



## NEWS

# Patients harmed by mesh implants address emotional parliamentary meeting

Rebecca Coombes

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Women with life changing side effects after transvaginal mesh implants led a call in the UK parliament last week for a suspension of the devices pending a full public inquiry.

The emotionally charged meeting, organised by a shadow cabinet member, Owen Smith, was also supported by doctors, surgeons, academics, and more than 20 MPs.

More than a dozen women testified to how mesh had left them disabled, in chronic and debilitating pain, needing a bladder or bowel removed where the mesh had shrunk and sliced into them, unable to have sex, or with psychological problems. The implants include vaginal mid-urethral tapes used to treat stress urinary incontinence, as well as mesh used to treat pelvic organ prolapse, made of polypropylene.

Since 2006 more than 126 000 women have had mesh implants and tapes for incontinence and prolapse in England. The implants are subject to an ongoing inquiry in Scotland, where mesh for women with pelvic organ prolapse is currently suspended.

A report by a working party set up by NHS England is due to report this week. An initial review published in Scotland in April was branded a “whitewash” by patients after failing to recommend banning the implants.

The safety of mesh implants has risen up the political agenda after campaigns by more than 2000 affected patients in the UK. A *Lancet* study, published last year,<sup>1</sup> found that mesh repair of prolapse carried a substantially increased risk of later complications—over three times higher than with traditional, non-mesh repairs. The paper said that mesh should not be the first line of treatment for prolapse, although it supported the use of mesh for incontinence.

Kath Sansom, a mesh recipient who set up the campaign Sling the Mesh, highlighted the lack of information on long term complications and the absence of mandatory registries for implantable devices.

She said, “There are black holes in data collection, little monitoring of patient outcomes, and a medical device regulatory system so weak that, in the last five years, we have witnessed the PIP breast implant scandal, the metal hip scandal, and now mesh—all under the nose of the MHRA [Medicines and Healthcare Products Regulatory Agency] that is supposed to be a watchdog for the NHS.”

Sansom said that clinicians did not reliably engage in data collection, such as the database set up by the British Society for Urogynaecology, or use the data to support their own clinical

practice. The only data captured are from women readmitted to hospital for follow-up surgery, she said.

“With mesh, many women go back and forth to their GPs begging for help or pain medication,” said Sansom. “They may be referred to their implanting surgeon but, because they are not admitted to hospital, their stories do not show up in the figures. There is a whole army of women missing from the data of risk of mesh surgery.

“We are not debating if mesh works. It can be a stronger, longer lasting fix than traditional surgery. But it has horrendous complications [that are] much worse than the original problem it sets out to fix—that is, incontinence or prolapse caused by childbirth.”

Suzu Elneil, a consultant urogynaecologist and uroneurologist at University College Hospital in London, said that complication rates seemed too far high, as research by her team using hospital episode statistics suggests that they are around 8.98%.

“If we are closing in on 10% complications we need to make sure the whole situation is revised,” she said. These figures contrast with a much lower risk of complication reported by the MHRA, of 1-2%.<sup>2</sup>

Carl Heneghan, professor of evidence based medicine at the University of Oxford, called for a public inquiry into the use of mesh and said that the rate of serious complications was much higher than currently reported.

“Everything we have been talking about has been obvious for 10 years,” he said. “In 2006 NICE [the National Institute for Health and Care Excellence] and Cochrane were alerted to the lack of long term data. There are 100 plus meshes in circulation, some with substandard design, approved because of massive holes in European legislation.”

Heneghan spoke of an investigation he had carried out with a Dutch television programme where he took an orange tangerine net and got it approved for use as transvaginal mesh.

During the two hour Westminster meeting, Smith raised the issue of informed consent, saying, “It’s remarkable how many women were told this is a quick, easy procedure, that it would sort out leakage, and [that] women would be able to carry on with jogging or yoga, but it was clearly a marketing ploy.

“The fact there isn’t a proper database, a registry for women who have had this implant, is clearly wrong. If it is a problem on anything like the scale we have heard today then we need to suspend its usage.”

Smith has called for an urgent meeting with England's health secretary, Jeremy Hunt, and is setting up an all party parliamentary group on mesh implants.

The law firm Wedlake Bell has launched a class action for women in England and Wales against a mesh manufacturer, Johnson and Johnson, and many similar legal cases have arisen around the world, including in Scotland. Last year a jury in Philadelphia, USA, awarded \$13.5m (£10.4m; €11.6m) in damages to Sharon Carlino against Johnson and Johnson.<sup>3</sup>

- 1 Morling JR, McAllister DA, Agur W, et al. Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997-2016: a population-based cohort study. *Lancet* 2017;358:629-40. doi: 10.1016/S0140-6736(16)32572-7. pmid:28010993.
- 2 Department of Health. Vaginal mesh implants: summary of benefits and risks. 5 Nov 2014. <https://www.gov.uk/government/publications/vaginal-mesh-implants-summary-of-benefits-and-risks>.
- 3 Christie B. Mesh implant review is a betrayal, say campaigners. *BMJ* 2017;358:j1711. doi:10.1136/bmj.j1711 pmid:28377470.

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