

The safety of surgical meshes used in urogynecological surgery



Many people suffer from stress urinary incontinence (SUI) occurring either alone or in association with pelvic organ prolapse (POP), leading to problems that can make things like lifting shopping bags or running for a bus more challenging and can rob people

of independence and dignity.

SUI can occur in people of any age, but is more common among women who have had children. Pelvic organ prolapse usually occurs in older women when the support mechanisms to their pelvic organs are stretched or torn and the pelvic floor muscles are weakened. The pelvic organs - the bladder, uterus (womb) and rectum - may not be held in the correct position and start to bulge or sag into or outside the vagina. This is known as a pelvic organ prolapse (POP).

In the early stages, pelvic floor exercises can help with SUI or POP. But sometimes, physical therapy and maintaining a healthy weight aren't enough. Then, many people consider surgery, with or without using a surgical mesh.

→ WHAT IS A SURGICAL MESH?

A surgical mesh is a medical device made from a synthetic (absorbable, partially absorbable or non-absorbable) material that is used to support weakened tissues. In urogynecological procedures it is permanently implanted with the aim to repair POP or to support the urethra in case of SUI.

Surgical meshes have been used since the 1950s to repair abdominal hernias and since the 1990s for treating male and female SUI, female POP and colorectal (bowel) functional disorders (CFD).

→ DOES THE USE OF SURGICAL MESHES INVOLVE RISKS?

While most surgical meshes are effective, they may be associated with risks (like any procedure involving surgery) including infection, tissue erosion, mesh exposure, shrinkage and side effects like pain and sexual dysfunction. Mesh exposure is the most common complication. Depending on the degree of the problem, additional surgery may be required to remove the mesh. But

sometimes, it is not possible to remove the mesh completely.

→ SHOULD SURGICAL MESHES BE THE FIRST CHOICE OF TREATMENT?

Non-invasive solutions should be considered before resorting to surgery. If these are not helpful or scientific evidence suggests these are inferior, the surgeon and the patient should take a shared decision whether or not to proceed on to a surgical approach. In the context of treating SUI, use of a synthetic mesh (called a 'tape') is currently considered the standard of care.

Based on current materials and existing evidence, the use of mesh implants can be considered in patients with POP. These can be implanted either vaginally or through the abdomen. The placement of a mesh by vaginal route is considered mainly as a secondary option if primary surgery has failed; or exceptionally as a first line surgical option for women for whom surgery using native tissue is expected to fail. For prolapse repair, it is important to consider that larger surface areas of mesh are needed than for SUI. When implanted via the vaginal route higher rates of mesh exposure are to be expected, based on current evidence.

→ WHAT FACTORS AFFECT THE SUCCESS OF SURGICAL MESH SURGERY?

The success of using mesh interventions varies therefore depending on the type of problem and its severity, the overall condition of the patient, the presence of risk factors, the surgical technique used and the skills and experience of the surgeon.

Generally speaking, more complications seem to arise when the mesh is inserted vaginally rather than abdominally for POP. In view of the larger surface areas of mesh used for POP as compared to SUI, the exposure rates seen with SUI are lower than when mesh is used for POP. Using the abdominal route for POP carries other risks related to the surgical approach, such as bowel injury. Patients should thoroughly discuss with their doctors the indication, alternatives (both surgical and non-surgical) and both benefits and risks in case a surgical mesh is deemed necessary.

This opinion primarily focuses on synthetic non-absorbable meshes and the risks of

using these in surgical interventions compared to the risks of classical surgical interventions.

→ ARE SOME PATIENTS AT GREATER RISK?

People who are overweight, who smoke, who simultaneously undergo associated procedures like hysterectomy have a higher risk of developing complications from surgical mesh implantation. There are not enough data available on the long-term use of non-absorbable meshes for POP repair, so it is normally not recommended for young people.

→ WHAT COULD BE DONE BETTER TO MAKE THE USE OF SURGICAL MESHES SAFER IN THE FUTURE?

The SCENIHR makes numerous recommendations in the Opinion, including:

- establishing European implant registries and evidence-based European Guidelines
- launching European studies on the long-term safety and performance of synthetic non-absorbable meshes
- conducting further research into novel materials and different technological techniques for manufacturing meshes, and on the application of regenerative medicine technology, such as the cellular seeding of graft materials
- setting up training programs for surgeons in association with European medical associations

This fact sheet is based on the Opinion of the independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): 'The safety of surgical meshes used in urogynecological surgery'

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http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en.htm