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Andrew Howlett  
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Public Petitions Committee  
The Scottish Parliament

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Our Ref RMC/PB  
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Dear Mr Howlett

Thank you for the opportunity to provide our response to the petition on behalf of NHS Grampian. We are aware of the petition and have discussed it previously in our Urogynaecology Multidisciplinary Team (UG-MDT) meeting. We have watched in detail the video session of the Parliamentary Petition Group.

First we would like to emphasise that we are very sympathetic to the devastating problems that these women are facing. We, as medical professionals, are dedicated to dealing with them effectively to improve their quality of life. The Grampian UG-MDT is already involved in managing a number of these complications for women in the North of Scotland.

We share the concerns that some women may have not been adequately counselled pre-operatively re possible outcomes, complications and the alternative surgical and non-surgical alternatives. Two of our clinicians are members of the Short Life Working Group (SLWG) convened by the Deputy Chief Medical Officer at the request of the Health Minister and the Scottish Government. The members of the SLWG have gone a long way to address this problem, with representatives and input from the petition group. The SLWG has produced a standard Patient Information Leaflet for synthetic mid-urethral slings (using a polypropylene mesh) for the treatment of stress urinary incontinence (currently in the proof stage for publication). We are also working on a similar information leaflet for women having prolapse surgery, with and without mesh.

The Scottish Pelvic Floor Network (SPFN), as a Scottish national body, is issuing a statement, reinforcing the advice from the Royal College of Obstetricians and Gynaecologists (RCOG) and the British Society of Urogynaecology (BSUG) urging all surgeons in its membership to adhere to the NICE guidelines in the management of both stress urinary incontinence and pelvic organ prolapse. These clearly specify that all suitable treatment options should be offered to women prior to undertaking any treatment or taking informed consent for surgery.

However, we would like to highlight that the parliamentary group has heard only one side of the story. Whilst we acknowledge that some women have experienced devastating effects on their health as a result of surgery, and extend them our great sympathy, these

may not always be due to the complications from mesh or tapes, as any surgery carries a risk of complications. It may not be possible to prove that the mesh, rather than the surgery itself, was the cause of the complications in any individual case. Serious complications are well documented in the medical literature following alternative surgical procedures that do not use synthetic mesh such as colposuspension, sacrospinous fixation, etc.

Unfortunately, the petitioners have mistakenly mentioned all polypropylene Transvaginal Mesh (TVM) surgery together in their petition. This confusion was clear in the Video session where the petition group acknowledged that the American Food and Drug Administration (FDA) proposes to re-classify mesh for prolapse surgery, but **not** tapes for incontinence surgery, as high risk devices. However, the Scottish Parliament is being asked to lead the way in banning both.

It is most important to understand that there are fundamental differences between synthetic (polypropylene) tapes used for stress incontinence surgery, and polypropylene mesh used for prolapse surgery. Although they are both made of the same synthetic material (Type 1 polypropylene mesh), they differ significantly regarding how much mesh material is used, how it is inserted, and in the evidence for the safety and effectiveness for the two different types of problems.

#### **For tapes for incontinence surgery:**

- It is a well-established fact that the large majority of women who have tape surgery for incontinence are cured of the problem, and “get their life back” as they would describe it. In the video session it is claimed that one in five cases go wrong. This is definitely not correct as far as “serious complications” (such as chronic debilitating pain or pain with intercourse) are concerned. Serious complications are well documented in the medical literature to be below the 1% rate. Some minor complications may occur more often but in general these resolve with time or simple treatment.
- While there are alternative procedures for urinary incontinence (such as anterior repair or colposuspension, which do not involve the use of tapes) women can experience similar devastating complications. The failure rate after anterior repair is much higher (40%), so therefore many women need repeat surgery which itself has a higher risk of complications. Open colposuspension (through an incision in the abdomen) can work as well as tape surgery (80-90% success rate) but it has a higher complication rate and women stay longer in hospital, they have a longer recovery time, more postoperative pain, and a higher chance of needing surgery later for prolapse.
- The Scottish Pelvic Floor Network (SPFN) is currently involved in two large multi-centre HTA-funded randomised controlled trials in the UK for evaluating surgical and conservative treatment of urinary incontinence in women: (a) the “SIMS Trial”: this study compares the standard polypropylene tape surgery for urinary incontinence with a smaller tape, known as a mini-sling. The latter utilizes 50% less mesh volume and can be easily tolerated under local anesthesia using less invasive surgery; and (b) The “OPAL Trial”, investigating the optimal regimen for conservative treatment using pelvic floor exercises with and without biofeedback as an alternative treatment for SUI in women. Patient-reported outcomes and experience are the primary outcomes assessed in both these two large clinical trials.

## For mesh for prolapse surgery:

- The reason why gynaecologists started using mesh is because of the high failure rate after prolapse surgery. Up to one third of women need repeat surgery for prolapse, and that in itself has a higher chance of complications. It was hoped that by reinforcing the prolapse repair with mesh, the chance of recurrence would be less, women would have fewer prolapse symptoms, and a reduced need for repeat surgery. There is some information that this actually is the case (summarised in the Cochrane review about prolapse surgery, Maher et al 2013), but there is not enough long term data. However, there is not as much information about this as there is for tape surgery for leaking urine (Ogah et al 2009).
- While up to 1 in 20 women may need further surgery for mesh removal, in the vast majority of cases this is for a small area (less than or equal to 2cm) of mesh which has come to the surface and needs to be recovered in vaginal skin: this is a minor procedure.
- It is very rare for women to need to have all the mesh removed, and indeed this may not be possible in some cases and may result in damage to pelvic organs, recurrence of the prolapse symptoms or failure to cure the complications such as pain. It is these women who may have long term effects on their health and quality of life, but we would emphasise this is rare. Similar symptoms can occur after prolapse surgery where mesh is not used.
- Aberdeen is taking the lead in a large UK randomised controlled trial (PROSPECT) which is due to report soon. Around 1500 women were randomised to having mesh or not for their prolapse. The results will be crucial in establishing the value of mesh in the management of women with prolapse, especially those who need to have repeat surgery for prolapse, for whom the use of mesh is thought to be potentially most useful.
- Until the full results of PROSPECT are known, women should be given all access to all suitable treatment options. This will include all known information on mesh, including the FDA warning and the FDA information for patients. Women should be allowed to make their own informed decision about treatment without being denied an option of effective treatment by a blanket ban.

Regarding the other points in the Petition; these are being addressed by the SLWG and the SPFN. Pending final recommendations from the SLWG, draft statements include:

- Members are encouraged to regularly audit the results of the surgical procedures they conduct for both incontinence and prolapse, preferably using a national registry such as that provided by BSUG or the British Association of Urological Surgeons (BAUS). They should present and discuss their own audit results during their annual appraisal.
- The SPFN proposes that reporting complications to the MHRA should be made mandatory. The Health Boards in Scotland are urged to facilitate the introduction of national registries into routine practice via the Caldecott Guardians.
- However, while registration may enable regulatory authorities to monitor the occurrence of complications, the most important advance for women is that specialist services should be set up in tertiary referral centres. Women who do have serious complications (whether due to mesh or other types of incontinence or prolapse surgery) must have access to, and receive, specialist care and appropriate treatment.

Finally, medical recommendations should be based on medical literature, high quality medical research focused on patient-reported outcomes and clinical expertise. We must avoid basing any recommendations on the basis of media or political pressure.

We hope this is helpful to the Scottish Parliament Public Petitions Committee in making recommendations for future practice.

Yours sincerely

**Richard M Carey**  
**Chief Executive**

Copies to: Dr Christine Bain, Clinical Director  
Dr Kevin Cooper, Urogynaecologist  
Dr Mohamed Abdel-Fattah, Urogynaecologist.  
Professor Cathryn Glazener, Professor of Health Services Research

#### **References**

Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews 2013, Issue 4. Art. No.: CD004014. DOI: 10.1002/14651858.CD004014.pub5.

Ogah J, Rogerson L, Cody JD. Minimally invasive synthetic suburethral sling operations for urinary incontinence in women. Cochrane Database of Systematic Reviews 2009, Issue 4. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub2.