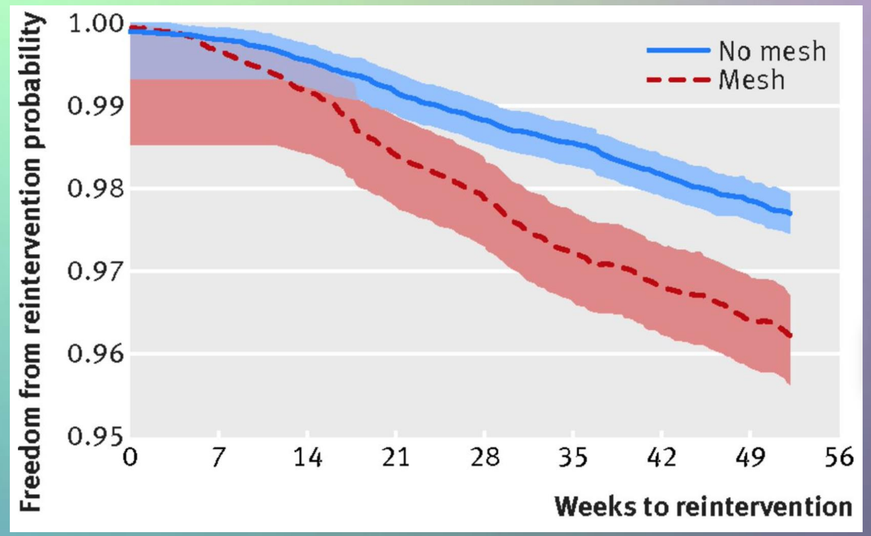
- at least 17% erosion at 1 year

- 42% by 7 y

of those with erosion- more than half require surgery (Milani et al 2018)

FDA approved meshes from 1999 + based on 'substantial equivalency' to other meshes,

Publication of randomised clinical trials occurred at a median of 5 years after device approval (range 1–14 years



Author/ Year of publication/ Study type	Study type	Number Patients/ Procedure or mesh type	Cure rate (%) / follow-up.	Complications		
				Intraoperative (surgeon related)	Mesh related	Others
Attempt to decrease total amount of synthetic mesh by using composite mesh instead of Type 1 polypropylene mesh.						
Milani AL [80] 2011*	PMS	127; Prolift +M	77.4 / 1 year	Bladder perf 2.3%; blood transfusion 0.8%	Mesh exposure 10.2%; pelvic pain 3.9%; denovo Dyspareunia 2%	NS
Cervigni M [81] 2011	PS	97 POP; Collagen coated PPM	64.9 / 1 year	NS	Mesh exposure- 21.6%; denovo Dyspareunia 11.3%	*Denovo* SUI 19.5%
Araco F [82] 2009	RS	36; anterior prolapse with Composite Bovine pericardium & Polypropylene	35 month; 91.7	No bladder perforation, hematoma, infection & BOOVaginal perforation- 5.6%	Vaginal erosion 8.3%	*Denovo* SUI 10%
Karp DR [83] 2011	RS	65; (35- no midline fascial plication 30- plication) with Perigee & intexen (biological graft)	6.2 month; 66- no placation; 73- plication	No intraoperative complication	Erosion -0; denovo dyspareunia 9.2%	NS
Culligan PJ [84] 2010	RS	120: POP with Avaulto solo	1 year; 81	No intraoperative complication	Erosion 11.7%; pain [illegible]	NS
Overall		445 patients	Mean 75.6%, 15.5 month		Erosion 0-21.6%; dyspareunia 2-11.3%	
Attempts to avoid use of trocars and possibly minimize pain related complications associated with same						
Alcalay M [85] 2011 *	PS	20; Endo Fast Reliant System# (trocarless system)	85 / 1 year	Nil	Mesh exposure 5%; Device related Dyspareunia 5%	*Denovo* SUI 10%
Zyczynski HM [86] 2010*	PMS	136; Gynecare prosima pelvic floor system# (nonanchored mesh)	76.9 / 1 year	Nil	Mesh exposure 8%	Failure to retain vaginal support device for 21 days associated with higher failure.

PMS-prospective multicentric study; PS- prospective study; RS- retrospective study; *- company sponsored

DEFINITIONS - IUGA/ICS

TERMS USED	DEFINITION
PROSTHESIS	A fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure
A: Mesh	A (prosthetic) network fabric or structure
B: Implant	A surgically inserted or embedded prosthesis
C: Tape (Sling)	A flat strip of synthetic material
GRAFT	Any tissue or organ for transplantation. This term will refer to biological materials inserted
A: Autologous Grafts	From the woman's own tissues e.g. dura mater, rectus sheath or fascia lata
B: Allografts	From post-mortem tissue banks
C: Xenografts	From other species e.g. modified porcine dermis, porcine small intestine, bovine pericardium
COMPLICATION	A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery
CONTRACTION	Shrinkage or reduction in size
PROMINENCE	Parts that protrude beyond the surface (e.g. due to wrinkling or folding with no epithelial separation)
SEPARATION	Physically disconnected (e.g. vaginal epithelium)
EXPOSURE	A condition of displaying, revealing, exhibiting or making accessible e.g. vaginal mesh visualized through separated vaginal epithelium
EXTRUSION	Passage gradually out of a body structure or tissue
COMPROMISE	Bring into danger
PERFORATION	Abnormal opening into a hollow organ or viscus
DEHISCENCE	A bursting open or gaping along natural or sutured line

Table 3 Subclassification of Complication Categories to specify the presence of pain (by the patient only, not the partner) associated with the abnormal finding and the grade in terms of the presence and severity of symptoms

Grade of pain	Symptoms
a	Asymptomatic or no pain
b	Provoked pain only (during vaginal examination)
c	Pain during intercourse
d	Pain during physical activities
e	Spontaneous pain

	General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1	**Vaginal**: no epithelial separation Include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)	**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)	**1D** = Abscess
2	**Vaginal**: smaller ≤ 1cm exposure	**2A**: Asymptomatic	**2B**: Symptomatic	**2C**: Infection	**2D** = Abscess
3	**Vaginal**: larger >1cm exposure, or any extrusion	**3A**: Asymptomatic 1-3A*a* if no prosthesis or graft related pain	**3B**: Symptomatic 1-3B (*b*-*e*) if prosthesis or graft related pain	**3C**: Infection 1-3C /1-3D (*b*-*e*) if prosthesis or graft related pain	**3D** = Abscess
4	**Urinary Tract**: compromise or perforation Including 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	**Rectal or Bowel**: compromise or perforation including 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	**5D** = Abscess
6	**Skin and / or musculoskeletal**: complications including 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	**6D** = Abscess
7	**Patient**: compromise including hematoma or systemic compromise	**7A**: Bleeding complication including haematoma	**7B**: Major degree of resuscitation or intensive care*	**7C**: Mortality * *(additional complication - no site applicable - **S 0**)	

NOT EROSION!

Haylen et al 2011

DIAGNOSIS

HISTORY
- vaginal or pelvic pain,
- vaginal discharge or bleeding,
- odour, recurrent infection, abscess development (incl perianal abscess)
- recurrent UTI/bladder stones/haematuria
- dyspareunia, or pain experienced by the sexual partner
- LUTS - obstructed voiding, CISC dependence, de novo DO

EXAMINATION
- Speculum, EUA
- cystoscopy
- Proctoscopy

INVESTIGATION
- 3D USS
- MRI
- VCMG

Risk factors for vaginal mesh exposure.

Risk factor for mesh exposure
Patient-related factors
Smoking
Diabetes mellitus
Patient age
Surgery-related factors
Postoperative urethral dilatation
Excessive sling tensioning
Surgeon experience
Combined vaginal and abdominal approach for mesh placement
Inverted ‘T’ colpotomy
Concomitant hysterectomy

Bergersen et at 2019

WHAT CAN WE DO - SUI

Exposure - <1cm2 - can treat conservatively with topical oestrogen + review (NICE 2019) up to 1/3 of all exposures improve with oestrogen

PAIN
- 60-80% improvement in dyspareunia
- Partial /complete removal
  - Relief of pain in 72 vs 76%
  - Recurrence of SUI in 28 vs 65%
  - Repeat SUI surgery in 14 vs 37%
- Worsening pain in up to 9% after removal

VAGINAL COMPLICATION
  - 16% of partial removal for exposure required further surgery
  - complete vs partial - SUI recurrence 44 vs 8%

VOIDING DYSFUNCTION
  - Excision worse than division in terms of rec SUI (51 vs 13%)
  - mesh revision surgery:
    - 23% resolved de novo DO
    - 79% resolved obstructed voiding

EVIDENCE IS LIMITED - meta analysis of <25 papers (carter et al 2019)

MESH USE WORLDWIDE

US + Canada
- POP - no meshes commercially available
- SUI - high vigilance
- Oct 2019 - JnJ paid $117m to resolve claims in 41 US states, over 100,000 lawsuits ongoing

UK
- SUI - paused 2016- 2019, now high vigilance SUI - in exceptional circumstances
- POP - not possible to have vaginal mesh surgery for pelvic organ prolapse on the NHS unless there's no alternative and the procedure cannot be delayed

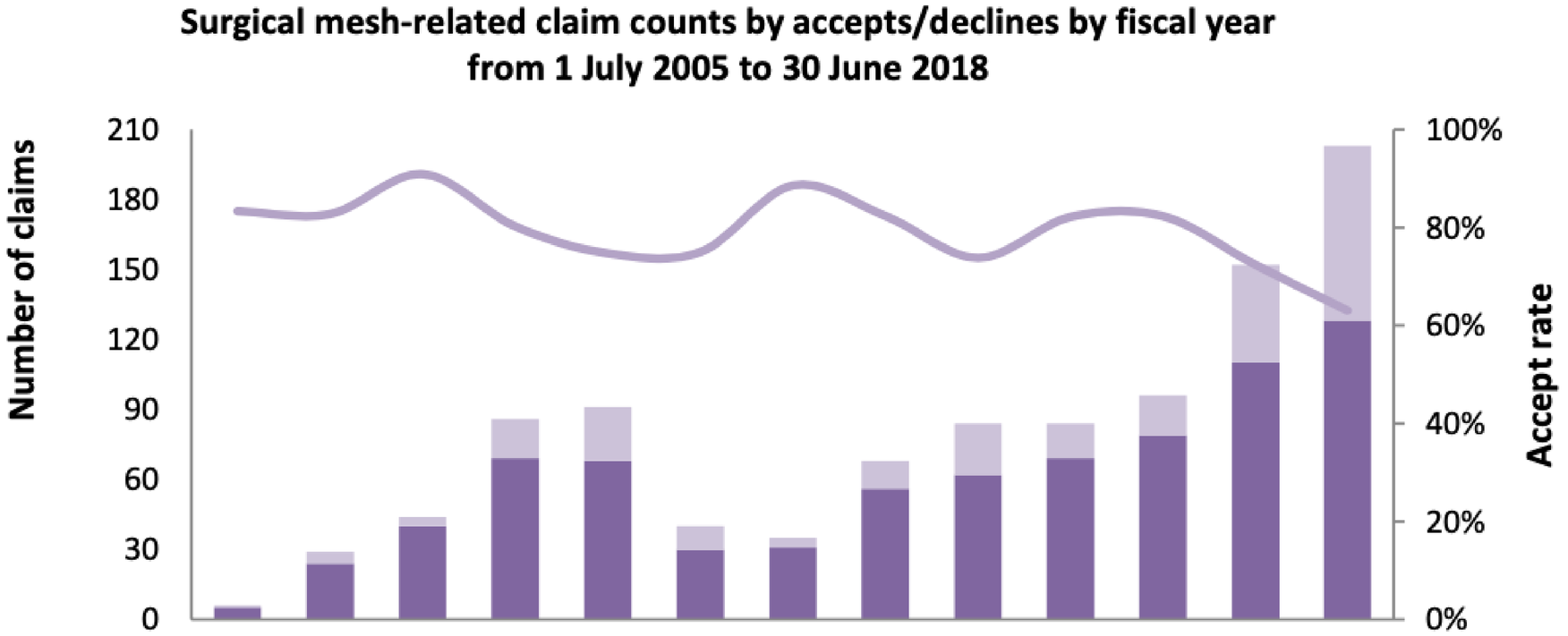
NZ
- POP - no mesh in use
- SUI - TVT acceptable, TOT only if exceptional circumstances

Australia
- transvaginal POP - removed from market. SUI mesh reclassified to High Risk
- class actions for POP, SUI Senate Inquiry; some mesh removed from market; 2018-2020 JnJ class action for pelvic mesh; JnJ appeal lost 2021

Europe
- Can use POP mesh only if primary native tissue surgery failed
- SUI mesh still common place

mesh manufacturers have paid close to $8 billion in settlements.

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



	2005 /06	2006 /07	2007 /08	2008 /09	2009 /10	2010 /11	2011 /12	2012 /13	2013 /14	2014 /15	2015 /16	2016 /17	2017 /18
Total decision	~7	29	44	86	91	40	35	68	84	84	96	152	203
Decline	<4	5	4	17	23	10	4	12	22	15	17	42	75
Accept	5	24	40	69	68	30	31	56	62	69	79	110	128
Accept rate	~71%	83%	91%	80%	75%	75%	89%	82%	74%	82%	82%	72%	63%

Note: Claim counts fewer than four (n=1, 2 or 3) are presented as "<4". To provide approximate percentages and totals, "<4" is assumed as 2.

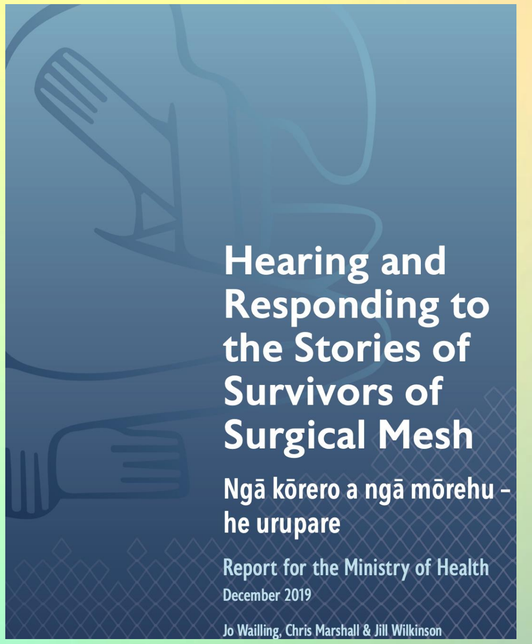
Figure 2 shows that ACC made cover decisions on 1,018 surgical mesh-related claims over 13 fiscal years.

RESTORATIVE JUSTICE NZ 2019

This report, commissioned by the Ministry of Health from Victoria University's Diana Unwin Chair in Restorative Justice, summarises the themes that emerged from a restorative process to hear from New Zealand men and women affected by surgical mesh.

Between August and October 2019 over six hundred mesh injured people shared their stories through either one of 32 forums held throughout New Zealand or to an online database. Additional stories were heard from family and whānau of people affected by mesh and health professionals.

The report highlights the severity of the harm and the impact on the lives of those who experience complications from surgical mesh.



The report groups the needs to address surgical mesh harm into the following workstreams:

- credentialling of surgeons
- specialist multidisciplinary mesh services
- informed consent
- safety culture and systems
- acknowledgment of harm
- responding to mesh harm both now and in the future.

HOW CAN WE UNDO THE HARM?

- Listen to your patients, believe them not the investigation results
  Don’t tell them they’re imagining things/its all in their head.
  Advocate for them to get holistic care

- Treat those harmed in an MDT context - psychologist, pain specialist, physio etc.

- Ensure something similar doesn’t happen again:
  Thorough robust consent process
  Audit your own outcomes - contribute to national registries with outcomes
  Report adverse events nationally, no blame system - if you think there’s an A/E report it
  Don’t work in silos - new/experimental techniques discuss at MDT with appropriate experience
  Don’t drop all the ‘old techniques’ in favour of newer techniques

- Regulatory agencies -
  Higher standards before ‘approval’
  Quicker action when issues reported

FURTHER READING

Restorative justice surgical mesh: https://www.health.govt.nz/system/files/documents/publications/responding-to-harm-from-surgical-mesh-dec19.pdf

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Niemi K, et al. Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. American Journal of Obstetrics and Gynecology. 2010; 203:235.e1-.e8.

Management of mesh complications following surgery for stress urinary incontinence or pelvic organ prolapse: a systematic review. Available from: https://www.researchgate.net/publication/335968172_Management_of_mesh_complications_following_surgery_for_stress_urinary_incontinence_or_pelvic_organ_prolapse_a_systematic_review[accessed Feb 15 2021].

Milani AL, Damoiseaux A, IntHout J, Kluivers KB, Withagen MI. Long-term outcome of vaginal mesh or native tissue in recurrent prolapse: a randomized controlled trial. International urogynecology journal. 2018 Jun;29(6):847-58.

Bergersen A, Hinkel C, Funk J, Twiss CO. Management of vaginal mesh exposure: A systematic review. Arab J Urol. 2019;17(1):40-48. Published 2019 Apr 4. doi:10.1080/2090598X.2019.1589787

Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Neurourol Urodyn. 2011;30:2–12.