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Contents

1. Mesh Complications

What is the risk of mesh-related chronic pain?

Our understanding of the incidence of chronic pain, one of the most serious and most life-reducing mesh-related complication, has consistently increased over the last two decades. Early studies reported around 1% risk of chronic pain, which subsequently increased to around 5% and, most recently, reported as 18% in the Offiah & Freeman study in 2021 (1). I suspect such increase over time is contributed to by our improved knowledge, better ability to attribute chronic pain to the mesh device and the longer-term follow up.

Are mesh complications inherent to the mesh device?

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) statement appears to describe the mesh-related complications as one of the "*inevitable consequence of all surgical interventions*". I expected the statement to acknowledge the fact that the use of a mesh device has added new mesh-related complications over and above those associated with the surgical interventions in this field.

The RANZCOG statement "*strongly emphasise that the US FDA publications which address the safety of mesh, clearly state that traditional MUS were not the subject of their safety communications*".

The 2011 Food and Drug Administration (FDA) warning / Public Health Notification (PHN) indeed focused on the use of mesh devices for pelvic organ prolapse, rather than the mesh MUS. It is noteworthy, however, that the PHN executive summary had stated "*among the 2874 reports (injury, death and malfunction) 1503 were associated with pelvic organ prolapse (POP) repairs, and 1371 were associated with stress urinary incontinence (SUI) repairs*".

As prolapse surgery uses a larger sheet of mesh, compared to the slim tape MUS, the incidence of mesh-related complications with prolapse is inevitably higher than that with mesh MUS. However, the spectrum / range of mesh-related complications is very similar, regardless of the amount of mesh used or whether the indication of mesh implantation was prolapse or incontinence.

It is noteworthy that the FDA has changed its description of the mesh-related complications from '*rare'* in 2008 to '*not rare*' in 2011. Currently, we know that mesh-related complications following the mesh MUS are very common.

Could mesh complications be reduced by improving surgical skills?

The petitioners suggest that the long-term mesh-related complication, the reason behind the ongoing suffering of the mesh-affected women, is related to "*surgeons implant mesh incorrectly*".

In my view, the risk of chronic pain and most other long-term complications are due to the mesh device itself, rather than surgical skill employed during its implantation. According to the scientific evidence, and my own clinical and medico-legal experience, the most common risk that can be reduced by surgical experience and skill is the intraoperative organ damage, which is already known to cause no or little long-term consequences.

While surgical experience is important, it is noteworthy that it is not associated with reduction of the device-related chronic pain and other long-term conditions. Despite the high surgical skills employed, a recent multicenter United Kingdom (UK) randomised controlled trial (1) confirmed the incidence of chronic pain 12 years following mesh midurethral sling (MUS) surgery as one in six (18%).

Despite the presence of a robust UK surgical training programme in urogynaecology and female urology, and notwithstanding establishing that mesh MUS surgery should take place only by credentialled and experienced surgeons, the UK pause continues to remain in place. The mesh pause is based on the precautionary principle (2) and I believe is also underpinned, at least partly, by to the understanding that the device-related risks could not be adequately mitigated by improving surgical skills.

The concept that long-term problems are largely or solely due to the mesh device itself, rather than adequate surgical skill during implantation, has also been acknowledged by the legal system. For example, in 2019, The Federal Court of Australia found the pelvic mesh devices from the main manufacturer, including those implanted during the mesh MUS in question, were "*not fit for purpose"* and of "*unmerchantable quality"*.

Is scientific evidence supportive of the safety of the mesh MUS procedures?

It is true there has been over 2000 publications on the issue of the use of pelvic mesh devices in the treatment of stress urinary incontinence (SUI). I reviewed most of these publications whilst conducting 2 large systematic reviews of the scientific evidence on the subject in 2013 (3) and in 2019 (4). It becomes clear to any reader that the vast majority (over 90%) of the 2000 publications on this matter are low-level evidence i.e. expert opinion or relatively small cohort studies. The more reliable evidence from randomised controlled trials (RCTs), and their systematic reviews, contributed just over 100 of the 2000 publications (5%).

Moreover, none of the RCTs were powered to adequately report on the safety of mesh devices. All RCTs were powered to detect a difference in the success of the procedure in treating the SUI condition in women and only a few studies followed women up for 5 years or more. The lack of long-term follow up to detect safety issues is a serious drawback that affected even the higher quality studies.

In general, real-world data could offer an alternative in determining the long-term safety of interventions. I am unaware, however, of any health system that was able to accurately code the emerging mesh-related complications, or the developing surgical corrective procedures, in a timely and prospective manner that would allow reliable retrospective reporting.

Such limitations have affected several nation-wide studies, including that from Scotland published in 2017 (5). Hospital coding did not catch up with the rapid development of the mesh devices, their implantation procedures, the conditions caused by their complications and the required corrective procedures. The significant underreporting of mesh-related complications has been acknowledged by most, if not all, medical device regulators.

2. Specific Surgical Procedures

The TransObturator Tape (TOT)

The transobturator procedure can cause serious harm, particularly in injury of the obturator nerve, causing chronic pain and limitation of mobility. Damage to the obturator nerve could not be reliably prevented, even in the best of hands, mainly due to the anatomical variations among individuals.

In addition, such nerve injury could not be diagnosed during surgery, could present for the first time several years later, and usually has an unfavourable prognosis, even if the mesh device is surgically removed in its entirety. For the reasons above, I believe this procedure should be banned, rather than allowing it in "*exceptional circumstances*" as in RANZCOG's statement.

The Single-Incision Sling (SIS)

RANZCOG suggests this procedure could be performed within a research trial. However, in my view, there is no need to wait for further scientific evidence before engaging the precautionary principle for the SIS procedure.

The SIS had already been tested in a robust clinical trial (6) published in April 2022. There are no meaningful clinical advantages of the SIS device over the standard mesh MUS. In fact, the risk of dyspareunia (pain during sexual intercourse) was higher with the SIS variant, compared to the standard mesh MUS.

Despite being one of its birthplaces, I believe the Australian government had already suspended the SIS procedure on 28 November 2017. I understand such suspension would not allow new trials. In my view, rather than implant more women within a new trial, the important research in this matter would focus on exploring the long-term outcome for the women already implanted with SIS.

The Retropubic Mesh MUS

This is the main procedure that RANZCOG wishes to remain available for women in New Zealand.

I note the RANZCOG's statement suggests surgeons "*should only operate within their capabilities and the scope within which they are credentialled*". As stated earlier in the submission, an inadequate surgical technique by those who are not credentialled is mostly associated with intraoperative complications e.g. bladder injury (which is largely inconsequential), but less so with the long-term life-changing complications e.g. chronic pain.

Evidence has confirmed that at the end of the learning curve of implanting mesh MUS, the risk of intraoperative bladder injury by an individual surgeon significantly drops. In any event, bladder injury does not seem to have any long-term complications as it is diagnosed and repaired intra-operatively.

On the other hand, the long-term complications are largely inherent to the mesh device and has little to do with surgical skills. This risk of such complications could not adequately be mitigated by allowing only well-trained and credentialled surgeons to operate.

It is noteworthy that the Offiah & Freeman study (1) was conducted in 11 renowned tertiary referral centers and the mesh MUS procedures were performed by well experienced and credentialled surgeons, almost all of whom were the clinical leads for their own hospitals. Despite best surgical expertise, the risk of long-term complications such as chronic pain was reported as 18%, 12 years following the mesh MUS surgery.

There was no difference between the transobturator and the retropubic mesh MUS in this study, which suggests that, in the long-term, the retropubic tape may still lead to a risk of chronic pain similar to that of the transobturator tape. Therefore, I do not expect improving surgical skills to significantly reduce the long-term mesh-related chronic pain for mesh MUS, regardless of whether it is implanted using the retropubic or transobturator approach.

3. Surgical Alternatives to Mesh Procedures

Comparative Efficacy

The Burch colposuspension was the gold standard continence procedure before the introduction of mesh mid-urethral slings (MUS). Moving from the more invasive open abdominal approach to the laparoscopic / keyhole one was the natural progression / evolution course for the colposuspension procedure two decades ago.

Unfortunately, such evolution was halted by the introduction of the mesh MUS.

It is noteworthy that the main advantages of the mesh MUS procedure to patients are related to recovery i.e. shorter time in theatre, shorter hospital stay and quicker return

to normal activities. While the keyhole colposuspension achieves those advantages, the mesh MUS is technically much easier to perform, as it does not require advanced surgical skills.

I agree with the statement from RANZCOG that the laparoscopic colposuspension requires advanced surgical skills. In my view, the continuation of the mesh procedures is likely to keep surgeons' laparoscopic skills relatively low in this context. Due to suspension of mesh procedures the UK, an increasing number of surgeons are leading the development of the laparoscopic colposuspension procedure, which is back on track to return to the gold standard status.

I led the research team conducting the systematic review of laparoscopic colposuspension from the Cochrane Collaboration (reference 7 in RANZCOG submission). The colposuspension procedure using the open approach yields similar success rates in treating the incontinence, as would the mesh MUS. After reviewing the literature with my colleague researchers, we have no reason to believe the laparoscopic colposuspension would be any less effective than the open approach or the mesh MUS.

In my view, the main reason behind the relatively low-quality evidence with regard to laparoscopic colposuspension is the low rate of performing this procedure. Surgeons generally prefer the mesh MUS option, as it is quicker and requires relatively low surgical skill. In my view, developing the surgical skills required in this area is key to balanced patient counselling.

Comparative Safety

It is my opinion that the statement from RANZCOG "*there is strong evidence that the MUS is associated with less pain compared to historic options that have been used to treat SUI"*, must relate to the woman's immediate postoperative pain, rather than chronic pain.

The more invasive the surgical procedure, the higher the pain levels expected in the first few days after surgery. In general, any abdominal surgery (e.g. colposuspension) is expected to cause more postoperative pain, compared to any vaginal surgery (e.g. mesh MUS). In any event, the postoperative pain following abdominal surgery is temporary / transient. I expected the statement to be clear that chronic pain (rather than postoperative pain), and other long-term mesh risks, are the main reasons behind the call to suspend the mesh MUS procedures.

There have been no scientific studies that reliably compared the risk of chronic pain between colposuspension and mesh MUS. However, and despite being the gold standard for almost 3 decades (70s, 80s and 90s), there has been no consistent reports of chronic pain with the colposuspension procedure, and there has been no calls for its pause. On the other hand, the increasing reports of the risk of chronic pain have started to emerge after only one decade of using the mesh MUS procedure, from 1-5% in 2010 to 18% in 2021.

The RANZCOG statement quoted the 2019 ruling from The Federal Court of Australia for the 5% incidence of chronic pain following mesh MUS procedures. The scientific evidence referenced by The Court in this respect came from the systematic review published by Blaivas et al in Nature in 2015 (7). The review reported 4.1% risk of pain beyond 6 weeks, with the added 1% incidence of neurological symptoms due to nerve injury.

The incidence of chronic pain with the colposuspension procedure must be rare. On the other hand, chronic pain following the mesh MUS is very common and is due to the mesh-induced scarring due to chronic inflammation, secondary to foreign body reaction.

If chronic pain develops following colposuspension, the condition is curable, or at least treatable, by removing the offending stitch(es), which is relatively easy from the surgical perspective. On the other hand, mesh removal surgery is technically more difficult to perform and is of uncertain outcome, with only 50% reported success in improving chronic pain.

I note RANZCOG's submission described the risk of detrusor overactivity and voiding dysfunction with the colposuspension procedure, but did not report the relevant figures for mesh MUS. I note the Cochrane systematic reviews (8) of the scientific literature showed no significant difference in these complications between colposuspension and mesh MUS. RANZCOG's suggestion that the risk of prolapse is higher with colposuspension, however, is agreed and is evidence-based.

It is noteworthy that the colposuspension procedure is currently the first surgical treatment mentioned in the recommendation by the UK National Institute for Health and Care Excellence (NICE) in 2019 for treatment of stress urinary incontinence in women.

4. Patient Counselling

The Patient Information Leaflet (PIL)

The first national patient information leaflet (PIL) to mention chronic pain specific to the mesh tape procedures for stress urinary incontinence in women was published by the Scottish Government in June 2014. A subsequent UK-wide version was published in May 2017. I led the clinical teams developing both leaflets.

The New Zealand PIL published in July 2019 is an update of the UK leaflet, following modifications by clinical societies, including RANZCOG, and the Patient Advocacy Group *Mesh Down Under*.

As it is now 4 years later, the PIL needs updating to change the risk of chronic pain from "*common*" to "*very common*" or one in six. I called for a similar update to the UK leaflet in a letter published by the British Journal of Obstetrics and Gynaecology in

2021 (9)(10). As mesh procedures remain suspended in the UK since July 2018, the UK leaflet had not been updated.

I note the New Zealand PIL referenced the patient decision aid for surgical treatment of stress urinary incontinence (SUI-PDA) (11), developed by the MDT I am a member of in NHS Ayrshire & Arran, Scotland.

Based on the SUI-PDA, the MDT has recently published a 4-minute video (12) to demonstrate the relevant surgical procedures, both mesh and non-mesh / native tissue surgery. The video would be helpful to women who prefer to visualise the surgical techniques, rather than read about them.

The video can be viewed here: https://youtu.be/rKRrSV0QVMk.

Will some women be disadvantaged if mesh procedures are suspended?

RANZCOG is "*committed to ensuring women are given evidence-based guidance and are offered an appropriate range of treatment options, in line with their own goals and values*".

Since the suspension of mesh procedures in Scotland in 2014, I have used only non-mesh / native tissue continence surgery e.g. colposuspension, natural tissue sling or bulking agent injections. We did not witness any disadvantage to women and did not face a situation where only the mesh MUS would be suitable.

I led the local multidisciplinary team (MDT) in developing the first validated patient decision aid (PDA) in this matter in 2016 (11). The PDA takes the patient's goals and values into consideration and assesses their confidence in the choice made (13).

Following the suspension of mesh procedures in Scotland in 2014 and the rest of United Kingdom in 2018, the national focus naturally moved towards supporting women who suffered mesh-related complications, improving skills in complex mesh removal surgery, and consolidating skills in non-mesh / native tissue surgery to improve outcomes for women suffering from urinary incontinence.

The non-mesh / native tissue procedures i.e. colposuspension (open and laparoscopic), autologous fascial sling and urethral bulking agent injections became routine practice in many UK units. In my hospital, we had no women (or surgeons) who specifically asked for a mesh procedure in the last 9 years.

The number of mesh MUS procedures in the UK had already dropped by almost a half (48%) in the few years preceding the pause in July 2018. The suspension of mesh procedures allowed the development and evolution of the time-honoured non-mesh native tissue surgery and restored the trust of many women in the surgical treatments offered for the SUI condition.

Will counselling be balanced enough to support informed consent?

I note the RANZCOG statement that "*the clinician's responsibility is to support the patient to make the best decision for them*".

Balanced counselling is dependent on the clinician's perception of the mesh-related risks and on their surgical skill level in relation to non-mesh native tissue surgery. The RANZCOG statement quoted only a 5% risk of chronic pain and confirmed relatively low surgical skills in non-mesh / native tissue surgery.

Is the risk of chronic pain an important factor in women's choice of surgical procedure?

In my experience, women do attach significance to the risk of chronic pain with mesh surgery for incontinence. Regardless of the quoted percentages, women who become aware of any material risk of chronic pain associated with such devices, and who are meaningfully offered the alternatives, do not choose the mesh MUS option.

On the other hand, almost half of women who were not warned of the risk of mesh-related chronic pain will choose the mesh option (14), probably to take advantage of its perceived recovery-related benefits.

Urinary leakage is not a life-threatening condition but is one that significantly reduces quality of life. In the presence of equally successful and safer alternatives, it is difficult to imagine a situation where a well-informed woman would accept the material risk of chronic pain and specifically requests the mesh MUS option, for quicker recovery and sooner return to daily activities.

Could bias in surgical skills affect counselling?

I would expect the vast majority of surgeons who perform continence procedures for women to be more familiar with implanting mesh MUS rather with its alternatives of colposuspension or the native tissue sling. It is only natural that hidden bias would affect counselling.

Consideration, therefore, would be given to the concept of documented, objective and value-based patient choice, to be subsequently supported by a discussion with the surgeon. This approach has been adopted in NHS Ayrshire and Arran, where I work, and in many other UK hospitals.

5. Responses to the Pelvic Mesh Matter

Interdisciplinary difference in positions

The RANZCOG "*does not support the call"* to suspend the mesh MUS procedures, whilst the Royal Australasian College of Surgeons, the body representing urologists, stated "*we are neither for nor against this proposal*".

A similar response took place in the UK four years ago. The "*strong opposition"* from the British Society of Urogynaecology (BSUG), the body that advises the Royal College of Obstetricians & Gynaecologists (RCOG), was different from the response by the British Association of Urological Surgeons (BAUS). The latter did not oppose the suspension, fully engaged with it, and did not subsequently call for its lifting.

The Māori population

There is evidence of a relatively higher prevalence of SUI in the Māori population, but no evidence of a higher rate of surgery or any impact on health-seeking behaviour in this context. I am not aware of a clinical study of the impact of the pelvic mesh matter on the Māori population.

It is not clear whether mesh complications have affected the Māori population differently, when compared to European or Pacific Island women. Cultural differences and health-seeking behaviour could be barriers to accessing the level of care required in this respect.

It may be worthwhile exploring ways of reaching out to the Māori population affected by the pelvic mesh matter to raise awareness of the condition, improve attribution of symptoms to the procedure and communicate the treatment options available.

Government and Parliament Responses

It is the norm for Government to follow the advice from Clinical Societies and Royal Colleges on the pelvic mesh issue, at least initially, as would be the case in other areas in medicine. However, one of the main reasons Parliament has to deal with this matter is that pelvic mesh implantation is an area of medicine that suffered a significant lack of self-regulation by us, clinicians.

It is noteworthy that both the 2014 mesh suspension in Scotland and the 2018 pause in the rest of UK were introduced when the relevant Parliament intervened. Both decisions were made when a Parliamentary Committee witnessed the harm to people and urged Government to engage the precautionary principle. Where there are risks of serious damage, the lack of scientific certainty shall not be used as a reason for postponing the safety measures necessary for prevention.

Despite the initial opposition from some UK Clinical Societies and Royal Colleges to both the 2014 and 2018 decisions, there were no subsequent regrets by Parliamentarians or Government Officials. Subsequent scientific evidence and several other unfolding events confirmed, and continue to confirm, that the original decision to suspend all mesh procedures was the right course of action.

The perception of the balance between benefits and risks on a population level, and a subsequent decision whether or not to suspend such procedures, largely depends on the thickness of the safety goggles of those in authority.

In exercising the current responsibility towards the safety of women considering continence surgery in New Zealand, it is noteworthy that the campaigners' / petitioners' aim is not to alleviate any suffering they may already have themselves. From experience of similar patient campaigns in the UK, it is my understanding that their aim is to prevent other people from facing similar consequences.

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