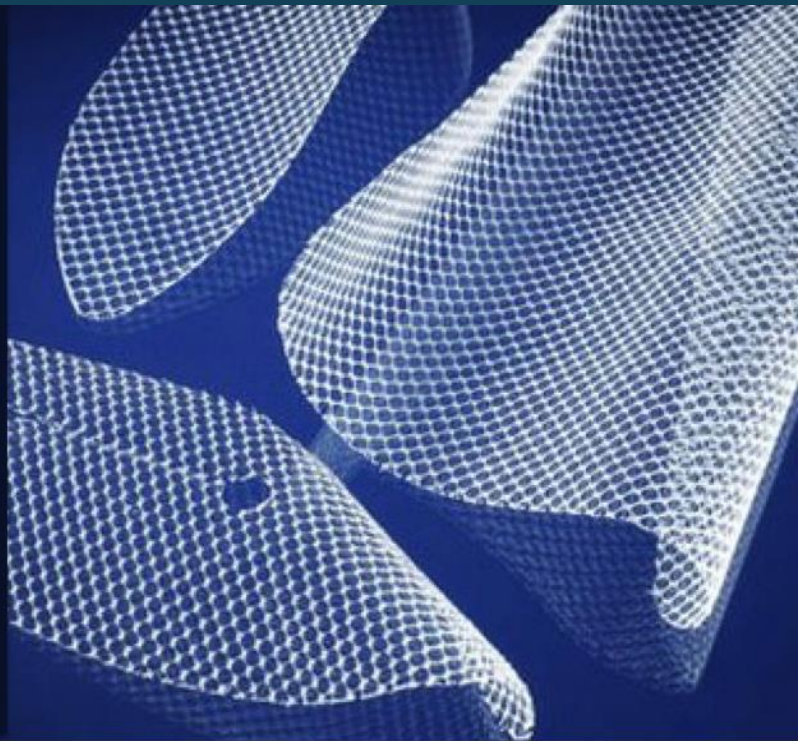


# Surgical mesh adverse reactions

A consumer voice on early identification in the  
GP setting

Patricia Sullivan 28 July 2017



New Zealand support group

# MESH DOWN UNDER™

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

[www.meshdownunder.co.nz](http://www.meshdownunder.co.nz)

# SMAR

## Surgical Mesh Adverse Reaction

### Kiwi mum warns of surgical mesh nightmare that destroyed her life



CHRIS SWELTON / FAIRFAX NZ

Alison with husband Jeff and children Latham, 13, and Jack, 10.

### Surgical mesh issues 'literally destroying lives'

1:15 pm on 3 June 2016

Share this



Tracking surgical mesh devices would be a partial victory for those dealing with the mesh's painful complications, but doesn't go nearly far enough for sufferers.



### Woman faces long health battle after surgical mesh operation

SAMANTHA GEE

Last updated 11:32, June 1 2016



### Patients who say surgical mesh has made their lives a 'living hell' question why it's still being used

CATE BROUGHTON AND MICHELLE DUFF

Last updated 05:00, June 4 2017



## Who am I?

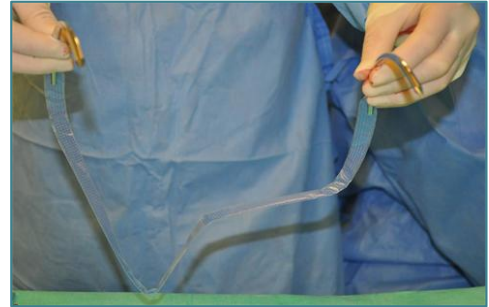
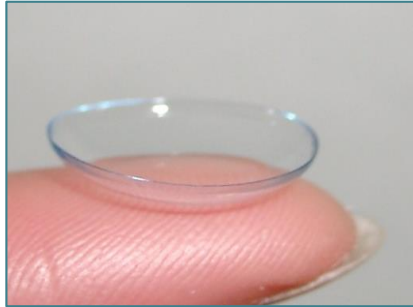


*“For outstanding services to nursing and academic achievement”*



## Risk classification

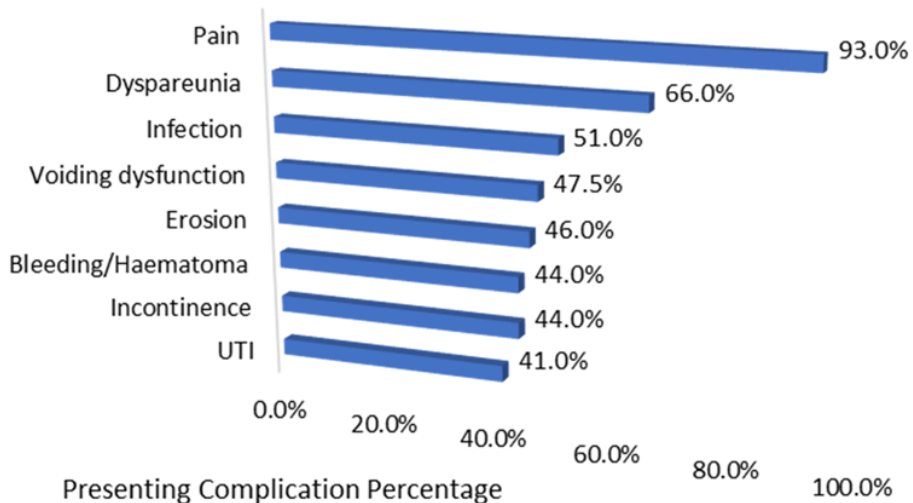
### Class II “medium harm”





## Mesh Down Under 2016 Survey

**93% of Mesh Down Under 2016 Survey Participants Presented with Pain Complications.**





## Current data collection

## Existing concern yet slow progress...



'Nothing has been achieved' - anti-mesh campaigners |  
Nine To Noon, 9:29 am on 19 June 2017 | RNZ

Three years after parliament's health select committee began inquiring into the use of surgical mesh, and a year since it made seven recommendations, anti-mesh...

RADIONZ.CO.NZ

NEW ZEALAND / HEALTH

## Surgical mesh data not stacking up?

2:54 pm on 19 March 2017

Share this



A group supporting people with surgical mesh problems says more and more treatment injuries are happening based on the number of claims being filed.





## Product concerns

We fashioned  
a mandarin net  
into a medical device



0:55 / 55:35

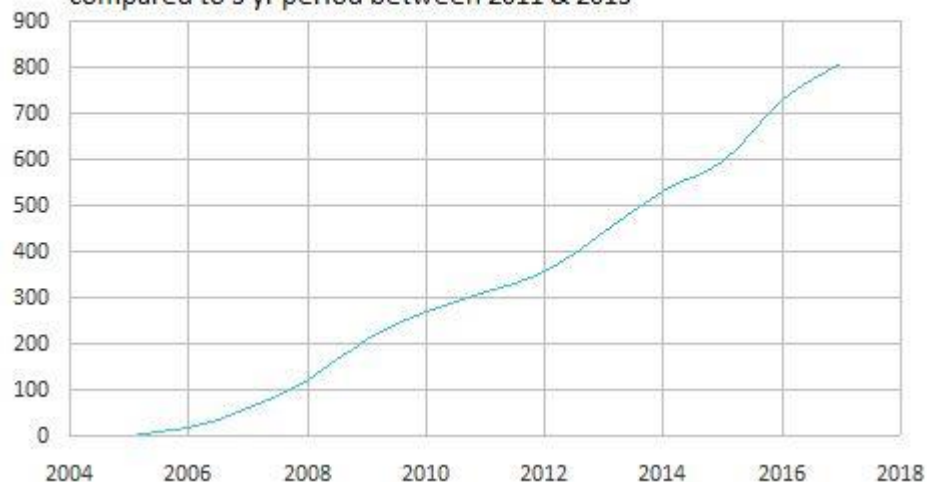


CE mark for sale (Full episode english subtitles) | RADAR  
(AVROTROS)



## Surgical mesh treatment injury decided claims

Increase of 62% for 3 year period between 2014 & 2016 compared to 3 yr period between 2011 & 2013



year	No. of decided Surgical Mesh TI claims	Total Cumulative decided Surgical Mesh TI Claims
2005	2	2
2006	16	18
2007	41	59
2008	62	121
2009	87	208
2010	62	270
2011	43	313
2012	42	355
2013	90	445
2014	87	532
2015	63	595
2016	134	729
2017	81	810
(Till 30 June 2017)		
SOURCE: ACC		



## **Survey results**

### **Analysis of Surgical Mesh Survey (Pilot Study September 2016)**

- **Sample size of 60 of the 197 Mesh Injured New Zealanders who are members of the Mesh Down Under support group**
- **Response rate = Just over 30%**

# Pelvic Organ Prolapse



**Get the Facts,  
Be Informed,  
Make YOUR  
Best Decision**

 **ETHICON**  
Women's Health & Urology  
[www.gynecare.com](http://www.gynecare.com)

Pelvic Organ Prolapse in Women:

*It's Common.  
It's Treatable.*

*Would it surprise you...*

to learn that while it's rarely talked about, approximately one out of three women aged 45 or older has some degree of pelvic organ prolapse? By age 80, more than one out of every 10 women will have undergone surgery for prolapse. Pelvic organ prolapse can affect a woman's daily life limiting physical and sexual functioning. Depending on its severity, it can cause pressure-like discomfort, at times pain and almost always disturbances in normal bladder and rectal function.

The good news is that you don't have to suffer with it. You can do something about pelvic organ prolapse, and you have choices. The newest choice is GYNECARE PROLIFT® Pelvic Floor Repair Systems, a revolutionary new minimally invasive surgical technique that offers promising long-term results for women with pelvic organ prolapse. During this procedure, the surgeon uses a soft synthetic mesh specially designed for placement through the vagina to support pelvic organs that have "dropped out" of their normal position (prolapsed).

Synthetic meshes, commonly used in abdominal wall hernia repair, are now being used in pelvic reconstructive surgery.

visit [www.gynecare.com](http://www.gynecare.com)

## What can I expect during the procedure?

The surgery takes only one to two hours and can be performed under regional (spinal or spinal) or general anesthesia.

## What can I expect after I go home?

After the surgery you will usually stay in the hospital for one night. Many patients return to normal daily activities within three to four days. Most completely recover in a two to three week period. During this time there should be very little interference with daily activities, although you will have to avoid heavy lifting, strenuous exercise and intercourse for up to six weeks.



## What are the risks?

All surgical procedures present some risks. Although rare, complications associated with the procedure include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury. There is also a small risk of the mesh material becoming exposed into the vaginal canal.



## Is GYNECARE PROLIFT right for me?

Pelvic floor repair procedures with GYNECARE PROLIFT are appropriate for almost all patients, including overweight patients, elderly patients, and even those who have undergone previous operations for pelvic organ prolapse or stress incontinence. As with any surgery of this kind, this procedure should not be performed on pregnant women, infants or children. It should also not be considered by women who plan a future pregnancy. Only a complete physical examination and consultation with your physician can determine which procedure is right for you.

visit [www.gynecare.com](http://www.gynecare.com)

**GYNECARE PROLIFT® Total Pelvic Floor Repair System**

**GYNECARE PROLIFT® Anterior Pelvic Floor Repair System**

**GYNECARE PROLIFT® Posterior Pelvic Floor Repair System**

## INDICATIONS

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

## CONTRAINDICATIONS

When GYNECARE GYNEMESH PS mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

## WARNINGS AND PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.
- Acceptable surgical practices should be followed in the presence of infected or contaminated wounds.
- Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.
- Avoid placing excessive tension on the mesh implant during handling.
- Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures.

## ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

- The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.
- Transient leg pain may occur and can usually be managed with mild analgesics.
- Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

## ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
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## Post operative complications

1. Pain
2. Erosion
3. Hematoma

### Post operative symptoms/complications

Table R: Pain

	Number of respondents	%
Yes	56	93.3
No	4	6.7
No response	-	-
TOTAL	60	100.0

Table S: Erosion

	Number of respondents	%
Yes	27	45.8
No	32	54.2
No response	1	-
TOTAL	60	100.0

Table T: Hematoma

	Number of respondents	%
Yes	11	18.6
No	48	81.4
No response	1	-
TOTAL	60	100.0



## Post operative complications continued

### 4. Recurrence

### 5. Infection

### 6. Urinary tract infection

Table U: Recurrence

	Number of respondents	%
Yes	25	42.4
No	34	57.6
No response	1	-
TOTAL	60	100.0

Table V: Infection

	Number of respondents	%
Yes	30	50.8
No	29	49.2
No response	1	-
TOTAL	60	100.0

Table W: Urinary Tract Infection UTI

	Number of respondents	%
Yes	24	40.7
No	35	59.3
No response	1	-
TOTAL	60	100.0



## Post operative complications continued

7. Voiding dysfunction
8. Painful intercourse/intercourse impossible
9. Unexpected bleeding
10. Incontinence (urinary and fecal)

Table X: Voiding dysfunction

	Number of respondents	%
Yes	28	47.5
No	31	52.5
No response	1	-
TOTAL	60	100.0

Table Y: Painful Intercourse/Intercourse impossible

	Number of respondents	%
Yes	39	66.1
No	20	33.9
No response	1	-
TOTAL	60	100.0

Table Z: Unexpected bleeding

	Number of respondents	%
Yes	15	25.4
No	44	74.6
No response	1	-
TOTAL	60	100.0

Table G10: Incontinence (Urinary & Fecal)

	Number of respondents	%
Yes	26	44.1
No	33	55.9
No response	1	-
TOTAL	60	100.0



## GP awareness

76.6% of respondents did not feel that their GP was aware of surgical mesh complications and symptoms

Table AD:

Told GP

	Number of respondents	%
Yes	46	78.0
No	13	22.0
No response	1	-
TOTAL	60	100.0

Table AF:

Told Implant Surgeon

	Number of respondents	%
Yes	59	98.3
No	1	1.7
No response	0	-
TOTAL	60	100.0

Table AJ: GP aware of surgical Mesh complications & symptoms

	Number of respondents	%
Yes	7	14.9
No	36	76.6
Don't know	4	8.5
N/A	12	-
No response	1	-
TOTAL	60	100.0



## Mesh symptoms and complications

### Physical

- 1: Groin/leg pain  
(**NEUROPRAXIA**)
- 2: Back/abdominal pain
- 3: Recurrent UTI's
- 4: Vaginal sloughing
- 5: Dyspareunia
- 6: Voiding dysfunction
- 7: Incontinence (bw/bl)
- 8: Systemic pain/rashes
- 9: Auto-immune – CFS
- 10: Fibromyalgia

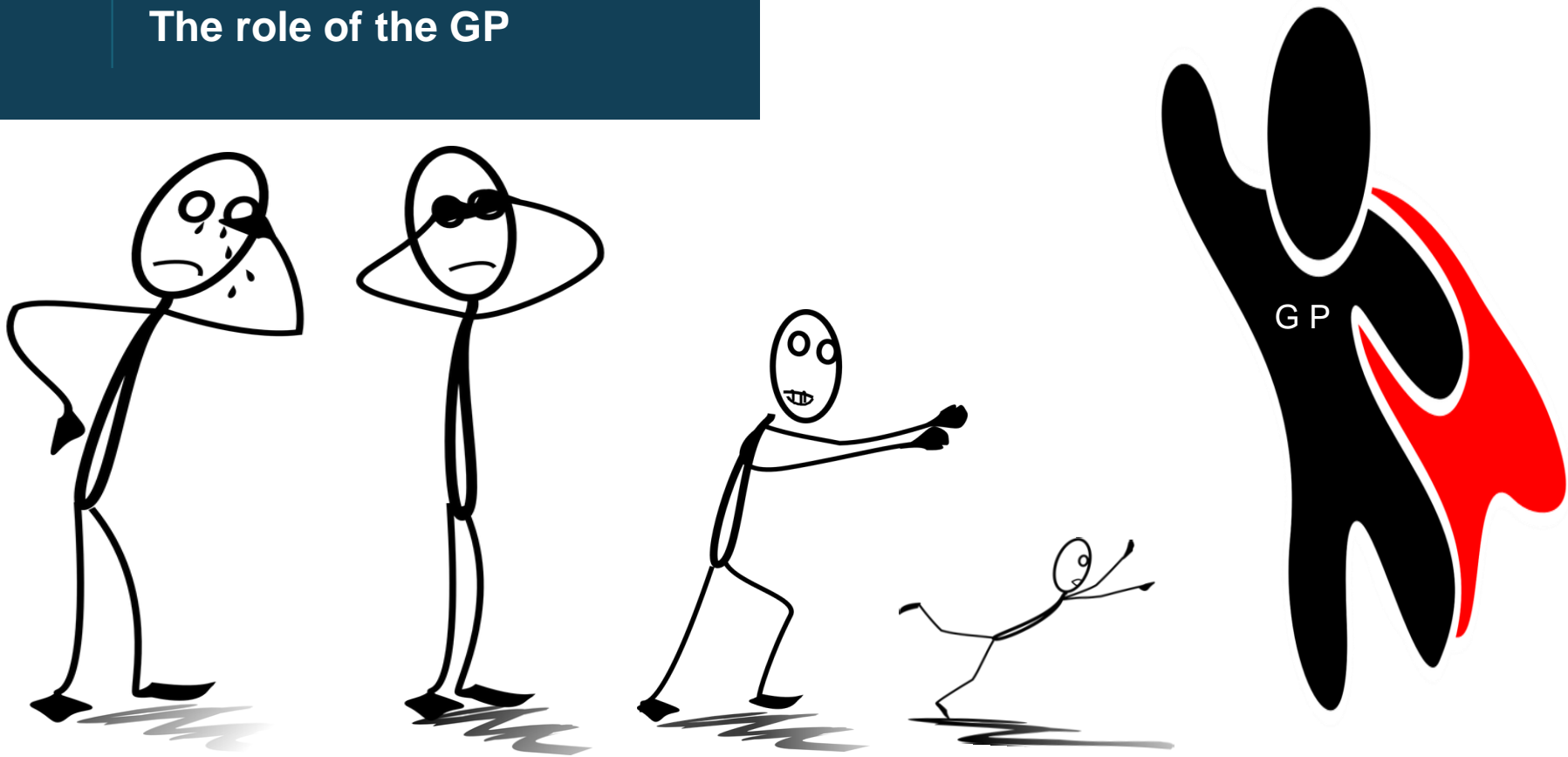
### Neurological

- 1: Anxiety
- 2: Depression
- 3: PTSD
- 4: Adjust. Disorder
- 5: Suicidal thoughts

### Other

- 1: Can occur immediately or up to 15 years later
- 2: Chronic pain syndrome
- 3: Central Sensitisation
- 4: Huge family impact
- 5: Loss of general health

## The role of the GP





## Recall response

### Device recall action search for products containing mesh. Commencement date after 1 Jul 2012

Number of product recall actions: 7

Date	Brand Name	Recall Action
19/05/2017	<a href="#">Skin graft meshers</a>	Instructions for use to be updated
1/08/2016	<a href="#">Novus TIGRR® Matrix Surgical Mesh</a>	Instructions for use to be updated
30/05/2016	<a href="#">Ethicon Physiomesh Composite mesh</a>	Product to be returned to supplier
22/09/2015	<a href="#">Ethicon Gynemesh PROLENE Soft (PS) Mesh</a>	Instructions for use to be updated
25/07/2013	<a href="#">Atrium CQur Mesh</a>	Instructions for use to be updated
25/07/2013	<a href="#">Atrium CQur Mesh VPatch</a>	Instructions for use to be updated
23/04/2013	<a href="#">Leica LPC Fine Mesh cassettes Pink</a>	Product to be returned to supplier

### Recall Action Definitions

[Explanation of the terms used to describe and define therapeutic product recall actions.](#)



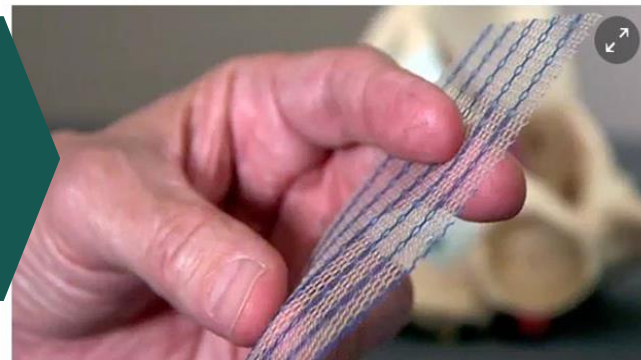
## Where do we go from here?

'SMAR' surgical  
mesh adverse  
reactions  
recognised

**RECALL**

### Senior doctors call for public inquiry into use of vaginal mesh surgery in UK

Experts draw comparisons with the thalidomide scandal as they reveal that traumatic complications are more common than official figures suggest





Maps

## ACHIEVING BEST OUTCOMES

## Prompt diagnosis crucial

- 1: Generally, a very gentle but thorough PV exam will identify vaginal mesh erosion
- 2: Red flag for GP's highlighting mesh implants on hospital discharge notes
- 3: Adequate pain relief to prevent chronic pain syndrome
- 4: Pelvic Pain does exist

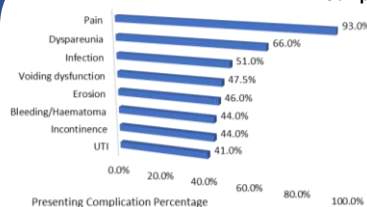
Thank you!

# Any questions?

For full survey and detailed analysis see:  
[www.meshdownunder.co.nz](http://www.meshdownunder.co.nz)

You can contact me at [patricia@meshdownunder.co.nz](mailto:patricia@meshdownunder.co.nz)  
Or [charlotte@meshdownunder.co.nz](mailto:charlotte@meshdownunder.co.nz)

### 93% of Mesh Down Under 2016 Survey Participants Presented with Pain Complications.



60 of the 197 mesh injured New Zealanders from the Mesh Down Under Website participated in the survey.

Of these 50% were Age 40-49 at time of mesh implant

45% were 5-9 years since mesh implantation, and 17% were 10-14 years since mesh implantation

15 % Reported GP aware of surgical mesh complications

44 made a claim to ACC of which 2/3 were accepted

## Regional Symptoms

Non specific pain<sup>2</sup>  
Nerve pain (pudendal, obturator) and muscle spasm  
Dyspareunia (painful sex)  
Mesh erosion causing discharge, bleeding, Infection  
Urinary dysfunction (voiding, incontinence, UTI)  
Incontinence Bowel and Bladder

## Regional and Systemic pain

symptoms develop as a result of: neuronal sensitization, cross-talk and pain centralization<sup>3</sup>.

It is no longer acceptable that pain be just managed.

We must accept that pain can be treated.

## Chronic Mesh Pain

The most common surgical mesh adverse reaction<sup>1</sup>.

Presentation and clinical implications vary greatly.

Some suffer pain immediately after the mesh implant.

Others start to have trouble much later, it may be a decade or so.

**Timing of pain onset** in relation to tissue incorporation, mesh break-down and shrinkage should be considered.  
Symptoms of obstructive urination, defecation, or Dyspareunia suggest mesh misplacement.  
Often associated with retraction of the vaginal epithelium<sup>2</sup>.

## Systemic Symptoms

### Allergic/immunologic<sup>2</sup>

Fibromyalgia  
hypersensitivity,  
inflammation,  
Rash, fever  
Mental Injury

Diabetes  
Lupus  
Chronic Fatigue  
Scleroderma  
Thyroid problems

Allergic or immune reactions to mesh may present immediately or in a delayed postoperative period.

1. Delavierre D, Rigaud J, Sibert L, Labat J. Definitions, classifications and terminology of chronic pelvic and perineal pain. Progres en urologie: journal de l'Association francaise d'urologie et de la Societe francaise d'urologie. 2010;20(12):853-64.

2. Rogo-Gupta L, Raz S. Pain complications of mesh surgery. Complications of Female Incontinence and Pelvic Reconstructive Surgery: Springer; 2013. p. 87-105.

3. Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. Obstetrics & Gynecology. 2010;115(2, Part 1):325-30.