

PE1517/HHHH

Petitioners' submission of 30 July 2019

It is almost seven years since we began our campaign to raise awareness of the dangers of plastic polypropylene mesh implants which were used to treat tens of thousands of women across Scotland for stress urinary incontinence and pelvic organ prolapse.

Our campaign has seen many highs and many lows, from the suspension of mesh across the UK to the continuing threat created by the many surgeons and influential health officials who clearly still wish to use mesh despite overwhelming evidence of life-changing injuries to so many patients around the world.

When we started this journey, there was little public awareness of the devastating side effects of mesh implants. We are pleased to say that is no longer the case, and the public are now very much more aware.

We are all ordinary women whose lives have been changed forever by mesh. Everything we now know we have had to learn along the way, and we are eternally grateful for the understanding and support we have received from the Scottish Parliament and MSPs from every party, and in particular the Public Petitions Committee and all its members.

The Committee understood immediately the significance of our campaign, and our concerns not just for the women who have already been injured, but future generations who could also be at risk.

We are gratified that mesh implants have been recognised as one of the biggest medical scandals of modern times, often compared to Thalidomide because of its devastating results on victims and their families. New damning evidence continues to surface, including just days ago as Chartered Chemist Dr Chris DeArmitt revealed that testing of the plastic material in mesh was less than you would expect on a vacuum cleaner or washing machine!

We expect that in the future we will look back at the use of mesh implants as one of the most shameful periods in medical history, where medical devices were implanted in patients with little or no evidence to prove either efficacy or safety; that patient injury and concern was widely ignored and regulation failed not just here in the UK but elsewhere in the world.

Although we have achieved so much, we have grave concerns that not all lessons have been learned to prevent similar scandals occurring in the future, such as hernia mesh which is causing similar life-changing injury to so many.

There is still a lack of accountability; regulation is far from adequate, and the mandatory register we asked for so devices in future can be more easily monitored for adverse effects is still a long way off.

We continue to believe medical manufacturers still hold an unhealthy influence over professional bodies and research studies, something that needs robust regulation.

While we applaud the stance Scottish Health Secretary Jeane Freeman has now taken in suspending the use of transvaginal mesh implants across Scotland, we have very real concerns that it took so long for it to happen in spite of the overwhelming evidence of patient harm.

We thank former Health Secretary Alex Neil for his intention to suspend transvaginal mesh from 2014, and find it deeply concerning that despite his clear intent almost 800 more women were implanted by the two health boards, Glasgow and Lothian, which ignored the suspension. As a consequence, women received those devices despite the concerns and without a fully informed consent of the information available at the moment.

It is lamentable that throughout Shona Robison's tenure as Health Secretary, she failed to address the flouting of the suspension. Chief Medical Officer Catherine Calderwood also failed to address this, something which undoubtedly put many more women at risk of life-changing injury.

We also have concern that while Jeane Freeman has publicly stated that she and she alone would make the decision as to whether mesh will ever be reintroduced, Scottish Government officials were already planning to do so as referenced in the minutes of the so-called Accountable Officers Group headed by Ms Calderwood's deputy Terry O'Kelly.

Ms Freeman stated there is no prospect of mesh being reintroduced in the foreseeable future. However, there are many questions surrounding exactly who knew what and when, and who is responsible as the minutes most definitely point to mesh being reintroduced. We believe there needs to be a parliamentary debate on this issue to settle pressing unanswered questions and to afford full transparency.

We applaud Jeane Freeman for taking the steps to bring in overseas experts to help train surgeons here and to treat women who have suffered devastating injuries which have led to the loss of life, careers, marriages, homes and have had a huge toll on our families.

Despite claims in the minutes of the Accountable Officers Group meetings that Scotland's mesh removal service is held in 'high regard', our members have little trust or faith in their competence.

We earnestly hope that Dr Veronikis can bring some of his skills to the table and surgeons here will take the opportunity to learn from him.

Presently, we have many women who have had so-called 'full removal' operations, but who are now worse off as a result; some of them left in wheelchairs and even more disabled as a result. We firmly believe this is due to the lack of removal skills among Scottish surgeons.

Many patients have also discovered that the 'full removal' written into their medical records, were not in fact full removal of the implant, but just a few centimetres. It is deeply disappointing that surgeons are not being transparent with patients. Mesh removal is an extremely complex and highly skilled procedure, yet there has been

very little evidence of the training surgeons here have been given to allow them to offer this service, or how much has been spent doing so. This must change and greater emphasis must be placed on repairing the damage caused by mesh implants.

It's ironic that the surgeons now held up as mesh removal experts are the self-same surgeons who implanted mesh inside patients and then spent years denying there was any issue with them, to the extent that women were being sent to see psychiatrists as their pain must be 'all in their head'.

It will take a huge sea-change in attitude and presentation for patients to be able to trust these surgeons again, particularly as most of these are the self-same surgeons who flouted the 2014 mesh suspension and implanted hundreds more women.

We must also raise our grave concerns at how long it has taken for the Scottish Government to respond to the mesh crisis, particularly as the cornerstone of NHS Scotland is supposed to be 'realistic medicine' which puts the person receiving health and social care at the centre of decisions made about their care.

We found the opposite to be true.

We first raised the need for Dr Veronikis to be brought to Scotland in January 2019, but this has only very recently been acted upon. Had it been acted upon when we first raised it, women like Claire Daisley would not be facing the prospect of losing both her bladder and bowel. Others may not have had to use their hard earned life savings to travel to the US to have their mesh removed fully and safely.

We still have no concrete date for Dr Veronikis to come to Scotland, despite the fact his input is so crucial to mesh-injured patients who stand any chance of getting a safe, full removal and the opportunity to regain some of the lives they have already lost.

Again, we hope lessons will be learned, and acted upon quickly.

We understand work is ongoing with regards to the restricted use protocol. We would like to put on record that two of the recommendations of NICE guideline, published in April 2019, have been withdrawn.

This withdrawal, within 10 weeks of publication of the national guideline, is believed to be unprecedented in the history of the national institute. It was brought about after Baroness Cumberlege asked for clarification of the conflicting recommendations from NICE over the last two years.

We eagerly await the publication of the Cumberlege Review into mesh.

In March this year (2019), Ms Freeman asked for stronger representation of the patient views to the Scottish Government dealing with planning the mesh complication service in Scotland. Ms Freeman invited Dr Agur, Consultant Urogynaecologist, to meet with us, understand our views and represent them to the Government group. Dr Agur established a team with us including Ms Voula Granitsiotis, lead female Urologist in NHS Lothian and Ms Hui-Ling Ong, medical

student from the University of Glasgow, to capture our views in an objective service evaluation in order to highlight areas in the service that require improvements. The evaluation survey and results are attached to this report.

An SBAR document, situation background assessment and recommendation was represented to the Scottish Government Group on Friday 14/06/2019, and is also included in our submission, in a link in the annexe.

Ms Freeman announced the establishment of a complex case review unit within NHS Scotland. We ask for this Unit to be established in NHS Lothian as the vast majority of our group had procedures in Ayrshire and Greater Glasgow and Clyde and would prefer to be seen elsewhere with clinicians we have more confidence in.

We ask that the composition of the group looking after the complex case review unit follow those recommended by the National Institute of Health and Care Excellence in England, to include a Gynaecologist, Radiologist and Urologist. We ask that all women should be offered the opportunity to be involved directly with their care and attend the meetings discussing their complex cases.

The development of a care pathway for the mesh injured women in Scotland is crucial, and we ask that we be part of that. We did start to contribute to such a pathway as members of the Government Expert Group back in 2014 before this work paused in 2016.

“Mesh is an avoidable risk – it is a life-time risk”

Thank you for your time and for hearing our voice.

Annexe

A Situation background assessment and recommendation was represented to the Scottish Government Group on Friday 14 June 2019

http://www.scottishmeshsurvivors.com/pdf/SBAR_SMS_for_Publication_230619.pdf

Clinical application of 2D and 3D pelvic floor ultrasound of mid-urethral slings and vaginal wall mesh

by Annika Taithongchai & Abdul H. Sultan & Pawel A.

Wieczorek & Rane Thakar - <https://doi.org/10.1007/s00192-019-03973-2>

Received: 15 January 2019 /Accepted: 22 April 2019 The International

Urogynecological Association 2019

Changed Women: The Long-Term Impact of Vaginal Mesh Complications

by Guinn Ellen Dunn; Brooke L. Hansen, MD; Marlene J. Egger, PhD; Ingrid Nygaard, MD, MS; Ana C. Sanchez-Birkhead, APRN, PhD; Yvonne Hsu, MD; and Lauren Clark, RN, PhD

April 2014.

https://www.researchgate.net/publication/261881802_Changed_Women_The_Long-Term_Impact_of_Vaginal_Mesh_Complications

Management of Pelvic Mesh Complications in Scotland

**Preliminary Results of a Service Evaluation
Co-designed by Patients and Clinicians**

Service Evaluation Team:

Hui-Ling Ong, Medical Student, University of Glasgow – Project Design, Data Analysis and Interpretation of Results

Elaine Holmes, Campaigner, Scottish Mesh Survivors – Conception, Project Design, Data Collection and Interpretation of Results

Olive McIlroy, Campaigner, Scottish Mesh Survivors – Conception, Project Design, Data Collection and Interpretation of Results

Wael Agur, Lead Urogynaecologist, NHS Ayrshire & Arran – Project Design and Interpretation of Results

Voula Granitsiotis, Lead Urologist, NHS Lothian & NHS Greater Glasgow & Clyde Mesh Complication Service – Project Design and Interpretation of Results

10 June 2019

Aim of Service Evaluation

The aim of this project is to describe the experience of the mesh complication service as reported by a sample of the mesh-injured women in Scotland. The project included surgical and non-surgical treatments to identify potential areas for improvement.

Methods

- Anonymised Evaluation Form – co-designed by clinicians and expert patient representatives.
- Data Collection – by patient representative group
 - At the meeting organised by the Independent Medicines and Medical Devices Safety (IMMDS) Review Team (Baroness Cumberlege Review Team) on the 17th April 2019 and,
 - Via online mailing list to members of the campaign group, Scottish Mesh Survivors. Women who used the mesh complication service were invited to complete the evaluation form.

Results

Demographics:

The total number of respondents who completed the evaluation form was 51 (see Flow Chart), 36 responses were completed at the IMMDS meeting and additional 15 evaluation forms were completed online during the subsequent three weeks.

The average age at first (or only) vaginal implant surgery was 47 years. Eight (8/51) women had more than one device inserted. Figure 4 shows the distribution of NHS health boards where the mesh devices were implanted.

The average duration from implant surgery to the onset of mesh-related adverse event was 0.9 years (0-11). The average duration from implant surgery to any explant surgery was 5 years (0-14 years).

Non-surgical Treatment

Most women were offered ultrasound/MRI scan (29, 56.9%) and physiotherapy/ pain clinic referral (31, 64.6%). However, only 6 (18.8%) respondents found

physiotherapy/pain clinic helpful. Twenty-five respondents (81.3%) found non-surgical treatment unhelpful.

Mesh Removal Surgery:

28 (54.9%) respondents underwent at least one mesh explant procedure. Only 4 respondents received total removal surgery, and 24 received at least one partial removal procedure. 12/28 (48.5%) had received more than one removal procedure. Figure 5 shows the distribution of NHS health boards where the mesh device was explanted. Flowchart 1 shows the type of mesh explants procedures.

Perioperative Management:

Prior to surgery, only 10 (38.5%) women felt they had enough time to discuss the removal surgery with their surgeon. *Following surgery*, only 4 (16%) obtained photographs of their removed mesh device. Eleven women (44%) were offered post-operative physiotherapy / pain clinic review.

Outcome of mesh explant surgery:

Initially, seven women out of 24 (29.1%) felt better, however, only one maintained improvement long-term. The other six currently feel 'much worse' or 'very much worse'. Only one patient felt worse initially, but now feels 'much better'.

Currently, only 3 women out of 24 described improvement, one eventually had total removal of her mesh device and the others had 2 excision for mesh exposure procedures. However, all three women were offered postoperative physiotherapy and pain clinic referral.

Of the four who had total removal, 2 were not offered any further management following removal surgery. Initially, one felt 'very much better', one felt 'a little bit better', one felt 'no change' and one felt 'a little bit worse'.

Four respondents described no change, and 13 feel worse. No patient who indicated partial removal stated that they feel better currently. Nineteen women (76% of those who had removal surgery) have rated their current general health at 50 or less.

Flowchart 2 shows the patient outcome following mesh explants procedures.

Interpretation of Results

The TransObturator Tape (TOT) was the most commonly implanted device indicated by the respondents. This could be due to:

- the relatively high frequency of use, as the TOT used to be the most commonly performed procedure for incontinence in Scotland prior to suspension in June 2014.
- The location of Cumberlege Review meeting in the West where, compared to the East, the TOT was much more prevalent.
- The fact that the TOT is more difficult to surgically remove in its entirety, compared to the retropubic mesh tape, leading to persistence of chronic symptoms. Women with persistence or recurrence of chronic pain were more likely to self-select, attend the IMMDS Review meeting and/or remain members of the safety campaign.

The average implant-to-adverse-event period is around one year. This would inform the proposed timing of a routine postoperative review at one year following all mesh implant procedures, with an earlier review if necessary.

The average implant-to-explant period is 5.3 years. Therefore, it appears the average duration of time spent in recognition, diagnosis and non-surgical treatment of mesh-related adverse events is 4.3 years. This period would appear too long to women suffering from chronic pain, particularly those who had indicated that non-surgical treatments e.g. physiotherapy / pain clinic were not very helpful.

Most patients complaining of chronic pain/dyspareunia were offered a scan (ultrasound/MRI). Pelvic scans are useful in identifying the location of the mesh device and in ruling out other causes of pelvic pain e.g. orthopedic causes.

Despite suffering mesh-related adverse events, mostly chronic pain and dyspareunia, over half of the respondents did not undergo any mesh explant surgery. Unfortunately, the evaluation form did not ask for the reasons behind not undergo surgery.

Our results showed that the vast majority of surveyed women had persistent chronic pain (48/51) and dyspareunia (43/51) after receiving a partial, rather than total, mesh removal surgery. Partial mesh explant surgery does not appear to be highly effective in addressing the most troublesome mesh-related symptoms of chronic pain and dyspareunia.

Self-selection may have impacted the results. The evaluation forms were completed by women who remained symptomatic and bothered enough with their symptoms to attend the IMMDS Review meeting or to remain active members of the safety campaign group

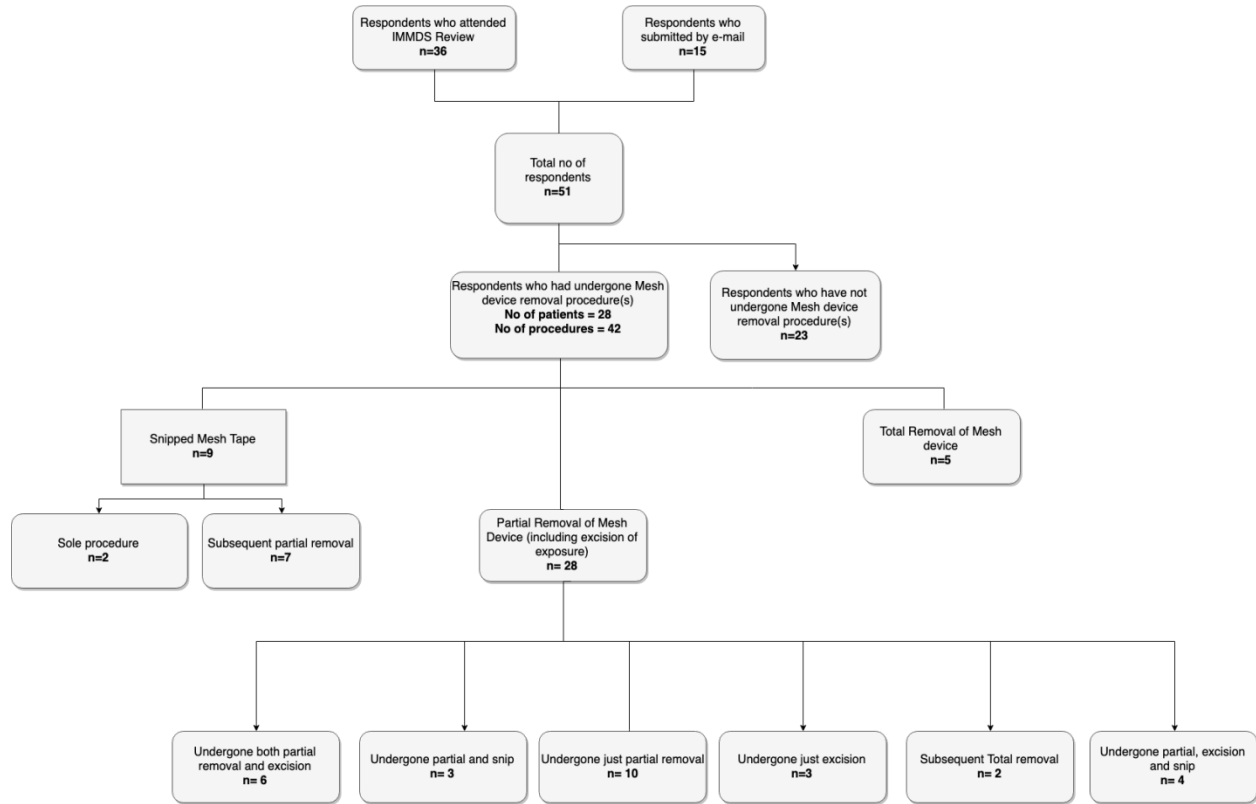
and respond to the online request to participate in this evaluation. Some women may have been cured of chronic pain and dyspareunia following partial removal surgery but have never completed the form.

In addition, time factors may have impacted these results. The last mesh explant procedure in this population was performed 2 years ago (2017). Mesh complication centres were formally established with requirements as advised by RCOG, BSUG and BAUS. In Scotland, the mesh centre in Lothian & GGC was established in May 2016 based on the expertise available at the two major health boards. Prior to establishment of this service, mesh removal surgery (snipping of small erosion or to relieve retention, excision of vaginal mesh exposure, partial and complete removal for chronic pain and/or urinary tract erosion) were performed in all Scottish Health Boards.

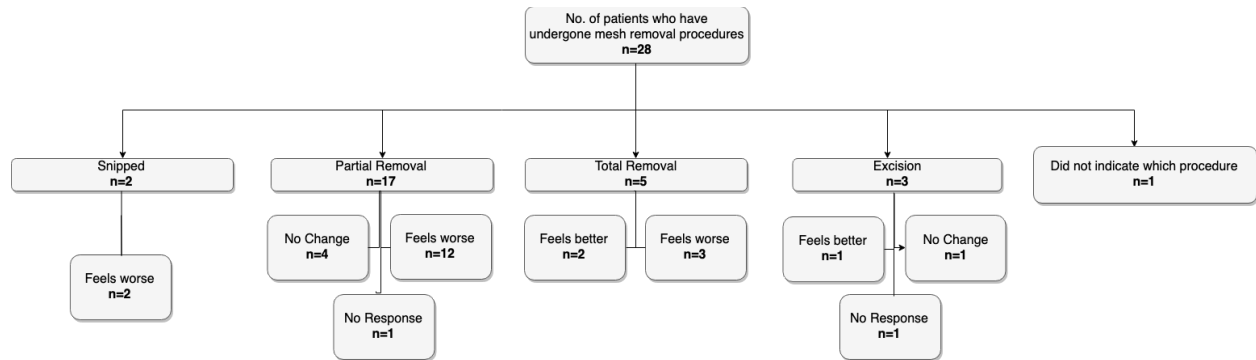
The results of this evaluation, therefore, may not have reflected any changes in clinical or surgical practice that could have taken place over the last two years. The surgical skills required for complete mesh device removal and the knowledge gained by assessing and managing mesh complications over time may have gradually improved over the last two years. However, such possible improvement was not have been captured in this evaluation.

There is no specific training on dealing with mesh complications The Royal Colleges training curriculum did not include recognition and treatment (surgical or non-surgical) of vaginal mesh complications. Mesh complications have been dealt with by physiotherapists, pain specialists, continence nurses, subspecialist urogynaecologist, female urologist and colorectal surgeons. The service remains not highly-specified nor purposefully funded.

Flowchart 1: Type of mesh explant procedures.



Flowchart 2: Current individual patient outcome of mesh explant procedures.



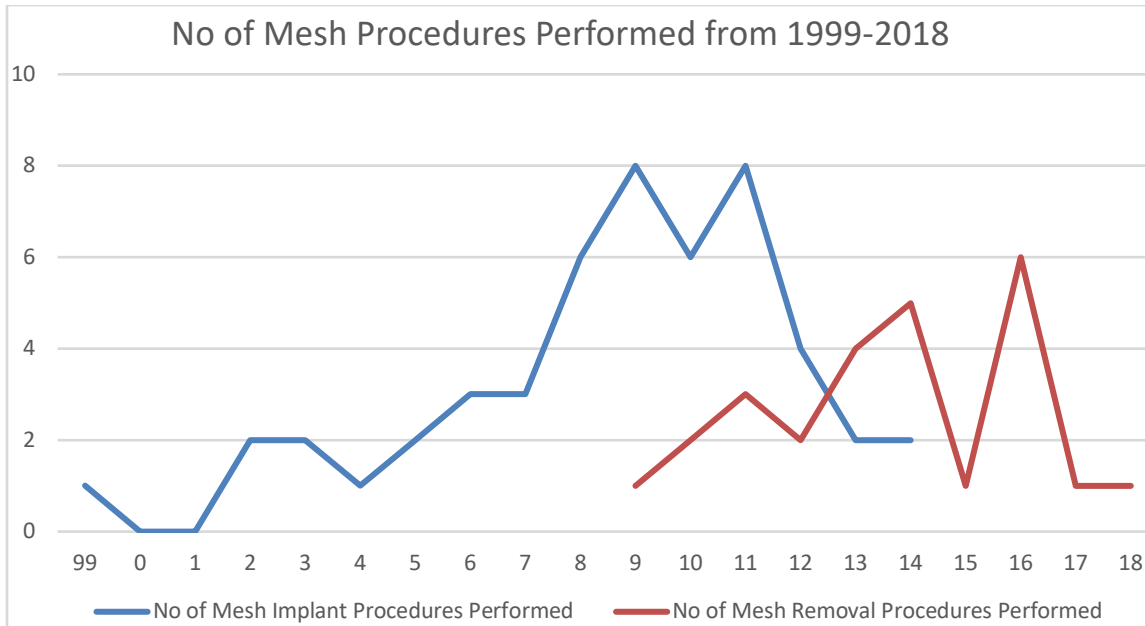


Figure 3: Line graph showing the number of mesh implant and explant procedures performed from 1999 to 2018.

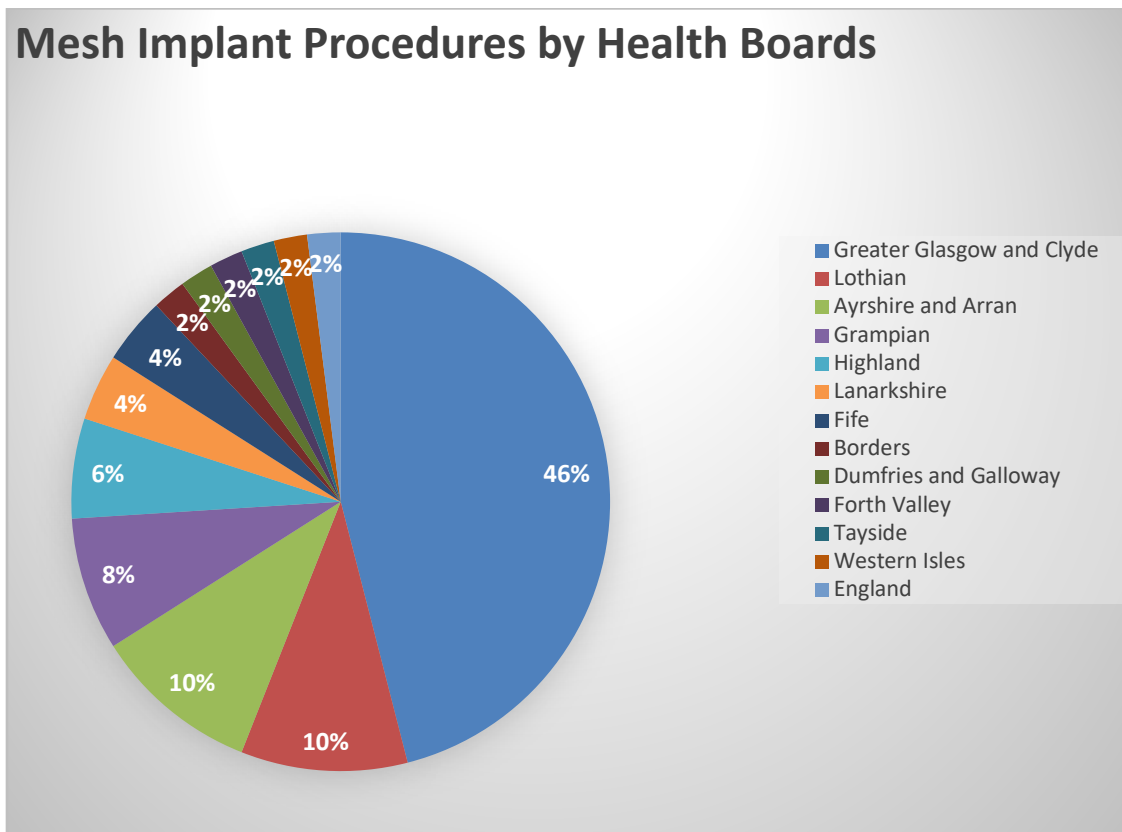


Figure 4: Pie chart showing number of patients who received mesh implant procedures according to NHS health boards.

Mesh Explant Procedures by Health Boards

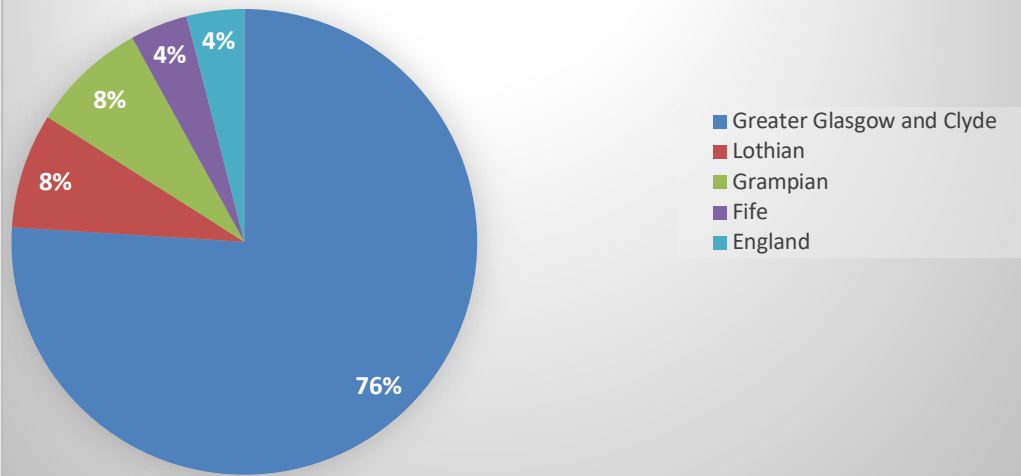


Figure 5: Pie chart showing number of patients who received mesh explant procedures according to NHS Scotland health boards.

Type of Original Mesh Implant

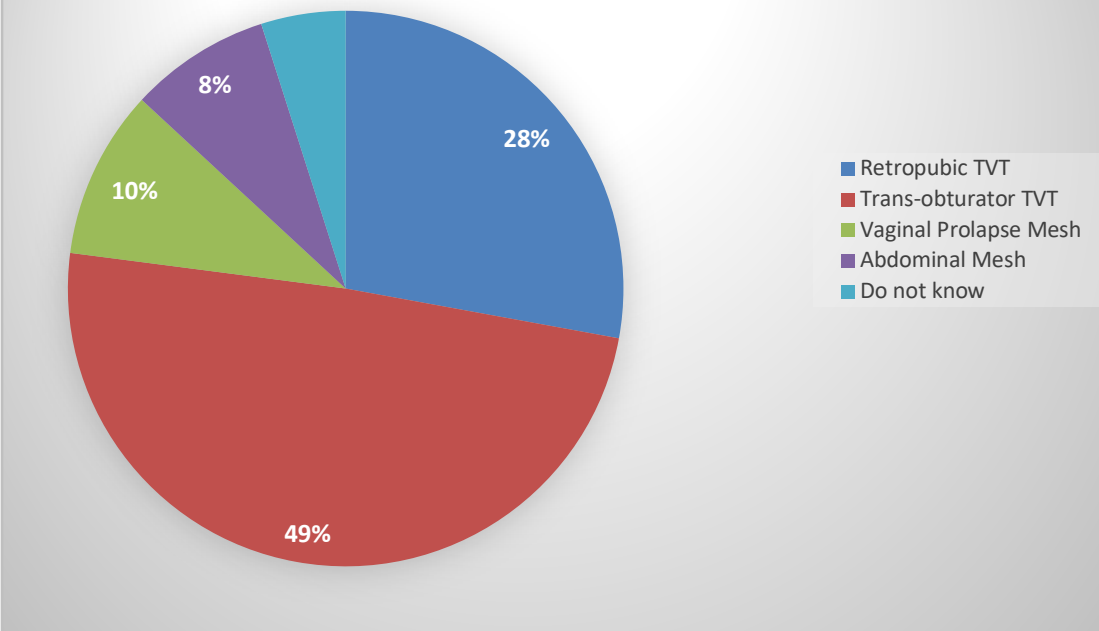


Figure 6: Pie chart showing the types of mesh implant procedures performed on respondents.

Table 1: Distinct symptoms entities experienced by respondents

Chronic Pelvic Pain	48					
Vaginal Erosion	18					
Bladder/Rectal Erosion	10					
Dyspareunia	43					
Others 40	Infections	21	UTI	10		
	Bleeding	6				
	Urinary Retention	13				
	Lack of Mobility	3				
	Generalised Pain	10				
	Suspected Autoimmune	17	Alopecia	2		
			PMR	1		
			Fibromyalgia	4		
			Reactive Arthritis	3		
			SLE	1		
		Pernicious Anaemia	1			
		Rheumatoid Arthritis	3			
		Rash	2			
	Sjorgens Syndrome	2				

Distinct Symptom Entities Experienced by Respondents

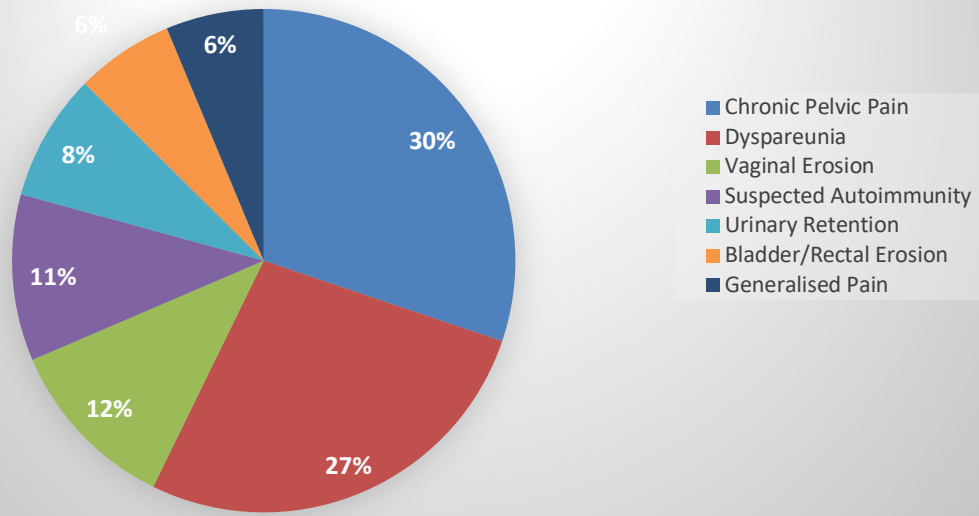


Figure 7: Pie chart showing types of distinct symptom entities experienced by patients.

Type of Mesh Removal Procedure

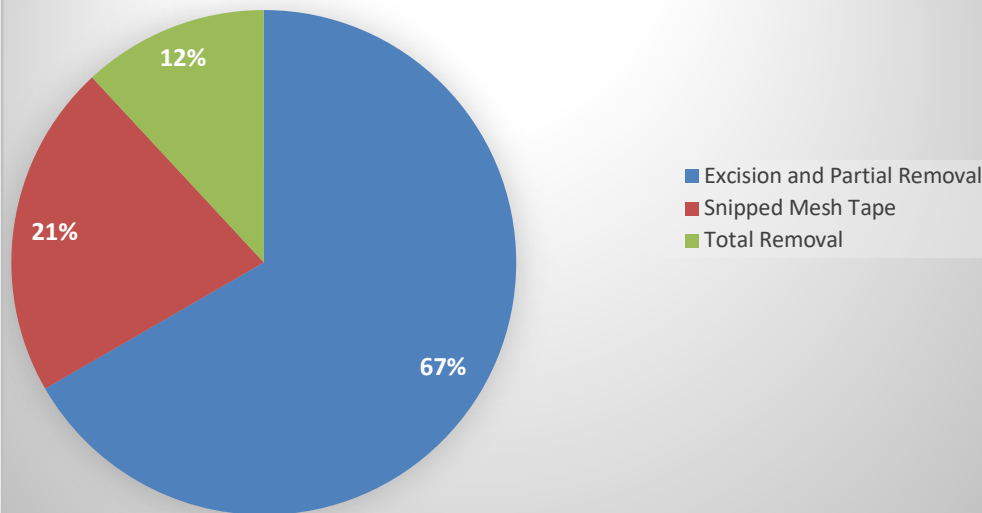


Figure 8: Pie chart showing types of mesh removal procedures performed on respondents.

		Current Improvement						
		Very Much Better	Much Better	A little Better	No Change	A Little Worse	Much Worse	Very Much Worse
Initial Improvement	Very Much Better	1	0	0	0	0	0	0
	Much Better	0	0	0	0	0	2	0
	A little Better	0	0	1	1	0	2	2
	No Change	0	0	0	3	0	1	2
	A Little Worse	0	0	0	0	1	0	1
	Much Worse	0	1	0	0	0	0	1
	Very Much Worse	0	0	0	0	0	0	5

*Line denotes figures that represent no change in condition between initial removal of mesh and now

Table 2: Comparison showing initial improvement (after receiving mesh removal procedures) against current improvement in patient's condition.

Management of Pelvic Mesh Complications in Scotland

A Patient-Clinician Co-design Service Evaluation Form

Please complete this short evaluation regarding your experiences with the pelvic mesh complication service. Please do not include your name, your doctor's name or other identifiable information.

1. About you:

- a. Year of birth: _____
- b. Year(s) of receiving pelvic mesh implant(s): _____
- c. **CITY(IES)** of residence (where you received the implant) _____
- d. Type of pelvic mesh implant you received (**tick all that applies**):

Procedure name	Description	Tick if applicable
Retropubic TVT (Mesh tape)	Inserted vaginally Two small cuts above the pubic bone	
Transobturator TOT (Mesh tape)	Inserted vaginally Two small cuts in the groin	
Prolapse mesh (vaginal)	Mesh patch – variable place of cuts	
Prolapse mesh (Abdominal)	Bikini line or key hole tummy surgery	
I do not know the type of the mesh implant		

- e. What year do you believe mesh complications started? _____
- f. Type of complication (**tick all that applies**):

Complication	Tick if applicable
Chronic pelvic / leg / groin / buttock pain	
Mesh erosion (exposure) in the vagina	
Mesh erosion into the bladder, urethra/rectum	
Pain during sexual intercourse	
Other(s) – please state e.g. infection, bleeding, retention of urine, generalised pain / autoimmune conditions. _____	

2. Management of Mesh Complications:

a. Were you offered Investigations e.g ultrasound / MRI scan? YES / NO

Comments:

b. Alternative options e.g. physiotherapy or pain clinic review? YES / NO

c. Did you find these alternatives helpful? YES / NO

Comments:

d. Have you had any mesh removal surgery? YES / NO

If NO, please hand this sheet back to the provider

If YES, please proceed with the following questions:

e. Year of first removal surgery: _____

f. How many removal procedures? _____

g. **CITY(IES)** where you had the removal surgery _____

h. What type of mesh removal procedures?

Mesh removal procedure	Tick all that apply	Number of times procedure was undertaken
Excision of mesh erosion (exposure)		
Mesh tape snipped (may include a centimetre of mesh device)		
Partial removal of mesh device		
Total removal of mesh device		
I do not know the type of the mesh removal surgery		

i. Did you feel you had enough time to discuss the removal surgery with your doctor/surgeon? **YES / NO**

j. Did you obtain photographs (with a ruler) of the removed mesh device? **YES / NO**

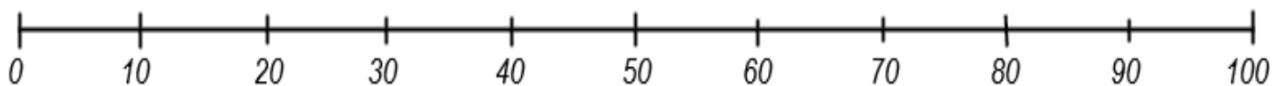
k. Were you offered further physiotherapy/pain clinic review? **YES / NO**

3. Improvement after mesh removal procedure:

<u>Initially, I felt:</u>	<u>Currently, I feel:</u>
Very much better <input type="checkbox"/>	Very much better <input type="checkbox"/>
Much better <input type="checkbox"/>	Much better <input type="checkbox"/>
A little better <input type="checkbox"/>	A little better <input type="checkbox"/>
No change <input type="checkbox"/>	No change <input type="checkbox"/>
A little worse <input type="checkbox"/>	A little worse <input type="checkbox"/>
Much worse <input type="checkbox"/>	Much worse <input type="checkbox"/>
Very much worse <input type="checkbox"/>	Very much worse <input type="checkbox"/>

How do you rate your current **GENERAL HEALTH TODAY** on a scale from 0 (worst health condition) to 100 (best health condition)?

Please circle the number below:



4. Suggestions

What would you suggest to improve the pelvic mesh complications services in Scotland?