Comment on the nature of complications from polypropylene slings for female stress urine incontinence

Surgical implantable polypropylene, a mesh made by plastic fibers in a knitted pattern, has been used since the 1950s in the repair of complex hernias and other abdominal wall reconstruction procedures (1). Over the last 15-20 years a specifically constructed polypropylene mesh has been implanted in the pelvic floor for the treatment of pelvic organ prolapse (2, 3) and, in the late 1990s, the same material, in tape form, has been used for the surgical treatment of stress urinary incontinence (SUI). With the use of specific insertion tools a thin tape of polypropylene mesh is placed as a sling under the urethra (or bladder outlet) creating a pelvic hammock to keep it closed during normal activities (4).

Over the years, a small but steadily growing number of serious complications – predominantly chronic pain and mesh erosion/extrusion – have been reported. These have initially been reported after hernia and pelvic organ prolapse repair (5-10) but recently also after sling surgery (11-16). The true incidence of complications, however, is not known, as less than 25% of patients return with their sling problems to the same surgeon, who has put it in (12, 13). Additionally, underreporting is a major issue (14).

Chronic pain is predominantly caused by scar tissue forming where the host tissue meets the material as a foreign body response to the implant (5-10, 11-17). Early scar tissue (granulation tissue) is swollen and rich in cells and blood vessels - soft and fragile (20). It enters the solid plastic graft by in-growth of cells, nerves and vessels on one hand and serves as a soft, easily eroded membrane on the other (20). The granulation tissue will mature with encapsulation of the polypropylene material, but full healing is inhibited due to the persistent presence of the foreign body (20, 21). The typical fibrous scarring is lacking, and instead the graft ends up being surrounded by foreign body giant cells and chronic inflammation ensues (20, 21).

A close correlation between chronic inflammation in association with a foreign body and low grade chronic infection has previously been demonstrated (22-24). The sling insertion procedure for SUI is performed via the vaginal wall or the thigh skin, neither of which are sterile, and the risk of contamination with microorganisms and formation of biofilm (i.e. aggregates of microorganisms in a self-produced protective matrix resistant to degradation by scavenger cells and antibiotics) is as high as with the pelvic organ prolapse (POP) mesh (9).

The main complication after sling surgery is pain, and this can only be eased by removing the sling and its scar tissue capsule. However, problems often remain, as nerves and vessels become entrapped in the woven material (5, 7, 18), and the pain, which results from the permanent abnormal neuronal activation triggered by the implant, may persist even after material removal (6, 7). Chronic pain following mesh insertion has been recorded in up to 19% of patients with hernia (6), in up to 30% of patients with POP (25) and in up to 20% of patients with SUI sling surgery (13).

Polypropylene is a type of solid plastic made with the intent of creating support. Plasticity is limited and pain, including pain during sexual intercourse, is a major issue of concern (15) along with material erosion (13) and infection (14). Synthetic slings are associated with vaginal extrusion and urethral erosion rates that are 10 times higher than rates for organic slings (25). It is well known that infection due to contamination with microorganisms is difficult to treat in the presence of foreign materials, including teeth, prostheses and other indwelling devices (20-24).
The sterile milieu of the peritoneum differs from that of the vagina, and tissues surrounding vaginal grafts show significantly higher scores for inflammation and neovascularization and lower scores for fibroplastic proliferation than tissues surrounding abdominal grafts (15). Infection should not be underestimated in the presence of any foreign implanted material (9), and it is highly likely that host tissue erosion and material migration are linked to contamination with microorganisms such as bacteria and fungi, with or without biofilm formation (20).

In the presence of a foreign body like the polypropylene sling, biofilm formation is a likely side effect and candidate for the painful low-grade chronic infection leading to erosion of the urethra and other pelvic organs as well as material exposure. We know from the literature and our present ongoing research that the risk of contracting a chronic infection is between 1-10% every time a foreign material is inserted into the human body. Historically, many adverse reactions related to this insertion have been impossible to link to the presence of microorganisms, and until recently, a combination of microscopy, culturing and molecular methods have been necessary in order to diagnose chronic, likely biofilm-assisted, infections (21, 22). Even using molecular techniques such as PCR and subsequent sequencing have required a load of $10^6$ bacteria - a very rare finding in chronic infections (27).

Today it is possible to identify less than 100 bacteria or fungi per sample using improved DNA extraction assays followed by PCR and sequencing. This increase in diagnostic sensitivity will give us a powerful tool in finding the pathology behind adverse events seen in combination with the insertion into the human body of not only meshes/slings but also other foreign materials. We therefore strongly recommend that chronic infection and the ongoing constant pain associated with this condition should be considered a potential risk in safety evaluations of surgical meshes and slings.

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