Submission to Senate Inquiry "Number of women in Australia who have had transvaginal mesh implants and related matters"

HP Dietz, KL Shek and V Wong, Sydney and Brisbane

Madam/ Sir,

Please allow us to make a submission to the Senate Inquiry "Number of women in Australia who have had transvaginal mesh implants and related matters". Hans Peter Dietz is a Urogynaecologist working at Nepean Hospital, Penrith, and a Professor of O/G with the University of Sydney. Clara Shek is a gynaecologist at Liverpool Hospital and Associate Professor of O/G at Western Sydney University. Dr. Vivien Wong is a Urogynaecologist in Brisbane and undertaking a PhD on prolapse mesh at the University of Sydney. Short CVs of all three authors are attached.

Our research group is considered a global leader in the imaging of slings and mesh implants internationally. We have published 10 studies and 25 review articles since 2005 dealing with mesh implants used in prolapse surgery. We have undertaken audit activities (examinations of women after incontinence and prolapse surgery) involving mesh implants since 1998.

As a result of following up on patients operated by at least ten individual surgeons using mesh, including the very first patients who had mesh kits implanted in Australia in 04/05, we think we have a comprehensive overview of what can be expected in terms of outcomes and complications. In total our research group has now seen over 1000 women with mesh implants. In the Penrith unit we have performed 113 Perigee (anterior mesh) procedures between 2005 and 2016. This relatively low number for an Australian subspecialty unit is due to a restrictive indication for such meshes, especially after 2006. In essence, we have used such meshes only in women in whom we expected a high likelihood of failure of conventional surgery, and only for cystocele, i.e., bladder prolapse.

The key to our ability to detect women at high risk of failure of conventional surgery has been the development of a diagnostic technique, 'Pelvic Floor Ultrasound'. In 2007 the first author of this submission published the first textbook/ atlas for this method. Our group has conducted over 50 courses in this technique over the last ten years, and over 140 colleagues from all over the world have spent weeks or months in our unit to learn the technique since 2006. It is the only method able to show mesh after it is implanted as these materials cannot be seen with Xray, CT or magnetic resonance imaging. Figure 1 shows a Perigee mesh under the bladder. We'd be happy to help the committee understand where those meshes are and what they do in holding up the pelvic organs, with the help of stills and video clips as well as with 3D- representations of mesh within the pelvis, if required.

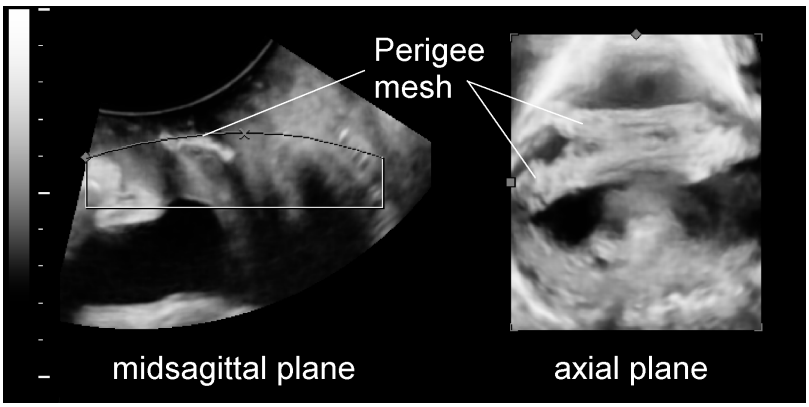

Figure 1: Perigee mesh under the bladder as seen in the midsagittal plane (vertical cut in the midline) and in the axial plane (as seen from below). This mesh was used in a patient with bilateral levator avulsion (see below) and permanently cured her bladder prolapse.

There is little doubt that the use of anchored mesh for repair of a bladder prolapse ('cystocele') reduces the likelihood of prolapse recurrence, and the Committee may already have heard information on this count. Provided a study does not mix all kinds of different meshes and all kinds of different forms of prolapse (and thereby produce what is called a 'type 2 error', a false negative result), this effect is obvious, as shown in the latest Cochrane Collaboration systematic review.(1)

Unfortunately, most literature on the subject treats all women as if they were the same. The above-mentioned systematic review is a good example. It states 'the utilisation of transvaginal permanent mesh needs to be individualised to those who accept the benefits and risk of these interventions.' without once mentioning the concept of individual risk- benefit ratio. The word 'recurrence risk' does not feature once in the entire 142-page document. Another statement reads: 'While it is possible that in women with higher risk of recurrence the benefits may outweigh the risks, there is currently no evidence to support this position.' This is untrue and contradicted by a recent trial listed in the Cochrane review. (2)

Over the last ten years it has become increasingly obvious that some women are at much higher risk of prolapse recurrence than others, mainly as a result of pelvic floor trauma in childbirth. One of our co-workers, Dr Friedman (Tel Aviv) has just performed a 'meta- analysis' of studies investigating recurrence risk(3) and found the following: 'Levator avulsion, pre-operative prolapse stage and family history were found to be significant risk factors for prolapse recurrence after reconstructive surgery. Avulsion was identified as the strongest individual predictor.' (Figure 2)

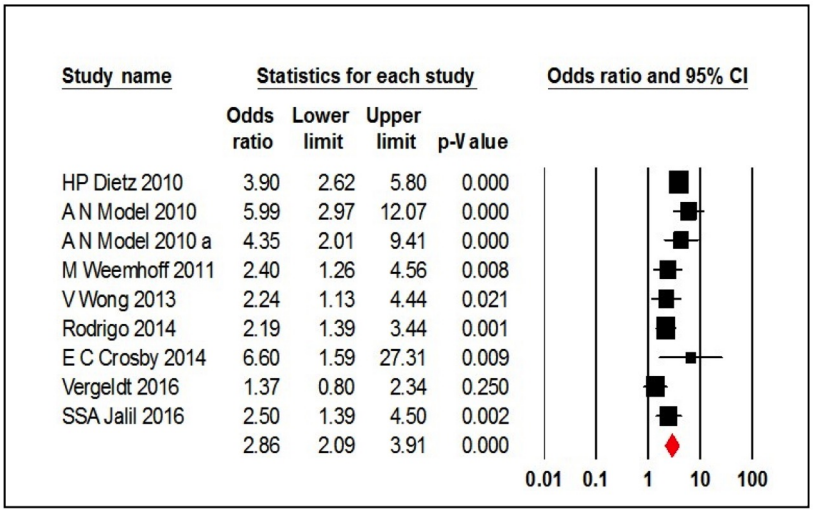

Figure 2: Meta- analysis of studies examining avulsion as a risk factor for prolapse recurrence. The odds ratio of prolapse recurrence in women with avulsion is 2.86 (2.09- 3-91) compared to women with an intact pelvic floor.(3)

'Avulsion' is a major pelvic floor muscle tear. It is the commonest form of major birth trauma in women who have given birth vaginally. It occurs in between 10 and 30% of all first- time mothers, depending on the size of the baby, the length of labour, and the mother's age at the time of birth. The lowest rates (<5%) have been observed in Nepalese women having their first baby at an average age of 21,(4) the highest rates (>60%) in Caucasian women needing a rotational Forceps delivery.(5) This form of trauma is the strongest factor in the development of prolapse of the womb and bladder. It was first described in 1943, but then forgotten until 2004.

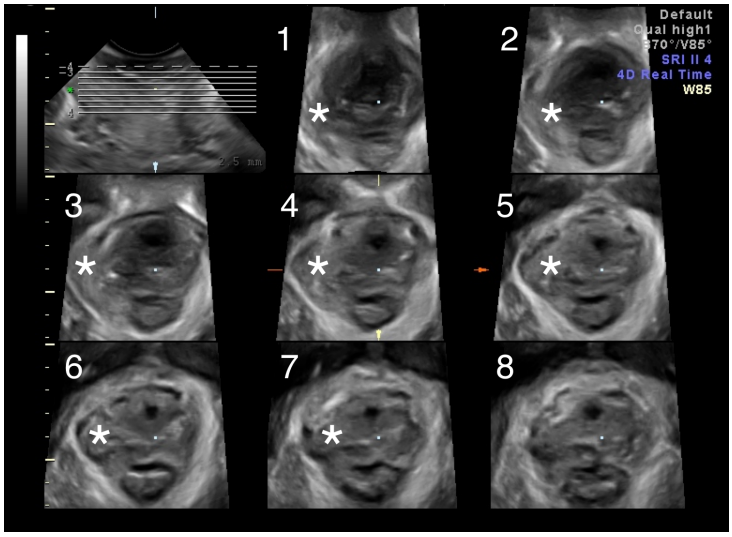

*Figure 3: Right- sided complete levator avulsion, seen from below. The patient's right side is seen on the left of slices 1-8. The trauma is marked with *. There is an obvious detachment of the muscle from its insertion on the pubic bone.*

This remarkable backwards step in the understanding of birth trauma and prolapse occurred mainly because there was no easy way to diagnose such tears. They most commonly occur behind intact vaginal skin: the vagina is more elastic than the muscle behind it, meaning that the muscle tears before the vaginal skin that covers it. Most such trauma is occult. (6) It was only in 2007 that the first such case was diagnosed immediately after birth and documented fully. (7) The recent rediscovery of this major factor in the development of prolapse means that many colleagues are not yet able to diagnose such tears. They simply haven't yet learnt how to do so. Clinical diagnosis by palpation is possible but not easy. (8)(9) Diagnosis usually requires imaging, either by ultrasound or magnetic resonance. (6)(10) Such imaging is only slowly becoming available and can now be obtained in most capital cities in Australia. Figure 3 shows a typical right- sided avulsion on tomographic ultrasound, illustrating the severity of the hidden damage.

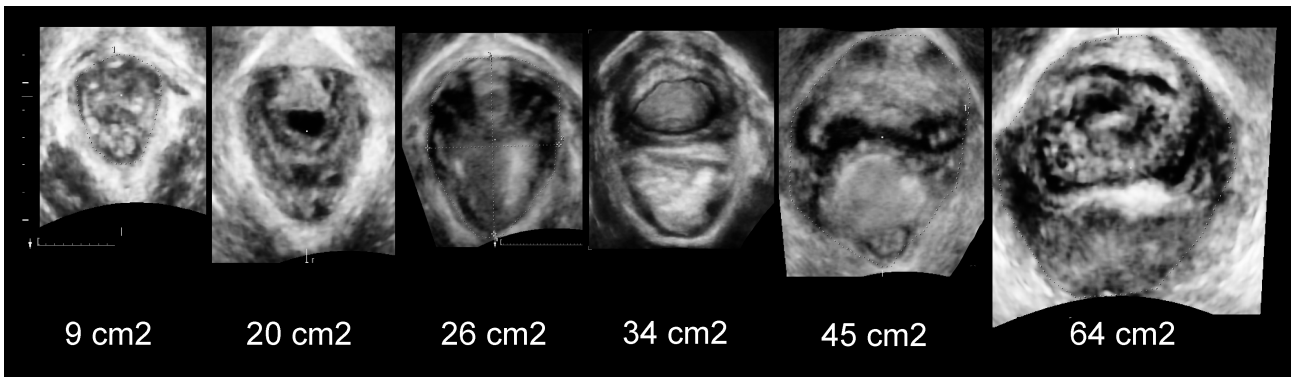

Figure 4: Variation in the size of the pelvic floor muscle opening (the 'levator hiatus'). The larger this opening, the higher the likelihood of prolapse (hernia) development and of failed prolapse surgery. The last two patients (45 cm2 and 64 cm2) had levator avulsion. The patient with a hiatal area of 64 cm^2 had an avulsion on both sides.

These considerations are of central importance for the mesh issue. Avulsion is a major factor in the development of prolapse, especially of bladder and uterus (womb). (11) It mainly affects the front of the opening in the pelvic floor muscle, widening and weakening it. This opening, the 'levator

hiatus' is the largest potential opening for hernia in the human body, (12) and its size varies enormously between people (Figure 4). It is v- shaped and formed by that part of the pelvic floor muscle that is damaged by 'avulsion', the 'puborectalis muscle'. The larger the opening of the levator hiatus, the higher the likelihood of prolapse and prolapse recurrence. (13) Pelvic floor muscle tears occur because in some women this opening and the muscle defining it has to stretch between 3 and 5 fold,(14) resulting in the muscle being torn off its origin on the pubic bone. This can have a major impact on the size of this opening(15).

This is important as it may explain the observation that mesh works particularly well in women with avulsion,(2) probably because properly anchored meshes such as the Perigee and Anterior Prolift (both now unavailable in Australia) run right across the site of the muscle tear, compensating for the effect of the muscle damage. The benefit of such mesh seems to be largely limited to patients with avulsion, while it seems nearly useless in those with an intact pelvic floor. (16) In 2013 our group published a study on 334 women after bladder prolapse repair, with an average follow-up time of 2.5 years (see Figure 5).(13)

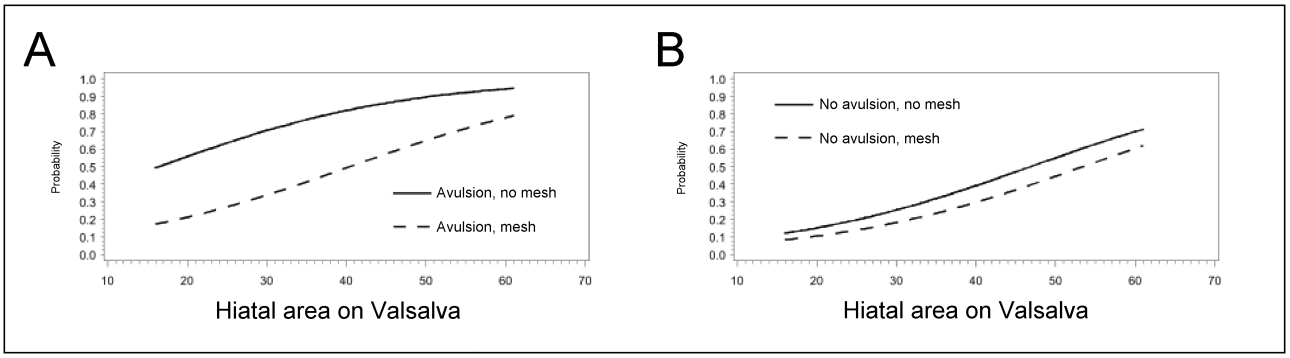

Figure 5: Probability of finding a prolapse at an average follow-up time of 2.5 years after prolapse repair, in women with avulsion (left) and with an intact pelvic floor (right). The solid line is the probability of recurrence in women after conventional (native tissue) repair, the stippled line is the same after Perigee or Anterior Prolift (anchored) mesh. For example, a patient with an avulsion and moderate 'ballooning' at 30 cm2 would run half the risk of a prolapse returning after mesh than after native tissue repair (about 30% versus 65-70%). From (13).

What does this mean for the mesh debate?

We believe, and have said so repeatedly,(17) (18) (19) (20) that it is useless to consider the pros and cons of mesh use without first working out which patients are the most likely to benefit from any new technique in prolapse surgery. Diagnosis has to come before any treatment. To make sure we offer each patient the best treatment options for her condition, we first need to diagnose the condition properly- and we, as a profession, have simply not been doing our job. However, **we believe the fault does not lie where it is usually identified**. As surgeons we try to do the best by our patients, and the rapid uptake of mesh arose from an awareness that conventional surgery often simply doesn't work. If it did why should gynaecological surgeons go to the pains of learning entirely new, sometimes difficult techniques?

The main problem with prolapse surgery is not faulty surgery or faulty materials or products- it's faulty (or entirely missing) diagnosis. Patient selection is paramount. Progress in this field has been rapid over the last 10 years, but it takes decades for every colleague to catch up with new research, and some never will. As a result we did not learn fast enough how to individualise the assessment of risks and benefits of mesh use in prolapse surgery. Now the baby has been thrown out with the bath water.

In 2012 the first author wrote: “There is an increasingly acrimonious debate surrounding the use of anchored mesh in prolapse surgery. It is evident that clinicians and researchers working with this technology are under pressure from the public, from lawyers, regulators and colleagues. There is a risk that rapidly changing societal standards, championed by colleagues, lawyers and bureaucrats, will interfere with professional independence to such a degree that an entire new technology is lost before there has been time for clinical research to assess risks and benefits properly, before we learn which patients stand to benefit most, and before we get a chance to optimise implant design.”

This is exactly what has occurred. As we stated in a recent review: “It is depressing to see the demise of a surgical option precisely at the time when we are finally starting to understand the risks and benefits of that option in individual patients. It is equally depressing to counsel prolapse patients with levator avulsion and an enlarged hiatus …., and to confess that we are unable to provide optimal surgical intervention as a result of regulatory and medicolegal interference.”(20)

We now regularly see patients who are 80-90% likely to see their prolapse come back after conventional repair, without us being able to offer them an alternative that would be likely to reduce this risk by half. We do have several ongoing surgical trials in which we try to improve the success rate of prolapse surgery, (21)(22) but the one single proven option, Perigee/ Prolift anterior anchored mesh, is no longer available in Australia, and it will be years before we can confidently offer an alternative.

In summary,

We would like to ask the Committee to consider the following points:

1.) Some women are at a much increased risk of failure when having conventional prolapse surgery. It is counterproductive to ignore this and treat them all the same.

2.) Recognising those women requires training and improved access to pelvic floor imaging. Progress in this field has been slow, not the least due to a complete absence of funding.

3.) It is likely that prolapse of the bladder and womb in some women needs other than conventional surgery, and synthetic implants (mesh) may well represent the best choice in some.

4.) Pros and cons (risks and benefits) need to be discussed in every individual case, and adequate informed consent may not be possible without including the likelihood of the surgery failing, i.e., the prolapse coming back.

5.) It may be advantageous for the Commonwealth to support research in this field, especially as regards the development of diagnostic tools for risk assessment, and clinical trials of novel forms of prolapse treatment.

6.) Banning mesh altogether, or impeding the development of new surgical techniques in this field, would only perpetuate high failure rates. Progress would then occur in other parts of the world, with research done in locations that are much less likely to follow ethical precepts.

We thank the Committee for considering this submission and would be very happy to provide more information if required.

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