Anchoring – Is it a Significant Contributor of Mesh Related Complications? - a Literature Review

1 BACKGROUND

The use of mesh in vaginal surgery for the treatment of pelvic organ prolapse (POP) has historically been found to provide good anatomical results, however it is accompanied by higher intra- and post-operative complications which include organ perforation, bleeding and mesh related adverse events such as mesh erosion, mesh contraction and pain[1,2]. Literature supports the conclusion that mesh fixation is the main reason for complications with current available mesh techniques.

2 MESH COMPLICATIONS

2.1 CHRONIC PAIN & PAINFUL INTERCOURSE (DYSPAREUNIA)

Mesh sheets that are implanted in the space between the bladder and the vagina are subject to anatomical forces and forces stemming from the scar tissue accumulation. Consequently, the mesh can fold on itself and bunch. It is well documented that mesh folding and contraction is the main reason for chronic pelvic pain and dyspareunia[3]. The mesh contraction and bunching can cause nerve entrapment as well as excessive tension on the fixated mesh arms, which both lead to pain. Partial removal of the mesh at the fixation points and reducing the tension on the mesh has been shown to resolve the symptoms in 90% of patients[4].

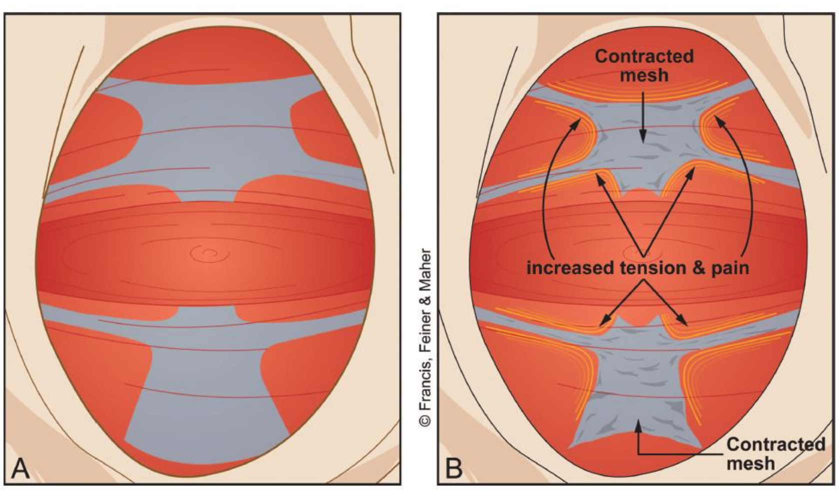

Fig. 1. Illustration of anterior and posterior vaginal mesh layout, showing an anterior mesh with four arms above and a posterior mesh with two apical arms below: at implantation **(A)** and after the body of the mesh has contracted by 30% **(B)**. Increased tension is demonstrated by the narrowing of the arms, and areas of pain are demonstrated by curved lines. Illustration: Stephen Francis. Copyright ©2009, Francis, Feiner, and Maher.

Feiner. Vaginal Mesh Contraction. Obstet Gynecol 2010.

It is also known that graft augmented colporaphy (mesh reinforced native-tissue repair) and J&J's "Prosima" kit, do not involve pelvic pain[5]. These two procedures include the insertion of Polypropylene mesh, which is not firmly fixated, and, therefore, no nerve entrapment or tension can be created.

2.2 MESH EROSION & MESH CONTRACTION

Elimination of mesh folding and bunching may also reduce exposure through the vaginal incision and may lead to a lower mesh erosion rate. Margulies et al., identified mesh folding in nine out of 13 patients suffering from vaginal mesh exposure[6]. Mesh folding might be an important contributing factor in mesh exposure because a folded mesh does not lie flat against the vaginal wall and therefore may interfere with the healing process at the incision site[6].

Anchoring as a main cause for mesh erosion was investigated retrospectively in a clinical trial proposing a different surgical fixation technique of a mesh product with high erosion rates (4-19%)[7]. The authors described that by altering the fixation points and technique alone, the erosion rate could be reduced to about 1%[7].

Current mesh kits provide a standalone mesh that is fixated at four corners (or two) in the pelvis. However, the implantation and securing techniques do not assure that the mesh is placed in a tension-free, flat, non-folded fashion, although emphasized in all manufacturer's instructions and training programs[3]. Even when placing the mesh in a flat and tension free configuration during the surgical procedure, there is no guarantee that dynamic pressures and scar accumulation construction forces will not cause mesh contraction and folding over time.

2.3 PORE SIZE & PORES CONFIGURATION CHANGES

The porous area of the mesh creates a scaffold for the subsequent ingrowth of dense infiltrate of fibrous tissue[8]. As part of mesh incorporation into the tissue, inflammatory processes are initiated after implantation, including fibrogenesis realized by fibroblast proliferation (fibroplasia). Further, blood vessels proliferation (angiogenesis), collagen synthesis and collagen maturation (cross linking) for scar tissue formation occurs[9].

During the scaring process a contraction of the wound area can be observed which leads to the 20-40% shrinkage of the mesh, 10 months post-implantation[10]. The porous of the mesh plays a significant role in this healing process. Microporous mesh leads to a significantly lower type 1 collagen deposition, compared to marcopourus mesh[8]. A greater distance between pores resists the ability of "bridging fibrosis" as it occurs in microporous meshes. In consequence "bridging fibrosis" leads to increased stiffness of the mesh while macropourus mesh allows a more flexible scar, which better mimics original anatomy and is more biocompatible (Figure 1)[8].

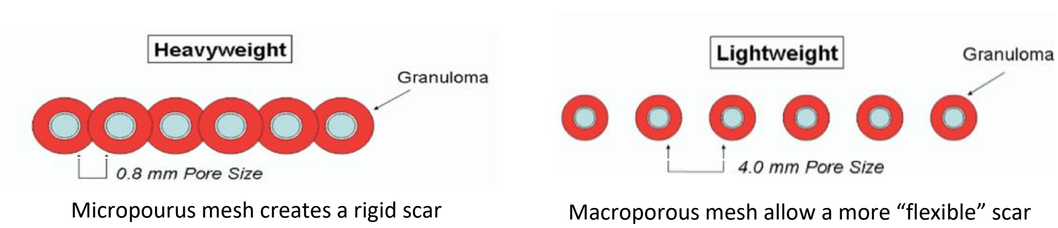

***Fig. 2**. Scar plate formation with small-pore mesh occurs because of bridging fibrosis. The large-pore meshes allow for ingrowth of healthy type 1 collagen between the filaments*[8]

Pore diameters of <1 mm are associated with an enhanced inflammatory response that accompany poor tissue in-growth and fibrotic encapsulation[11]. Large pores allow access for leukocytes and macrophages, as well as ingrowth of fibroblasts and collagen and neovascularization. All this contributes to lower infection rates and promotes tissue incorporation into the host[12].

After implantation prolapse meshes are thought to be more likely to lose their pore configuration, compared to hernia meshes[13]. Any mechanical force load onto the mesh dramatically decreases the size of the pore[14,15]. For example an application of 5N led to reductions in porosity for several investigated meshes, with values decreasing by as much as 87%[15]. As for current available mesh products, a total pore collapse is to be expected at some load[15]. The investigating authors emphasize that the maintenance of pore diameter needs to be considered in the design of future mesh products[15].

Lyra Medical anchorless concept, the SRS Implant, was developed to address these issues by allowing the mesh to remain flat, tension-free, maintaining pore size and pore configuration during the tissue infiltration process.

3 ANCHORLESS CONCEPT – SAFE BY DESIGN

Lyra developed an implant for the treatment of anterior vaginal wall and uterine prolapse, named Self-Retaining Support (SRS) Implant. The SRS Implant incorporates the advantages of commercially available POP meshes while eliminating the need for mesh fixation, which is believed to be the main cause for both intra and post-operative adverse events in currently available techniques.

The SRS technology was designed to ensure a safe treatment that addresses the root cause of current mesh-related complications.

INHIBITS MESH EROSION –

The solid frame enables the use of an ultra-light (16 gr.\m^2), extra-thin mesh (65µm fiber). It also retains the mesh tension and prevents it from folding, which can lead to erosion.

PREVENTS MESH CONTRACTION –

The solid frame acts as an opposing mechanical force that prevents the mesh from contracting, preventing pain and improving long-term efficacy.

REDUCES RISK OF BLEEDING & ORGAN PERFORATION –

The SRS concept eliminates the need for blind insertion of surgical instruments (trocars, anchoring instruments, etc.), reducing the risk of damage to surrounding anatomical structures.

MINIMIZES RISK OF PAIN & DYSPAREUNIA –

The SRS Implant ensures bladder support without causing tension across the vagina. The frame maintains the original tension-free, flat configuration therefore prevent pelvic pain.

MAINTAINS MACRO-POROUS MESH STRUCTURE –

The solid frame maintains the implant's flat orientation and the macro-porous structure of the supporting layer.

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