Action on faulty vaginal mesh took too long, now women struggle to access mesh surgery that works

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Credit: Gwendal Cottin/Unsplash

Last week, Johnson & Johnson reached a A$300 million settlement for two class actions brought by Australian women affected by complications from vaginal mesh products.

The products are surgically implanted to correct urinary incontinence or prolapse, where the vaginal tissues weaken and sag outside the vagina.

However, women involved in the class action experienced a range of issues with vaginal mesh implants, including chronic pain, painful intercourse and incontinence.

The first of the Australian class actions against Johnson & Johnson was filed in 2012. Justice Katzmann ruled the company hadn't fully researched these products (which carried significant risks), was motivated by commercial factors, and failed to give doctors or patients adequate safety information.

The following ten years have seen a radical overhaul in the use of vaginal mesh implants in Australia and throughout the world. But we've also seen unintended consequences, with some women not accessing care.

What has changed?

We now have strict training and credentialing guidelines for surgeons using vaginal mesh, plus detailed management protocols for pelvic floor disorders. Only surgeons with advanced training in pelvic floor surgery following their specialty training are able to perform vaginal mesh surgery.

All patients are first referred for extensive pelvic floor muscle training. Only those who don't respond to conservative treatment and whose incontinence has a major impact on their quality of life are referred for a surgical review.

Mesh repair for prolapse is considered only in patients with severe or recurrent prolapse in whom basic surgery using the patient's own tissues has failed. This tends to be patients with multiple health problems who are not fit enough for major abdominal surgery.

Registration for mesh products has been rigorously upgraded and

requires extensive pre- and post-marketing audit. This means implants are tested in lengthy clinicial trials before and after they're implanted in patients. Trials also compare the outcomes and complications to women having surgery without mesh.

Formal audit systems monitor women's long-term outcomes. And next year, all implants will have a unique device identifier. Similar systems are used for joint replacements and breast implants, allowing prompt review if there are concerns over a device.

All of these changes should have been standard practice a long time ago and will hopefully prevent similar mistakes in future.

Some women not seeking treatment

Through media coverage of the vaginal mesh issue, most of the population learned "mesh was bad." They may not have known anything about prolapse or incontinence but they clearly got the message mesh was something to avoid.

Following the 2011 United States Food and Drug Administration (FDA) safety update citing possible complications associated with vaginal mesh, there was a marked reduction in the use of vaginal mesh implants for prolapse surgery.

Over the past ten years, fewer women have had surgery for pelvic floor weakness.

This is most noticeable for a type of surgery for urinary incontinence, mid-urethral sling, which has dropped 64% from its peak usage in 2010–2011. A mid-urethral sling uses a thin band of mesh under the urethra to manage incontinence.

Prolapse repair requires a larger patch of mesh to support the weakened vaginal walls.

Both these products are made from the same polypropylene mesh. This is the same material used in sutures (stitches) for many decades.

However, prolapse repair is more complex and has a higher risk of complications than mesh continence surgery, where short- and long term outcomes are very good.

Yet we have not seen any significant increase in other non-mesh continence surgery to compensate for this.

It's possible more women are turning to physiotherapy treatment which can improve incontinence symptoms and is recommended as first-line treatment. Physiotherapy can also benefit women with mild to moderate vaginal prolapse.

However private physiotherapy care can be costly and difficult to access. There has also been an ongoing decline in physiotherapy and nurse continence services in public hospitals and community centers.

It is likely many women are not seeking help at all.

Mesh still has a place

The problem is, mesh is not inherently bad. Mesh has enabled surgeons to treat many women, including older or more frail patients, who aren't suited to more major surgery.

Vaginal mesh surgery for prolapse is well tolerated in elderly and frail patients. Since its introduction, the greatest relative uptake in continence procedures has been in women 75 years and older.

For incontinence, a mid-urethral sling is more effective with fewer complications than other procedures for incontinence.

The most effective surgical repair for severe and recurrent prolapse, particularly in younger women, is a sacrocolpopexy. Generally performed via keyhole surgery, this technique uses a mesh strip anchored to the triangular bone at the base of the spine to support weakened vaginal tissues.

> Johnson & Johnson reaches $300m settlement over pelvic mesh implants https://t.co/nzLWvWZlc4 Settlement of two Australian class actions is largest in country's history and subject to federal court approval. #healthlaw
>
> — Matthew Rimmer (@DrRimmer) September 12, 2022

Sacrocolpopexy has a good safety profile, is effective and durable—and wasn't part of the recent class actions.

But this is no longer available, as the manufacturers of mesh for sacrocolpopexy in Australia recently removed their products from the market. This was likely a commercial decision: the long-term studies required for registration of mesh products used in pelvic floor surgery are expensive and time consuming, and Australia is a relatively small market.

Mesh for vaginal prolapse had already been removed from the Australian Register of Therapeutic Goods in 2018, meaning it can't be supplied in Australia, after Australia's regulator classified it as high risk.

Progress has been made to protect patients from the harms of faulty mesh implants but we need to ensure women have access to safe, effective surgical procedures to treat incontinence and prolapse—and for

some women, this will include mesh.

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