

The Cumberlage ban – slings work differently from mesh sheets and should be restored

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COMMENTARY

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Comment

Earlier this year, all mesh sling and mesh kits were banned from the UK following the Cumberlage report. We should all support the Cumberlage banning of mesh sheets, but not slings^{1,2}. I write as the co-inventor of the midurethral sling¹ (MUS)] to present the historical and other scientific data which supports retention of the MUS. Slings work very differently from mesh sheets. They create new collagen to strengthen the ligaments which suspend the organs, fig1. A tape placed along the anatomical pathway of the pubourethral ligament “PUL”, fig1 cures stress urinary incontinence (SUI) by restoring the urethral closure mechanisms^{1,2,3}. The same methodology holds for slings in other ligaments⁴. A multicentre trial of 616 women⁴ demonstrated convincingly that mesh sheets are not required to cure major prolapse. Liedl et al reported 90% cure of vaginal prolapse (mostly 3rd or 4th degree) at 12 months using slings ONLY to repair cardinal and uterosacral ligaments. Vaginal herniations were re-attached, not excised. There were complications, some major, and erosion rates of 0-3%. However, there was a singular absence of the massive urine loss and nerve pain entrapments seen in the mesh sheet operations which develop the “Tethered Vagina” syndrome by fibrosis of the vagina^{5,6}.

Mesh sheets restore neither structural anatomy nor function. They are an ill-proven initiative which relies on blocking descent of the organs. A simple transperineal ultrasound will prove that the prolapse is still there, behind the mesh. The mesh sheets fibrose the vagina, removing the elasticity required for normal bladder function³. Unlike the MUS, mesh sheets placed behind vagina had little testing prior to commercial release and can cause major de novo complications such as massive urine loss from “tethered vagina syndrome”^{5,6} or nerve entrapment due to mesh shrinkage. Such complications are rarely, if ever, seen with MUS.^{1,2,4,6}

There are many worrying aspects of the Cumberlege report as regards the MUS. Absent from the report is one critical detail: Cumberlege does not differentiate between slings and mesh sheets applied behind vagina, which are a very different technology from slings.

The science for ligament support of organs is well accepted. Ligaments are fundamental to Delancey’s 1992 thesis of organ support, based on his extensive anatomical studies⁷. The 1990 thesis of Petros and Ulmsten, based on extensive animal and human studies^{1-4,6,8}, emphasizes the role of collagen as the key structural component of ligaments; *also emphasized is that the vagina requires elasticity for its role in bladder control*³.

Slings implant narrow 1cm tapes which harness the wound reaction from the implantation to create new collagen to reinforce weak ligaments, fig1. This is the core principle of the MUS and other sling operations. Slings attach the organs directly to the skeleton in a transverse manner, fig1. They have very little contact with the vagina, so they have very little opportunity to entrap nerves to cause de novo pain and they preserve vaginal elasticity needed for bladder function.

The Cumberlege report, though emphasizing the need for thorough scientific and clinical analysis for devices before being implanted in patients, has, in fact, abolished the most validated operation in the history of surgery. The MUS was not released until 1996, 10 years after the first animal experiments started in 1986, ironically, to test the safety and efficacy of the tape implantation, fig1, the very concern which seemed to dominate the Cumberlege report!

The animal testing included clinical monitoring over 3 months, anatomical studies, biomechanical testing of the neoligament on an Instron tensiometer, histology, bacteriology, radioactive Gallium studies, xray studies, regular biochemical and hematology testing of the animals⁸.

The first prototype operations commenced under strict EC surveillance between 1988 and 1993 at Royal Perth Hospital. They, too, were subjected to thorough clinical, bacteriological, radiological, hematological, biochemical, histological observations^{1,3}. By the time the MUS was released in 1996, the MUS had undergone 10 years study for safety and efficacy under Ethics Committee surveillance in several international locations and after several published papers. Since 1996, the MUS has been the subject of >1000 scientific papers, (including 17year data), 10,000,000 MUS surgeries, endorsement by almost every learned body. By comparison, mesh sheet surgery for prolapse has had virtually no scientific testing.²

The poor anecdotal evidence presented by the Baroness Cumberlege for abolition of the MUS did not meet its stated clinical/scientific criteria. Quoted was not data, but one expert’s singular case report of delayed onset of pelvic pain after MUS. As an expert, he should have known about Shull’s famous observation⁹, that repairing one part of the vagina, such as a cystocele, diverts pressure, to cause prolapse in another part of the vagina, for example, the apex. Apical prolapse is caused by decompensation of the uterosacral ligaments. Uterosacral ligament laxity is known to cause a number of co-occurring symptoms, pelvic pain, urge, frequency, nocturia, abnormal emptying, known collectively as the “posterior fornix syndrome”^{4,5,6,10}. Pelvic pain is an important element in this syndrome. The posterior fornix syndrome should be excluded in cases of de novo pelvic pain occurring weeks or months after the original MUS operations. Cardinal/uterosacral ligament repair of the prolapse⁴ would most likely have cured the pain symptoms as reported by the singular Cumberlege expert. Clearly not considered by the Cumberlege report were next generation MUS slings¹¹, 90% cure at 3 years, with no erosions at 3 years. They would put a whole new perspective on the Cumberlege complaints.

One cannot extrapolate a series of individual cases, (undoubtedly worthy in themselves) to a general ban on the most documented operation in the history of surgery. As things stand in the UK, the 30% of women with SUI have very little to help them now. The scientific evidence needs to be re-assessed. Slings work by reinforcing ligaments; mesh sheets work by blocking descent, a totally different technology. Let's hope reason prevails, that the scientific evidence is reviewed and the Cumberland "pause" is just that.

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Contribution Sole author

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Legend

Fig. 1- Polypropylene tapes "T" create new collagen (inset) to reinforce the 5 main suspensory structures –pubourethral (PUL), uterosacral (USL), arcus tendineus fasciipelvis (ATFP), Cardinal (CL), and perineal body (PB). Tapes attach ligaments transversely to the skeleton and have very little contact with the vagina, very different from mesh sheets which are placed as a sheet behind the vaginal wall.

Inset Figure from the original experiments in canines show formation of collagenous neoligaments formed by tapes.

