The rise and fall of mesh in urogynaecology surgery: the impact of inadequacies in the surgical device approval system

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Introduction

Mesh is a synthetic material used to reinforce a weakened area **(Figure 1)**.[1] It was first developed in the 1950s for the surgical repair of inguinal hernias.[1] It proved to be superior to conventional suture repair, making it incredibly popular in general surgery.[2] This led to mesh also being adopted in urogynaecology surgery in the 1990s,[3] including in the treatment of pelvic organ prolapses (POPs).[4] A POP is the descent of the bladder, uterus or rectum, from their normal anatomical position, into the vagina.[5] Symptoms may include a bulging sensation in the vagina, urinary incontinence and increased urinary frequency.[6] POP is a common condition; it is estimated that it affects 50% of women who have had children.[5] The aim of using a mesh implant in conditions of POP is to reinforce and support the weakened pelvic tissue.[5]

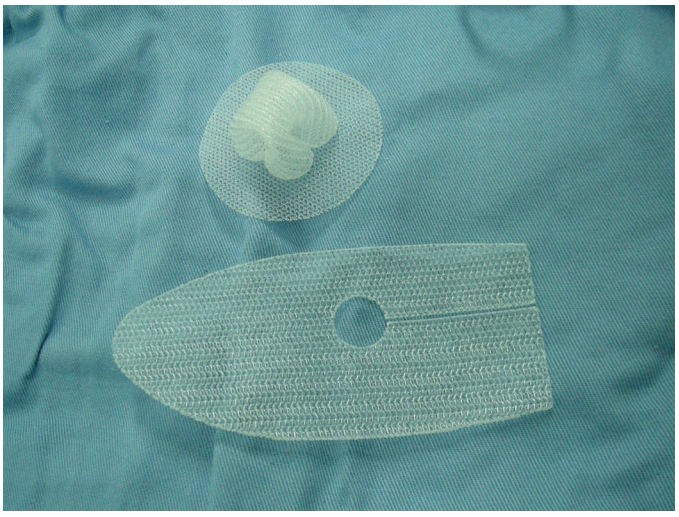

Figure 1: Mesh implant. Image reprinted from[7], under the terms of the Creative Commons Attribution-ShareAlike 3.0 Unported License (https://creativecommons.org/licenses/by-sa/3.0/)

Between July 2018 and April 2019, the use of mesh for POP was temporarily halted pending further investigations.[8,9] Years prior to this, women were reporting severe side-effects from mesh implants. A meta-analysis by Feiner et al in 2009 (n = 2653) found that mesh erosion through the vaginal tissue was the most common post-operative complication, with the incidence ranging from 4.6–10.7%.[10] Another post-operative complication includes dyspareunia (painful sexual intercourse), which affects 1.7–5.5% of patients.[10]

The long-term implications following mesh surgery have also been devastating for some patients. An independent review by the Scottish government enquired about patients' post-operative experiences. Some patient excerpts included:

> *"I have had four separate surgical procedures with no avail and now I have been left with severe problems."*[11]

> *"I am now 46 years old and the last 6 years of my life have been hell since being implanted with this device."*[11]

Whilst only a small proportion of patients were negatively affected by the mesh implants, these concerns were first raised decades ago.[12] Furthermore, there have been many litigation cases, worth millions of pounds, against mesh manufacturers.[13] However, the inadequacies in the approval system of such surgical devices meant that these problems went unbridled.[13]

This issue raises the question: is the current system for the approval of surgical devices adequate to ensure positive patient outcomes?

Issues with the approval system

It is difficult to comment on the details of the approval system of mesh in the United Kingdom, as this is managed by the Medicines and Healthcare Products Regulatory Agency (MHRA), which is not subject to Freedom of Information requests.[14] However, this is not the case for surgical devices in America. Although differences exist between the American and the UK medical-device approval system, the American system can provide some insight on the approval process of mesh implants and shed light onto the inadequacies that precipitated to the mesh scandal.

The Food and Drug Administration (FDA) are responsible for surgical-device approval in America. They classify medical devices into class I (low-risk), class II (moderate-risk) and class III (high-risk) categories. The higher the risk classification, the more stringent the approval process.[13]

Class II devices can gain approval if manufacturers demonstrate that the device is 'substantially equivalent' to a previously approved product, and no new clinical investigations are required.[13] Mesh was originally classified as a class II device.

The ProteGen sling (Boston Scientific) was approved in 1996 for use in urogynaecology surgery after it was deemed to be equivalent to a type of mesh used in hernia repair.[11] It was recalled after 3 years due to its high failure rates.[12] However, due to its moderate-risk classification, subsequent mesh models were approved on the basis of being 'substantially equivalent' to the 1996 ProteGen Sling, despite its removal from the market **(Figure 2)**.

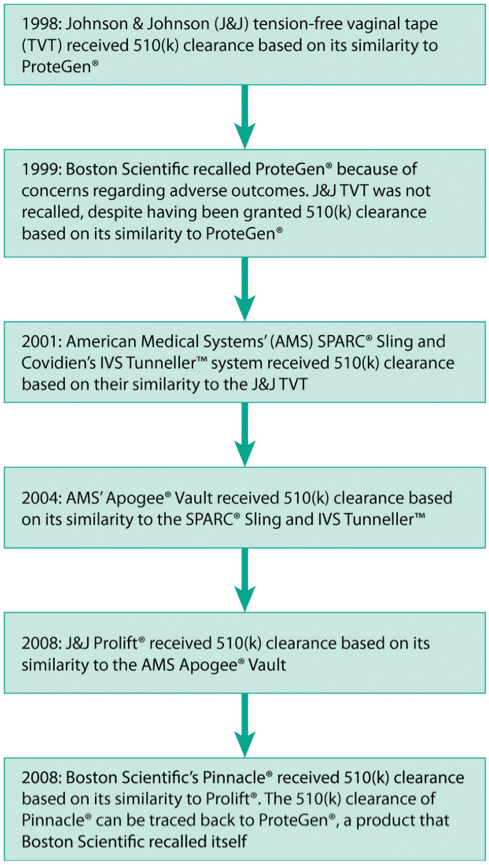

Figure 2: Cascade of mesh approval after the recall of the 1996 ProteGen sling. Image from Campbell et al[4], published with permission from John Wiley & Sons. ©2018 Royal College of Obstetricians and Gynaecologists

Future changes

Certain amendments have been implemented in an attempt to rectify the aforementioned problems associated with mesh implants. In January 2016, the FDA reclassified mesh as a class III (high-risk) device, now requiring more stringent tests prior to approval.[15] The European Parliament also followed suit and, in September 2017, it declared mesh as a high-risk device and instructed that new devices must be held under greater scrutiny.[3]

In April 2019, the temporary ban on mesh in England was lifted and recommendations were made for future practice. One particular recommendation was the introduction of a national registry for all mesh surgeries in England. Hospitals are now required to disclose information, such as the type of mesh used in each surgery. In addition to this, they must also monitor each patient's outcomes for at least 5 years.[9]

The implementation of such a registry may prove to be very helpful in the future. Any implants that are consistently associated with poorer outcomes can be swiftly recognised and removed from clinical practice. Hopefully, this could curtail and prevent such issues from arising again.

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References

1. Brown CN, Finch JG. Which mesh for hernia repair? *Ann R Coll Surg Engl*, 2010; 92(4):272–8.
2. Bittner R, Schwarz J. Inguinal hernia repair: current surgical techniques. *Langenbeck's Arch Surg*, 2012; 397(2):271–82.
3. Barber S. Briefing Paper: Surgical mesh implants. (2018) Available from: https://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-8108. Accessed: 27 January 2019.
4. Campbell P, Jha S, Cutner A. Vaginal mesh in prolapse surgery. *Obstet Gynaecol*, 2018; 20(1):49–56
5. Maher C, Feiner B, Baessler K, et al. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. *Cochrane Database Syst Rev*, 2016; 2(2):CD012079.
6. Jelovsek JE, Maher C, Barber MD. Pelvic organ prolapse. *Lancet*, 2007;369(9566):1027–38.
7. Doctoroftcm (2010) Hernia mesh. Available from: https://en.wikipedia.org/wiki/Surgical_mesh#/media File:Hernia_mesh_1.jpg. Accessed: 22 February 2020.
8. National Institute for Health and Care Excellence (NICE)(2017) Transvaginal mesh repair of anterior or posterior vaginal wall prolapse. Available from: www.nice.org.uk/guidance/ipg599. Accessed: 27 January 2019
9. National Institute for Health and Care Excellence (NICE)(2019) Urinary incontinence and pelvic organ prolapse in women: management. Available from: www.nice.org.uk/guidance/ng123/resources/urinary-incontinence-and-pelvic-organ-prolapse-in-women-management-pdf-66141657205189. Accessed: 2 April 2019..
10. Feiner B, Jelovsek J, Maher C. Efficacy and safety of transvaginal mesh kits in the treatment of prolapse of the vaginal apex: a systematic review. *BJOG*, 2009; 116(1):15–24.
11. The Scottish Government (2017) Transvaginal mesh implants independent review: final report. 2017. Available from: www.gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-9781786528711/pages/5/. Accessed: 5 August 2019.
12. Kobashi KC, Dmochowski R, Mee SL, et al. Erosion of woven polyester pubovaginal sling. *J Urol*, 1999; 162(6):2070-72
13. Heneghan C, Aronson JK, Goldacre B, et al. Transvaginal mesh failure: lessons for regulation of implantable devices. *BMJ*, 2017; 359:j5515.
14. Thompson M, Heneghan C, Billingsley M, et al. Medical device recalls and transparency in the UK. *BMJ*, 2011; 342:d2973.
15. U.S Food and Drug Administration (2016) FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks. 2016. Available from: www.fda.gov/newsevents/newsroom/pressannouncements/ucm479732.htm. Accessed: 28 January 2019