Journal of Pelvic, Obstetric and Gynaecological Physiotherapy, Spring 2019, **124,** 5–8

OPINION

The mesh controversy

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Abstract
The current controversy surrounding the use of mesh in gynaecological and general surgery is escalating at the time of writing, and looks set to be one of the biggest medical scandals of our generation. Pelvic health and musculoskeletal physiotherapists are both seeing patients with mesh-related complications who may be looking for a diagnosis, or seeking relief from pain and related symptoms. Pelvic health physiotherapists are likely to come across increasing numbers of women who have undergone removal of gynaecological mesh, and many of these individuals will experience the return of their symptoms of stress incontinence or pelvic organ prolapse (POP). Women with mesh complications, as well as those who are concerned about developing these problems in the future, are understandably angry and anxious. Both the landscape of healthcare, and the relationship between patients and healthcare professionals has altered, and will never be quite the same again. We need to adapt to these changing conditions in order to successfully restore confidence, and to support patients during their rehabilitation.

Keywords: complications, controversy, mesh, removal, surgery.

My role in mesh

I became involved in the current mesh controversy by chance, following a conversation with Kath Sansom, the leader of the Sling the Mesh campaign group (https://slingthemesh.wordpress.com). This initiated an interest and involvement in this area that has resulted in me supporting this group, which has 7500 members and is still growing. I have given written and oral evidence to the government's review group (see pp. 79–80), and delivered a presentation on mesh at the 2018 POGP Annual Conference (Robson 2018).

There are weaknesses in the processes involved in testing products to be used on patients. In 1996, Boston Scientific (Marlborough, MA, USA) launched the first mesh tape for stress urinary incontinence (SUI), the ProteGen Sling. In 1998, it was then relatively simple for Johnson & Johnson (New Brunswick, NJ, USA) to get their new tension-free vaginal tape (TVT) product, Gynecare TVT, cleared for use because there is a rule called "equivalence" that allows very similar products to be passed more easily. Unfortunately, more complications than expected occurred with the ProteGen Sling, including infections and erosion, and around 500 patients made complaints. The product was recalled, but there is no ruling that says similar products must also be recalled or tested. This meant that a variety of mesh products continued to enter the market and be prescribed, despite problems higher up the chain.

In 2003, the National Institute for Health and Clinical Excellence (NICE, now the National Institute for Health and Care Excellence) recommended TVT for SUI (after physiotherapy), but there was very limited data on long-term complications (NICE 2003). The organization recommended that 10-year data collection was required, but this never took place. In 2006, NICE recommended that women should be informed of the lack of long-term data, but many have reported that this never happened (NICE 2006).

In 2005, the Cochrane organization reported that there was a need for long-term studies, and that few trials had reported fully enough to be of significant use (Heneghan 2018). The majority of information seemed to be coming from experts making presentations at meetings, which is low in the hierarchy of evidence.

In 2001, prolapse mesh was reclassified by the US Food and Drug Administration as a high-risk

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rather than moderate-risk procedure, and in 2012, Johnson & Johnson withdrew a number of their products. However, safety was not cited as a reason, and therefore, surgeons generally moved on to alternative brands rather than question the use of mesh generally.

Some experts believe that reported complications such as pain and dyspareunia were not taken seriously. There is also a belief that consent was not adequate because of the lack of long-term data. Many women report that they were offered surgery for SUI, in particular, as a "quick fix", but few describe being offered physiotherapy for either SUI or POP, even though this is the first-line treatment recommended for SUI in women by NICE (2013).

What complications are people with mesh experiencing?

The original estimates of mesh complications ranged from around 4% for incontinence procedures to 8% for those for prolapse. Current estimates are around 10% for any mesh procedure (with an increase in reported complications for hernia mesh), and some estimates are as high as 40%. The reported symptoms include pain, infection, erosion, adhesions, loss of mobility and painful sex, and also a huge number of unexpected symptoms, such as fibromyalgia, insomnia and static shocks. Many reported symptoms have no objective evidence to support them, but individuals often share their symptoms in support groups and rely on validation from other members.

The pain ball diagram (Fig. 1) was one that I developed after noting down patient-reported symptoms from mesh support groups and social media over a 12-month period. I logged symptoms that were reported by at least two people, and were validated by at least one other. The size of each word represents the frequency with which it was mentioned, with the larger words being reported more often.

How does this impact healthcare professionals?

From my observations, there has been a shift in how healthcare professionals and the healthcare system are viewed. There used to be a certain level of automatic trust, especially for consultant medical and surgical staff. This is not always the case now, and there has been an enormous amount of anger directed towards doctors, and both the National Health Service and private healthcare system. There is also a considerable amount of fear, which can range from concerns about the waiting times for mesh removal to litigation issues, the return of incontinence or prolapse following removal, and whether complications will occur in currently asymptomatic individuals.

What should specialist pelvic health physiotherapists do?

In terms of managing patients who present with potential mesh complications, the most important aspect of our care is to listen to the patient's story without making a judgement. It causes immense distress to patients if they feel that they are not being believed. In terms of physiotherapy management, the key principle is to follow the way that we would usually work, and assess and treat each person as an individual.

It is also important to educate our non-pelvic health physiotherapy colleagues about the situation, since they are often the first-contact physiotherapist for individuals with mesh complications.

There are no assessment or treatment techniques that are contraindicated, but a few pointers follow:

- Patients who have documented or suspected mesh erosion are usually advised to avoid pelvic floor muscle (PFM) strengthening exercises or internal pelvic floor devices.
- Pelvic floor muscle relaxation and down-training should be beneficial for everyone.
- Patients who have undergone mesh removal can often start PFM retraining once the catheter has been detached, but if the removal was complicated, then they may be advised by the surgeon to wait, possibly for as long as 12 weeks.
- Pain management teams may see patients who are not suitable for mesh removal, or as part of the wider team at any stage in the removal process.
- Graded motor imagery, pacing, bladder and bowel retraining, relaxation, mindfulness, desensitization and graded exposure, biofeedback, and manual therapy may all be appropriate.
- Individuals may require treatment for compensatory movement patterns that they develop to cope with mesh complications.

What next?

There is ongoing work to develop four accredited mesh removal centres in the UK, and to improve the understanding of all healthcare

Figure 1. Word cloud showing the frequency of patient-reported symptoms associated with vaginal mesh.

professionals who may work with individuals with mesh complications.

It is recognized that the consent process for mesh removal surgery must be as thorough as the consent process for implanting mesh should have been. It is also important that mesh removal is carefully managed to avoid further problems. Many questions remain, such as: When is it wise not to remove mesh? Should you remove mesh in one go or in stages? Why do some people develop complications and not others? What is the best way to manage a return of SUI or POP?

The overall goal of future management is to provide treatment with the right person, at the right time and in the right place, but as yet, the way to do this is not entirely clear.

In April 2019, it is expected that the review body will report back with its findings, and outline what the way forwards is with regard to mesh. It is then expected that an investigation of some sort may take place into hernia mesh, but this has not been confirmed.

The complications and discussions surrounding mesh change frequently, and we need to remain aware of what is happening within our services at both the governmental and local levels to deliver the best care that we can to the patients whom we treat.

Acknowledgements

My thanks go to Virginia Rivers Bulkeley, a physiotherapist at University College Hospital, London, UK, for her support, and for providing

information on mesh complications and rehabilitation. Thanks also go to the many women who have shared their stories with me, and Kath Sansom from the Sling the Mesh campaign for encouraging healthcare professionals and mesh-injured women to work together.

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