

## Chapter 2

### The impact of transvaginal mesh procedures

For those reading this they are words on paper or on an electronic device, but for those of us living with mesh, and especially those that have suffered complications, they aren't words, but physical pain, emotional trauma, fear, embarrassment, ridicule, shame, disbelief, depression, anxiety, derision, and aloneness.<sup>1</sup>

2.1 Throughout this inquiry, the committee has repeatedly been told that the vast majority of women who have had transvaginal mesh procedures as part of treatment for stress urinary incontinence (SUI) or pelvic organ prolapse (POP) have not experienced complications as a result of their surgery and have experienced improved quality of life.<sup>2</sup> The committee also heard that the incidence and severity of complications was less for transvaginal mesh procedures to address SUI using mid-urethral slings (MUS).<sup>3</sup>

2.2 However, the vast majority of women who have written to the committee have experienced starkly different outcomes. Not only have these outcomes been severely adverse, but most of these women have experienced great difficulty finding medical practitioners who would accept that the symptoms they were experiencing were as severe as they claimed or that they were mesh related. Their struggles to cope with their symptoms and to find support and treatment have had far reaching and devastating impacts on their lives and the lives of their families. As the Health Issues Centre (HIC) noted in its submission to the inquiry, '[m]uch of the debate about the severity of this problem has been framed in terms of the good outcomes for the many outweighing the unfortunate experiences of a few.'<sup>4</sup>

2.3 The committee seeks to redress this by ensuring the voices of the women who bravely recounted their deeply personal and frequently traumatic experiences in submissions and evidence to this inquiry are heard. In this chapter, the committee considers the physical, social, emotional and financial impacts of complications associated with transvaginal mesh procedures. At the same time, the committee notes the accounts provided by women who have had successful outcomes from transvaginal mesh procedures and views of medical practitioners who consider there is a place for transvaginal mesh procedures in the treatment of SUI and POP.

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1 Name withheld, *Submission 110*, p. 1.

2 See, for example: Johnson & Johnson Medical, *Submission 23*, p. 10; Urogynaecological Society of Australasia (UGSA), *Submission 32*, p. 2; Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Submission 36*, p. 9.

3 See, for example: UGSA, *Submission 32*, p. 3; Continence Foundation of Australia, *Submission 35*, p. 2; RANZCOG, *Submission 36*, p. 7; Urological Society of Australia and New Zealand (USANZ), *Submission 42*, p. 3.

4 Health Issues Centre (HIC), *Submission 115*, p. 3.

2.4 In Chapter 4, the committee considers the advice and support provided to women prior to transvaginal mesh procedures and to those women who have experienced complications following their surgery.

### **The impact of mesh related health problems on women's lives**

2.5 As noted in Chapter 1, there are a number of different surgical procedures using urogynaecological mesh to address POP and SUI. The committee recognises evidence that indicates complications arising from transvaginal mesh surgery to address POP and SUI can differ in terms of incidence and clinical implications.

2.6 For example, RANZCOG submitted that complications that are specific to the use of MUS for SUI include mesh erosion and pain, particularly groin pain, while complications unique to transvaginal mesh surgery for POP include:

- vaginal exposure;
- mesh erosion into the urinary tract;
- mesh erosion into the bowel or rectum; and
- pain requiring mesh removal.<sup>5</sup>

2.7 In this chapter, while the committee has been mindful of this distinction between devices and procedures and clinical outcomes, the committee's intention is to provide a broad understanding of the range of complications that have been reported to the committee in evidence to the inquiry and, perhaps most importantly, the impact that these complications have had on women's lives.

2.8 The adverse outcomes of mesh procedures reported to the committee cover the gamut of physical, social, emotional and financial impacts. Ms Stella Channing, of the Australian Pelvic Mesh Support Group (APMSG), told the committee:

The women have lost their health, and in many cases they have lost their jobs, their careers, their homes and, in some cases, their husbands. The pain and complications cause them to be isolated from their friends and families, and many suffer from depression, anxiety and PTSD. Many women are shocked and in despair when they realise that they will probably never regain their health or their life back.<sup>6</sup>

### ***Physical impacts***

2.9 As noted in Chapter 1, the TGA has published an extensive list of adverse events that may be associated with mesh procedures.<sup>7</sup> In its submission, The APMSG told the committee that its members suffer with the effects of mesh erosion, nerve and

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5 RANZCOG, *Submission 36*, p. 9.

6 *Committee Hansard*, 25 August 2017, p. 3.

7 Department of Health, Therapeutic Goods Administration, *Urogynaecological surgical mesh complications*, <https://www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications> (accessed 5 January 2018).

tissue damage, urethral damage, perforated organs and debilitating, chronic pain.<sup>8</sup> The Royal Women's Hospital, Melbourne, (RWH) told the committee that the most frequent complications seen at that hospital include pain, mesh exposure through the vagina, infection, urinary problems and recurrence of the prolapse and/or incontinence.<sup>9</sup>

2.10 Many of the women who have provided personal accounts to the inquiry have experienced, or continue to experience, multiple complications following transvaginal mesh surgery. As the husband of one woman explained, since her operation, his wife has experienced extensive and debilitating symptoms that have impacted greatly on her health, wellbeing and quality of life. These symptoms, which have persisted even after the removal of the device, include:

- extreme hyper-sensitivity bilaterally in the groin area to the extent that even light pressure over the lower mid-line pubic area is very painful;
- 'nerve like' pain in both legs, becoming more intense when weight bearing on the leg and when walking for any period of time;
- inflammation and swelling of the lower abdomen;
- periodic greenish vaginal discharge with an offensive odor;
- extreme vaginal and vulva sensitivity and pain which varies in intensity, often manifesting as a sudden, sharp shooting pain when walking;
- periodic bleeding, especially after walking; and
- extreme pain when any attempt is made to examine her vagina, for example by intra-vaginal ultrasound.<sup>10</sup>

2.11 Regrettably, the committee has read and heard many similar catalogues of symptoms in the personal accounts presented to this inquiry.<sup>11</sup>

### ***Vaginal pain***

2.12 Across most of the personal accounts received, a recurring theme is the chronic and debilitating pain that impacts every aspect of women's lives.<sup>12</sup> Associate Professor Christopher Maher told the committee that chronic vaginal pain is the

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8 Ms Stella Channing, Director and Administrator, Australian Pelvic Mesh Support Group (APMSG), *Committee Hansard*, 25 August 2017, p. 3.

9 Royal Women's Hospital (RWH), *Submission 34*, p. 5.

10 *Confidential Submission 465*.

11 See, for example: Name withheld, *Submission 102*; Name withheld, *Submission 106*; Name withheld, *Submission 133*; Name withheld, *Submission 141*, Name withheld, *Submission 289*.

12 See, for example: Name withheld, *Submission 2*; Name withheld, *Submission 4*; Name withheld, *Submission 103*; Name withheld, *Submission 141*; Name withheld, *Submission 258*; Name withheld, *Submission 356*; Name withheld, *Submission 461*.

principal and most debilitating complication following transvaginal mesh for prolapse.<sup>13</sup>

2.13 In its submission to the inquiry, the Women's Health and Research Institute of Australia (WHRIA) told the committee that many women who are suffering as a result of transvaginal mesh pain have consulted the WHRIA and that '[their] suffering is so profound, that often words cannot convey the degree of human suffering we are seeing.'<sup>14</sup>

2.14 Ms Channing described the pain as never ending, debilitating chronic pain.<sup>15</sup> The following description of living with such pain is typical of the personal accounts received by the committee:

My life has been impacted in every way. I am in constant pain, so I cannot do what I used to do, and I must lie down horizontally every hour or so because the pain becomes unbearable. I have experienced bleeding, constant bowel and urination pain, and insomnia every night; I cannot sleep because I am in so much pain. I have always been very active, going to gym, walking, cycling, but everything is very limited now. Every movement hurts. I used to be sexually active prior to this, but now I absolutely cannot. It's just pain, pain, and more pain to merely exist.<sup>16</sup>

2.15 For some women the onset of pain was immediate following their surgery and has not abated:

When I came out of surgery the pain in my left hip was excruciating. Pain in that area over the years affected my pelvis also. I have only been painfree in those areas the past year. I have been to a hip professor who injected needles into my pelvis which has helped me this past year.<sup>17</sup>

2.16 At the committee's Sydney hearing, Gai described how she has lived with constant pain for ten years since surgery to address a prolapsed bladder:

For 10 years—and I don't know how many months, weeks or minutes that is—I have not had a day without pain. I woke up in agonising pain from the surgery. No amount of pain medication could help me. They phoned my implant surgeon who sent his offsider—he didn't even bother to come in....The pain is indescribably, but it doesn't matter because there's not 100 per cent of us—and I don't believe those statistics.<sup>18</sup>

2.17 In other cases, the pain did not commence until sometime after the surgery as the following statements indicate:

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13 *Submission 154*, p. [14].

14 Women's Health and Research Institute of Australia (WHRIA), *Submission 39*, p. 1.

15 *Committee Hansard*, 25 August 2017, p. 3.

16 Name withheld, *Submission 403*, p. 1.

17 Name withheld, *Submission 374*, p. 5.

18 Gai, *Committee Hansard*, 18 September 2017, p. 5.

The surgery was actually successful for quite a few years, but I started experiencing pain on my left side. I thought it was my Mirena coil, so I had it taken out. After several months of this intense pain continuing, I went to two private gynaecologists and through an internal examination they found out that it was actually my mesh implant causing the source of the pain.<sup>19</sup>

My mesh was implanted in the UK in 2007 and I experienced no complications until 2014, seven years later, when I went through menopause. For nearly two years then I experienced debilitating, life changing complications which ultimately resulted in me travelling to the USA for mesh removal in May 2016.<sup>20</sup>

2.18 Many women described the incredible difficulty of going about their daily lives whilst experiencing constant pain:

I kept working as I had to support my family, I have 3 children of my own, including a daughter living with Down Syndrome, and a step son from a blended relationship, but I was in constant pain, and by the end of a working day and often when I was at work, I was so exhausted, to the point of having to just lay down and not move with extreme pain, tiredness and anxiety. Drs kept telling me it had nothing to do with my mesh!<sup>21</sup>

2.19 Dr Thierry Vancaille, the Director of the WHIRIA told the committee that the Chronic Pelvic Pain Clinic at the Royal Hospital for Women in Sydney is seeing patients suffering with chronic pain after mesh surgery with increasing frequency:

Nerve pain is horrible; it burns, it stings, it feels like a ball stuck in the rectum and it does not go away. In 2017 so far, we have seen 54 new patients with nerve pain after mesh surgery and, since the middle of August, we see six new patients every week.<sup>22</sup>

2.20 Joanne, who was implanted with a tension-free vaginal tape-obturator (TVT-O) sling and posterior and anterior mesh, described for the committee the limitations that 'the burning chronic pain' that she has been living with place on her:

I was told by my implanting surgeon that I would be back at the gym within 10 days post implant procedure and that I would be like a 16-year-old virgin after the implants. To this day, I can't sit upright on a chair for longer than 15 minutes at a time due to the searing pain that travels across my lower abdomen and deep into my pelvis. I have pudendal nerve neuralgia that occurred on implant of the two meshes. It took a good 14 weeks, not 10 days, post implant before I was able to get out of bed and walk again. I still, to this very day, experience the same burning pain, even after the removal of both meshes. I describe my pain as being cut open and set alight. It's a deep, burning, searing ache that intensifies with movement.<sup>23</sup>

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19 Melinda, *Committee Hansard*, 3 August 2017, p. 13.

20 Andrea, *Committee Hansard*, 3 August 2017, p. 2.

21 Name withheld, *Submission 102*, p. 4.

22 *Committee Hansard*, 18 September 2017, p. 7.

23 *Committee Hansard*, 18 September 2017, p. 1.

### ***Mesh exposure/erosion***

2.21 Mesh exposure or erosion is also commonly reported in women's personal accounts.<sup>24</sup> Mesh exposure refers to the protrusion of mesh fibres through the vaginal wall.<sup>25</sup> The committee heard that mesh exposure and scarring of the vagina can lead to discomfort and pain, including bleeding and pain during intercourse.<sup>26</sup>

2.22 Respondents to an on-line survey conducted by HIC reported a range of complications related to mesh eroding the vaginal wall, including infections, discharge, adhesions to the bowel and bladder and faecal incontinence.<sup>27</sup>

2.23 The committee heard a range of statistics regarding the incidence of mesh exposure/erosion. Monash Health submitted that 15-20 percent of women present in the first two years following transvaginal mesh procedures and between 70 to 80 percent of these will require minor surgery to address mesh exposure.<sup>28</sup>

2.24 In its submission the Department of Health advised that some studies estimate the risk of mesh exposure following transvaginal mesh procedures to be ten percent for POP related procedures, compared to less than two percent for MUS procedures to address SUI.<sup>29</sup> Associate Professor Paul Duggan, Head of Obstetrics and Gynaecology at the University of Adelaide, advised that in a research trial he conducted, comparing mesh against traditional surgery for vaginal prolapse, nine percent of participants required further surgery to address complications predominantly associated with mesh extrusion.<sup>30</sup> The Urogynaecological Society of Australasia (UGSA) provided similar statistics, noting an incidence of vaginal mesh extrusion of between eight to ten percent for repair of POP and between one to two percent for treatment of SUI using MUS. However, UGSA stated that not all cases of vaginal mesh extrusion required treatment.<sup>31</sup>

2.25 Associate Professor Maher provided the committee with the following breakdown of the incidence of mesh exposure/erosion following transvaginal mesh procedures for POP:

- 18 percent of procedures for apical prolapse, with 9.5 percent of cases requiring surgical intervention; and

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24 See, for example: Name withheld, *Submission 58*, p. 3; Name withheld, *Submission 175*, p. 5; Name withheld, *Submission 176*, p. [1]; Name withheld, *Submission 179*, p. [1]; Name withheld, *Submission 390*, p. [1].

25 Department of Health, *Submission 19*, p. 19; UGSA, *Submission 32*, p. 3.

26 UGSA, *Submission 32*, p. 3; RWH, *Submission 34*, p. 5.

27 HIC, *Submission 115*, p. 9.

28 Monash Health, *Submission 47*, p. [3].

29 Department, *Submission 19*, p. 19.

30 Associate Professor Paul Duggan, *Submission 63*, p. [1].

31 UGSA, *Submission 32*, p. 3.

- 11.3 percent of procedures for anterior prolapse, with 7.3 percent of cases requiring surgical intervention.<sup>32</sup>

2.26 Associate Professor Maher submitted that mesh exposure or erosion was more common with larger mesh devices and that early trials with new low weight mesh suggest significantly lower exposure rates of between one to five percent.<sup>33</sup>

2.27 Medical practitioners advised the committee that erosion of mesh into the vagina can usually be easily addressed. In some cases mesh exposure can be treated with vaginal oestrogen creams, but some patients require surgery to remove the exposed mesh.<sup>34</sup> Dr Jenny King, Chair of UGSA, told the committee:

You can usually trim that really easily. I know that the husbands hate it, and we try to be sympathetic. That would be a complication we could fix quite easily...<sup>35</sup>

2.28 However, the committee understands that for some women the experience of mesh exposure or erosion is far from a minor complication and can be painful and distressing, requiring multiple surgeries,<sup>36</sup> as the following examples indicate:

Add to this my personal experience of trying to teach full time with a piece of plastic hanging out of an open wound in my vagina for the last three months. I can assure you that it was not just an inconvenience or a trivial or superficial incident.<sup>37</sup>

By 3 months post op I was getting pain in my vagina, bleeding and there was mesh eroding out through the side of my Vagina, I noticed a smell that I described as rotting flesh, I went to my GP, who thought I had a fistula and sent me back to my specialist for review. I saw him and he said it was just a small hiccup, he would 'snip' the small bit of mesh out in his surgery, and he did OMG, it hurt so much and I left, with him telling me to take a couple of Panadol and I would feel ok. This went on for a couple of years, with 4 major surgeries for mesh erosion and multiple trims in his rooms. I was assured this was not very common.<sup>38</sup>

2.29 Associate Professor Maher told the committee that erosion of mesh into the bladder or bowel, while reported, is 'incredibly uncommon' and that no case was reported in the 950 women evaluated as part of the Cochrane anterior mesh review.<sup>39</sup>

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32 Associate Professor Christopher Maher, *Submission 154*, pp. [13-14].

33 *Submission 154*, pp. [13-14].

34 UGSA, *Submission 32*, p. 3; RWH, *Submission 34*, p. 5.

35 *Committee Hansard*, 18 September 2017, p. 16.

36 See, for example: Angela, *Committee Hansard*, 3 August 2017, p. 12; Angela, *Committee Hansard*, 25 August 2017, p. 19; Harriett, *Committee Hansard*, 19 September 2017, p. 3.

37 Fiona, *Committee Hansard*, 18 September 2018, p. 23.

38 Name withheld, *Submission 102*, p. [7].

39 *Submission 154*, pp. [12-13].

2.30 However, submissions to the inquiry indicated the debilitating effects experienced by women whose mesh implants had either adhered to or penetrated their bowel or bladder.<sup>40</sup> One woman told of the surprise of medical staff when they discovered that the mesh had perforated her bladder:

After a succession of Urinary Tract Infections, pain when urinating and excruciating pain after urinating I was finally sent to see a Urogynaecologist to see if he could determine the cause of my discomfort. He recommended a Cystoscopy which enables the Doctor to see inside the bladder. I was fully conscious during this procedure watching with great intent the workings of my bladder when everyone – doctors, nursing staff and myself – were surprised to see mesh which had perforated my bladder...it was only after the surgery [to excise the mesh] that my doctor told me that the mesh was dangerously close to my urethra.<sup>41</sup>

2.31 Another woman told the committee of her experience following surgery to correct a prolapse of the bowel in 1989. Having experienced a range of symptoms from 2004 till 2007 she had surgery 'to remove what was assumed to be a partial obstruction in the bowel.' The 'blockage' was found to have been caused by the mesh which had become displaced and had pierced her bowel. While the mesh was removed, this woman now has a permanent colostomy bag.<sup>42</sup>

### *Dyspareunia*

2.32 Many of the women who wrote to the committee reported experiencing dyspareunia, or painful intercourse, following their mesh surgery.<sup>43</sup>

2.33 Monash Health told the committee that between 4.3 to 10 percent of women who received transvaginal mesh procedures at Monash and Mercy Health between January 2002 and December 2012 reported painful intercourse following their surgery.<sup>44</sup>

2.34 However, Associate Professor Maher advised the committee that the incidence of dyspareunia following transvaginal mesh procedures (9.9 percent) was similar to that following native tissue or suture repairs (8.8 percent).<sup>45</sup>

2.35 While many women reported that sexual intercourse was simply too painful to contemplate,<sup>46</sup> others told the committee that their husbands had suffered injuries as a

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40 See, for example: Name withheld, *Submission 109*; Name withheld, *Submission 113*, p. 8; Name withheld, *Submission 472*, p. 1; Name withheld, *Submission 477*, p. [2].

41 Name withheld, *Submission 462*, p. 6.

42 Name withheld, *Submission 109*, p. [2].

43 See for example: Name withheld, *Submission 102*, p. [1]; Name withheld, *Submission 113*, p. [6]; Name withheld, *Submission 148*, p. 1, 5; Name withheld, *Submission 258*, p. [1]; Name withheld, *Submission 289*, p. [2]; Name withheld, *Submission 390*, p. [4-5].

44 *Submission 47*, p. [3].

45 *Submission 154*, p. [13].

46 See, for example: Melinda, *Committee Hansard*, 3 August 2017, p. 14; Melanie, *Committee Hansard*, 25 August 2017, p. 21; Name withheld, *Submission 102*, p. 9.



result of mesh which had eroded through the vaginal wall.<sup>47</sup> One woman described for the committee the impact that her surgery had on her once 'healthy balanced relationship'.<sup>48</sup> She described how intimate sensations felt raw and painful and how she dreaded 'constantly failing with every painful attempt'

To add insult to this situation my husband began complaining that making love to me was like sleeping with a cheese grater. His penis would be cut when we had intercourse. The pain and embarrassment made me anxious, sick and depressed.<sup>49</sup>

2.36 The impact of this on women's personal relationships and emotional wellbeing is discussed further below.

### ***Urinary and voiding problems***

2.37 The most frequent issues reported to the HIC were problems associated with incontinence and persistent UTIs. Some respondents to the HIC survey indicated that while the transvaginal mesh procedure had addressed their incontinence, they were now experiencing difficulty urinating or emptying their bladder. Some respondents reported needing to self-catheterise.<sup>50</sup> These responses are consistent with personal accounts provided to the committee.<sup>51</sup>

2.38 Recurrent urinary tract infections are a common complication noted in the personal accounts provided to the committee, with many women expressing concern regarding their continued reliance on antibiotics<sup>52</sup>

2.39 Other women have experienced severe incontinence following mesh procedures.<sup>53</sup> In their submissions they described the challenges of going out: the need to wear incontinence pads, to know where the nearest toilet is; to carry spare clothes and the embarrassment and indignity when even these precautions are not enough:

It has completely changed my life. I presented with mild stress incontinence with exercising and 2 years on I have total and uncontrollable urinary incontinence. I have had multiple hospital admissions, surgeries, invasive investigations and a total loss of my pride as a woman.<sup>54</sup>

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47 See, for example: Name withheld, *Submission 4*, p. 1; Name withheld, *Submission 148*, p. 5; Name withheld, *Submission 429*, p. 6; Name withheld, *Submission 529*.

48 Name withheld *Submission 464*, p. 2.

49 Name withheld, *Submission 464*, p. 2.

50 HIC, *Submission 115*, p. 9.

51 See, for example: Kim, *Committee Hansard*, 3 August 2017, p. 1; Robyn, *Committee Hansard*, 25 August 2017, p. 21; Harriett, *Committee Hansard*, 19 September 2017, p. 5; Name withheld, *Submission 147*.

52 See, for example: Name withheld, *Submission 72*; Name withheld, *Submission 79*, *Attachment 1*; Name withheld, *Submission 114*; Name withheld, *Submission 392*.

53 See, for example: Name withheld, *Submission 87*, p. [4]; Name withheld, *Submission 420*, p. [4].

54 Name withheld, *Submission 458*, p. [6].

2.40 A number of women reported experiencing voiding dysfunction following their mesh surgery.<sup>55</sup> Some of these women have been advised that these difficulties are the result of the mesh obstructing the bowel,<sup>56</sup> while others have been advised that the dysfunction stems from the mesh being too tight.<sup>57</sup>

2.41 The Urological Society of Australia and New Zealand (USANZ) noted in its submission that international studies suggest that the incidence of such symptoms after transvaginal mesh surgery to treat SUI is low. USANZ noted 11 percent of patients experience new urgency symptoms (an overactive bladder) after MUS, with 3.9 percent of cases not responding to treatment and 5.3 percent of patients experiencing persistent or recurrent stress urinary incontinence.<sup>58</sup> Dr Atherton submitted that the risk of significant voiding disorder and urge incontinence is much higher following other major surgical procedures for the treatment of SUI than it is for surgery using MUS. However, Dr Atherton also noted 'when a complication is severe, whatever the nature of it, the woman's life is often severely and permanently changed.'<sup>59</sup>

### ***Impact of mesh complications on quality of life***

2.42 It is not surprising that alongside physical complications such as those described above, many women have experienced profound impacts on their quality of life following mesh procedures. Professor Vancaillie described for the committee the disastrous impact these symptoms have had on the lives of the women who have come to the WHRIA:

For some women, things have gotten better, but for quite a few, problems have gotten worse, resulting in true disaster with substantial loss of quality of life. They are unable to sit for any length of time, which means they can't enjoy such basic social interaction as a family dinner. They can't have intercourse. They have difficulty emptying their bladder or bowel. They have difficulty with basic physical activity, such as walking or going up flights of stairs. One patient who just turned 40 summarised it quite succinctly: "I can't afford feeling like an 80-year-old grandmother. I have to look after my young children, and I can't."<sup>60</sup>

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55 See, for example: Name withheld, *Submission 133*; Name withheld, *Submission 147*; Name withheld, *Submission 158*; Name withheld, *Submission 179*; Name withheld, *Submission 384*.

56 Name withheld, *Submission 113*, p. 8.

57 See, for example: Name withheld, *Submission 114*, p. [5]; Name withheld, *Submission 147*, p. 6; Name withheld, *Submission 385*, p. [3]; Name withheld, *Submission 521*, p. [3].

58 *Submission 42*, p. 3.

59 *Submission 98*, p. [7].

60 *Committee Hansard*, 18 September 2017, p. 7.

2.43 Many women described how they have withdrawn from social and family activities, too embarrassed to explain their symptoms to friends and family or simply unable to engage in normal social activity.<sup>61</sup> As one woman stated:

I don't make plans anymore, I don't go out much, I live a very reclusive life because I am embarrassed of my symptoms that I have been left with from these implants.<sup>62</sup>

2.44 Many women described the impact their symptoms had on their once active lives. Many of the personal accounts recounted a dramatic change in the range of activities that women could engage in.<sup>63</sup> One submitter wrote:

It was difficult to return to work, up to the day I had the operation I was very active, for the past 20 years I have worked at a special needs high school for behaviour disorders and emotionally disturbed teenagers. I have always prided myself as being an active team member of our staff. After the operation I felt I couldn't possibly do the things I used to be able to do with the kids. Playing basketball, dodgeball, football, netball, cricket etc. Gradually my weekly workdays diminished from 4 to 3 days to 2 days a week working.<sup>64</sup>

2.45 Another woman told the committee of the difficulty she experienced trying to live a normal life:

I dragged myself to work each day and on weekends I was bedridden. I was unable to do normal things like shopping, cooking and housework without debilitating pain and fatigue. My relationship with my family, friends suffered as I could not handle social activities. Not being able to care for my new grandson broke my heart. Surfing was impossible and walking the dogs or doing other light physical exercise was just too painful.<sup>65</sup>

2.46 Many of the personal accounts received by the committee describe the impact of mesh complications on women's family and personal relationships. As the accounts referred to above reflect, many women wrote of their inability to care for their children or interact with their grandchildren.

It has taken its toll on my family life as I am unable to enjoy many of the activities with my family as I am limited in my movement and still experience debilitating pain.<sup>66</sup>

2.47 Another significant social impact has been the limitations that these symptoms have placed on women's ability to work. While some women have been able to

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61 See, for example: Name withheld, *Submission 340*; Name withheld, *Submission 439*; Name withheld, *Submission 524*.

62 Name withheld, *Submission 101*, p. 3.

63 See, for example: Name withheld, *Submission 133*; Name withheld, *Submission 182*; Name withheld, *Submission 398*.

64 Name withheld, *Submission 289*, p. 4.

65 Name withheld, *Submission 67*, p. 1.

66 Name withheld, *Submission 102*, p. [5].

modify their working arrangements, by taking regular breaks throughout the day, modifying their work environment or the work they do<sup>67</sup>, others have found they are no longer able to work which has created financial stress for them and their families:

I was unable to work for two years ad (sic) then I made a very slow return to work because of the fatigue and relapses. Being unable to work has created financial stress on our family.<sup>68</sup>

2.48 Many of the submissions received from women told of the significant financial burden associated with treatment of complications from mesh surgery. Most of these women have faced significant out-of-pocket expenses, have taken significant time off work and have used up their sick leave and long service leave.<sup>69</sup> Personal accounts received by the committee frequently referred to amounts in the thousands of dollars for treatment of pain and other symptoms, with few of these costs covered by private health insurance.<sup>70</sup> For example:

I have to this point spent over \$12,000.00 to pay for all of this and I have ongoing drugs and acupuncture. Money I didn't have and had to ask friends and family to help.<sup>71</sup>

2.49 One woman told the committee that she had been prescribed a course of six injections of Hyaluronic acid to address nerve pain. She said:

I have currently had six of these injections with no desirable affect or improvement. The 'direct' cost for these injections has amounted to \$6,000, a fraction of the indirect cost on my business and loss of income.<sup>72</sup>

2.50 Another woman told the committee that out of pocket costs associated with her treatment have run into tens of thousands of dollars:

I cannot work because of my medical issues, which has caused financial problems. The costs for treatment for my pain and other symptoms is ongoing. I have spent tens of thousands of dollars out of pocket for treatment, after private health insurance claims. My last surgery cost \$8000+ out of pocket.<sup>73</sup>

2.51 Some women described the difficulties they have experienced accessing financial support through Centrelink.<sup>74</sup> Women have found it difficult to explain their symptoms and the impact this has on their ability to work. One woman described how after her surgery, she found she was only able to manage working 15 hours a week,

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67 See, for example: Name withheld, *Submission 67*.

68 Name withheld, *Submission 459*, p. 1.

69 See, for example: Name withheld, *Submission 220*, p. 4; Name withheld, *Submission 411*, p. 5.

70 See, for example: Joanne, *Committee Hansard*, 18 September 2017, p. 3.

71 Name withheld, *Submission 521*, p. [4].

72 Name withheld, *Submission 92*, p. 2.

73 Name withheld, *Submission 56*, p. 5.

74 See, for example: Joanne, *Committee Hansard*, 18 September 2017, p. 5.

'and even then it is difficult to maintain these hours.' However, she has been advised by Centrelink that she is capable of working at least 23 to 27 hours a week. Her attempts to explain her condition, even with the help of medical records and letters from her legal advisers have so far been unsuccessful. She said:

It makes me very angry and depress[ed] just because the outside looks fine doesn't mean I am.<sup>75</sup>

2.52 Another woman explained to the committee how low her experience of continually trying to explain her condition had brought her:

In the end, it drove me to the point where I had had enough and I was still in a lot of pain at that stage. About a year ago, I just thought: 'I'm ready to check out. I've had enough.' I had \$200 left in the bank. I had spent all my money that I had saved. I had nothing left.

I got onto a social worker who, ultimately, processed the application for me. But I spoke to, I would say, about 50 different people during that process and wrote so many letters, spent hours on hold. Every time I spoke to a different person in Centrelink, I'd have to tell the story again. It was just a nightmare.<sup>76</sup>

2.53 The committee heard that women have mortgaged or sold their homes, while others have come close to losing theirs as they struggle to meet spiralling medical costs.<sup>77</sup>

2.54 Others have experienced difficulties trying to access their superannuation.<sup>78</sup> As the following examples indicate, for some women, the delays and difficulties associated with this have caused them an additional layer of stress:

I am assisted by my husband who has had to take time off work. I am still on leave from work myself. Forced to serve the 395 day waiting period for my super to pay me 70% of my wage, the addition of \$50,000 to our mortgage means we struggle to make ends meet.

I wrote to my superannuation fund but was denied being able to waive the waiting period regardless of all the evidence my doctors are able to give them going back 5 years. Disgusting really, my family is suffering from this and why should they? My option now is to write to the Superannuation Ombudsman...The government knows the difficulties women are having with this tragic medical outcome yet why am I made to pay the price for something I did not ask to happen – unsure how I will cope financially, mentally, emotionally.<sup>79</sup>

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75 Name withheld, *Submission 68*, p. [2].

76 Joanne, *Committee Hansard*, 18 September 2017, p. 5.

77 Name withheld, *Submission 4*.

78 See, for example: Joanne, *Committee Hansard*, 18 September 2017, p. 3; Gai, *Committee Hansard*, 18 September 2017, p. 3.

79 Ms Harriett Desmond, *Submission 159.1*, p. [2].

2.55 A number of women who are waiting for surgery to remove their mesh told the committee of the lengths they have needed to go to in an attempt to raise the thousands of dollars required. Some have turned to friends and family for financial support:

The surgery cost is \$9,600 which I haven't got yet but have pawned my wedding rings, jewel[le]ry, set up a crowdfunding page and asked my children for money to help as I am determined to have it as I need this product out of me before it causes more damage. My three children live in the United States so going through all this on my own has been very stressful.<sup>80</sup>

2.56 Some women have drawn on every source of funds available to them, leaving them concerned for their future financial security and their ability to enjoy the quality of life many people might take for granted:

Removal costs will be approx. \$50000. I have not worked since this mesh was implanted in me in March 2011. The death of my father and an inheritance sum of money paid [off] the remainder of my mortgage and is funding my surgery...I live [off] income protection from my superannuation and have income streamed my super. Mesh has robbed me of a future, a career and my health. It robbed me of being able to provide family holidays for my children and me. It has taken away my social life and friends. They do not understand what a daily battle I have and it is just getting worse.<sup>81</sup>

2.57 Another woman observed: 'There is one thing I can say that the mesh does hold my pelvic floor up but at what cost now and in the future.'<sup>82</sup>

### ***The emotional toll***

To sum it up mesh has ruined my life.<sup>83</sup>

2.58 So many of the submissions received from individual women related the emotional toll that mesh related complications have had on their lives. The APMSG told the committee:

Many women in the APMSG have pain that is so debilitating, they have given up work, they can no longer have sexual intercourse with their husbands/partners, they are in pain every day, they are on a cocktail of pain medications, many have urinary tract infections and are on antibiotics. They are suffering from depression and anxiety, many have post traumatic stress disorder. Some women have suicidal thoughts because they can find no way out of their crippling pain.<sup>84</sup>

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80 Name withheld, *Submission 521*, p. [3].

81 Name withheld, *Submission 524*, p. 1.

82 Name withheld, *Submission 410*, p. [2].

83 Name withheld, *Submission 459*, p. 6.

84 APMSG, *Submission 130*, p. 6.

2.59 While some women spoke of the incredible support and understanding provided by their families,<sup>85</sup> most women who wrote to the committee about mesh related complications were all too keenly aware of the toll that living with their symptoms has had on their relationships with their families. For some women it is a daily struggle to push through the physical and emotional pain they feel:

On the receiving end are my husband, children and friends. I have attempted to keep my physical and emotional pain from the ones that I love, and I've pushed on through so hard so I always get back on track, back to being the mum that I always was and the hardworking woman I strive to be. Others cannot believe I'd end up broken, but I am. I suffer with post-traumatic stress, huge anxiety and I have recently accepted that, yes, depression is real. I now rely on medication so I can smile at my children, look at my husband and remind him of why he married me. I can't attend work anymore. I am no longer able to pretend that I am okay. The pain slowly kills your soul.<sup>86</sup>

2.60 For others, the deterioration of their relationships with family and friends, has left them isolated and lonely:

My life is broken, my children no longer see me as the person I once was, with the exception of my eldest who is older and more able to understand, therefore is able to tolerate me. The two younger rarely if ever see me. They cannot relate to me and now see me as an old confused lady. I try at times to revive my communication with them but they do not want this, see me as an embarrassment...<sup>87</sup>

2.61 As noted earlier, many women told the committee that following their surgery it was either extremely painful or impossible for them to sustain an intimate relationship and spoke of the emotional pain and grief that this had caused them.<sup>88</sup>

2.62 So many of the women who wrote to the committee spoke of the pain, both physical and emotional, that this had caused them and their partners.<sup>89</sup> One woman told the committee:

The first time we tried to have intercourse it felt like barbed wire inside me. My husband could also feel the mesh. This [came] as a massive shock as my professor had told me I would be like a new woman after childbirth everything would be tighter. I grieved for my sex life for a long time as my husband and I had only been married 6 months.<sup>90</sup>

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85 See, for example: Name withheld, *Submission 118*, p. [5]; Name withheld, *Submission 137*; Name withheld, *Submission 123*, p. 2; Name withheld, *Submission 149*, p. 5.

86 Harriett, *Committee Hansard*, 19 September 2017, p. 3.

87 Name withheld, *Submission 494*, p. 4.

88 See, for example: Name withheld, *Submission 82*; Name withheld, *Submission 105*, p. [5]; Joanne, *Committee Hansard*, 3 August 2017, p. 11.

89 See, for example, Name withheld, *Submission 110*, p. [11].

90 Name withheld, *Submission 374*, p. 6.

2.63 The committee heard that the inability to sustain intimate relationships has had far reaching impacts on women's emotional well-being. As a woman from the Tiwi Islands explained to the committee:

If you look at women in remote Indigenous communities...and at the impact of isolation on Indigenous women, you will find that if they have this mesh, they will be totally ostracised. When our women talk about sex, sex is not just sex; it encompasses a whole community and involves love, intimacy, touch deprivation—everything.<sup>91</sup>

2.64 For many women, the breakdown of their intimate relationships, together with the financial and other stresses associated with their complications, has led to the breakdown of their marriages and their family unit.<sup>92</sup>

I just became non-sexual. I ended up sleeping on the couch for two years and we tried so hard to stay together as a couple and a family but we just couldn't keep going. So 6 weeks ago, I moved in with my parents at the age of 52. I have no money, nothing of value (and neither does he). I left behind everything...we made the decision it would be best for our children to live in our rental home with my husband. I have lost the love of my life, my best friend and we hardly even talk anymore. I hardly see my children and I am absolutely devastated.<sup>93</sup>

2.65 The committee was struck by the number of women who reported the breakdown of their marriage.<sup>94</sup> The responses to the WHRIA's Pelvic Pain Impact Questionnaire suggest that of 124 women surveyed, 72 percent reported that pelvic pain had affected their levels of intimacy or sexual relationships.<sup>95</sup>

2.66 The Health Issues Centre told the committee that of the respondents to its survey of women's experiences following transvaginal mesh surgery, 88 reported a negative impact on their intimate relationships, including avoidance of sexual activity due to their own pain or that of their partner. 110 respondents reported relationship issues both as a result of their physical symptoms and the financial strain caused by the cost of treatment and multiple surgeries and often an inability to work.<sup>96</sup> Ms Elizabeth Howard, from the WHRIA, told the committee that in the WHRIA's

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91 Tracey, *Committee Hansard*, 25 August 2017, p. 23.

92 See, for example: Name withheld, *Submission 62*, p. [3]; Name withheld, *Submission 110*, p. [11]; Name withheld, *Submission 117*, p. 3; Name withheld, *Submission 257*, p. [1, 6]; Name withheld, *Submission 345*, p. [1, 5]; Name withheld, *Submission 395*, p. [1]; Name withheld, *Submission 398*, p. [2]; Name withheld, *Submission 400*, p. [1].

93 Name withheld, *Submission 110*, p. [11].

94 See, for example: Name withheld, *Submission 110*; Name withheld, *Submission 114*.

95 Professor Thierry Vancaillie, *Committee Hansard*, 18 September 2017, p. 11.

96 Health Issues Centre, *Submission 115*, p. 9.



experience perhaps as many as 50 percent of marriages breakdown following complications associated with transvaginal mesh implants.<sup>97</sup>

2.67 Some women have experienced nervous breakdowns that they attribute to the pain and anxiety their symptoms have produced,<sup>98</sup> while others spoke of suicidal ideations:

I feel isolated and alone. I feel angry and violated. I live in fear of not knowing which way to turn. My self-esteem is low. I am consumed with negative thoughts and require ongoing counselling.<sup>99</sup>

...

Its actually destroyed my life to the point that I thought I couldn't go on any further and suicide was an option.<sup>100</sup>

2.68 Many women have suffered these devastating symptoms unaware that other women have had similar experiences.<sup>101</sup> As one woman told the committee:

I have had my own history of mesh problems and it was only this year that I discovered that there are literally thousands of women in Australia and hundreds of thousands around the world who have had complications and side effects. For ten years I have thought that I was just about the only one who continued to suffer, that there was no help for me, nothing that could be done so I gave up...<sup>102</sup>

2.69 One woman told the committee of the relief she experienced once she discovered that she was not alone:

I have honestly thought of ending it all on several occasions as I often feel as if I'm so alone with it all and can't bear it any longer. Until recently I have found a group of ladies with the same issues because of mesh implants, they have helped me feel as though I'm not mad and I'm not alone, there are so many of us out there suffering in silence, like me. Until now we have not had a voice. It has been too embarrassing and personal.<sup>103</sup>

### ***Committee view***

2.70 The evidence provided to the inquiry by individual women demonstrates that complications following transvaginal mesh procedures have far reaching and, in many

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97 Ms Elizabeth Howard, Osteopath and Pain Management, Women's Health and Research Institute of Australia, *Committee Hansard*, 18 September 2017, p. 11.

98 See, for example: Name withheld, *Submission 101*, p. 1; *Submission 345*, p. [5].

99 Kylie, *Committee Hansard*, 18 September 2017, p. 24.

100 Name withheld, *Submission 401*. See also: Name withheld, *Submission 113*; Name withheld, *Submission 118*; Name withheld, *Submission 401*; Name withheld, *Submission 424*; Name withheld, *Submission 521*.

101 See, for example: Name withheld, *Submission 67*, p. 4; Name withheld, *Submission 97*, p. [3]; Name withheld, *Submission 396*, p. [3].

102 Name withheld, *Submission 110*, p. [5].

103 Name withheld, *Submission 551*, p. [1].

cases, devastating impacts on women's lives. In the words of one submitter, '[w]hen it goes wrong, it goes catastrophically wrong.'<sup>104</sup>

2.71 So many of the women who wrote to the committee or appeared at public hearings live with constant pain and a range of other debilitating complications that undermine their quality of life.

2.72 The committee acknowledges the impact of complications from transvaginal mesh procedures which encompass every aspect of women's lives. In many cases, women have become isolated from their families and friends and have had to endure their symptoms with limited practical and emotional support. In so many cases, the committee heard how women have been robbed of so much: their interests; their ability to parent; to work and to sustain close and loving relationships. At the same time they have lost their dignity and self-esteem and many have struggled with depression.

2.73 The committee notes the significant costs associated with managing the complications following transvaginal mesh surgery. In addition to significant out of pocket costs associated with pain management, scans and incontinence and mobility aids, women have used up their leave, drawn upon their superannuation, sold valuables and, in some cases sold or mortgaged houses and drawn on the generosity of friends and family to fund their treatment.

2.74 The committee considers that it is of no consolation to women who have lost so much to be told that they are part of a very small minority. The committee notes the observation of Mrs Elaine Holmes, from the Scottish Mesh Survivors Groups:

We are told that, for the majority of women, mesh is successful. We sincerely wish them continued good health, and hope they never suffer the hell that we do. Every transvaginal mesh survivor knows only too well what it is like to suffer from stress urinary incontinence and/or pelvic organ prolapse. Yes, it is uncomfortable, painful at times, unpleasant and embarrassing. However, neither is a life-threatening condition.<sup>105</sup>

### **Successful outcomes using mesh**

2.75 As mentioned earlier, the committee received evidence emphasising the many women who have experienced positive outcomes following transvaginal mesh procedures. The committee heard that vaginal mesh implants have provided 'excellent anatomical and quality of life results for the silent majority of women who have undergone surgery.'<sup>106</sup> Submitters expressed concern that insufficient attention was being focussed on the positive, life changing impacts of transvaginal mesh

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104 Gai, *Committee Hansard*, 18 September 2017, p. 5.

105 Mrs Elaine Holmes, Scottish Mesh Survivors Group, *Committee Hansard*, 19 September 2017, p. 36.

106 UGSA, *Submission 32*, p. 5.

implants,<sup>107</sup> and that women deserve the right to choose procedures most suitable to their particular circumstances.<sup>108</sup>

2.76 The committee also received submissions from women who were concerned at what they described as 'the Media furore' over the use of vaginal mesh for the treatment of SUI and POP. Many of these women were anxious that the committee should 'not take this knee jerk reaction too seriously.'<sup>109</sup>

2.77 The committee heard that in many cases women have suffered terribly for years before having surgery. A number of women described their experience of living with both bladder and bowel incontinence:

I was completely bladder incontinent, bowel incontinent; I couldn't have sexual intercourse. I continuously had bladder infections. I developed chronic thrush because of it. I was sick for years. My life revolved around having extra clothes, pads, being close to a toilet and hoping to God that when I had a shower my bowels wouldn't release themselves on me. That was my life.<sup>110</sup>

2.78 Another woman recounted similar experienced:

To be clear, my day revolved around timing my bladder and bowels, I had to make sure that I was close to a bathroom at all times, I had to carry spare clothes and underwear in case I soiled myself, I had to wear pads, If I wanted to have sexual intercourse I had to empty my bladder before, during and afterwards and at times my bowels as well. Sometimes I didn't make it to the bathroom on time. I cannot convey enough to you how humiliating this was for me.

This surgery has changed my life, I have not a single urinary infection since, I don't look for the bathrooms wherever I go, I can hold on if I need to, I don't have [to] carry a spare set of cloths with me, I can enjoy an intimate relationship with my husband.<sup>111</sup>

2.79 Another woman, who underwent major repair surgery for POP using mesh, described for the committee the distress caused by severe prolapse:

Whilst waiting to see [the surgeon]. I was extremely uncomfortable & distressed by the severity of my symptoms. Vaginal Prolapse is a very disturbing issue, one that I found very debilitating; it's a hard thing to put up

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107 See, for example: Name withheld, *Submission 176*; Name withheld, *Submission 229*, Name withheld, *Submission 231*, Name withheld, *Submission 235*, Name withheld, *Submission 236*, Name withheld, *Submission 237*, Name withheld, *Submission 296*; Name withheld, *Submission 473*.

108 See, for example: Name withheld, *Submission 300*.

109 See, for example: *Submission 32, Attachment 14*.

110 Timnat, *Committee Hansard*, 18 September 2017, p. 25.

111 Name withheld, *Submission 127*, p. [3].

with and the fact that there is so much discomfort, in my case made me feel unwell.<sup>112</sup>

2.80 This woman went on to say:

Whilst the initial recovery immediately after the surgery, was harrowing to say the least. I went home after 3 days in hospital, & spent a full 6-8 weeks following my specialists advice to take it extremely easy, no lifting, driving, housework, work etc. As this was my second time with this condition I followed her advice to the letter.

It is nearly 3 years since this operation, and for me it appears to be an ongoing success, I am not saying that I don't have issues that could be associated with the operation, but thus far I have no ongoing major complications associated with the actual Mesh.<sup>113</sup>

2.81 Another woman simply stated that '[g]oing from a severe prolapse to normality was a greater relief than I can explain to anyone who has not experienced this difficult problem.'<sup>114</sup>

2.82 This evidence was underscored by photographic evidence provided to the committee that highlighted the realities of living with severe prolapse.<sup>115</sup>

2.83 A number of submitters and witnesses expressed concern that a restriction on the use of transvaginal mesh would deny many women access to treatment appropriate to their particular circumstances.<sup>116</sup>

2.84 Ms Sunny Hutson, expressed concern that the discussion about urogynaecological mesh is 'focusing on only the material itself and not the crucial differences between the procedures that use it, the principles they're based on and their dramatically different outcomes.'<sup>117</sup> Ms Hutson explained to the committee that she had lived with the effects of severe pelvic organ prolapse for 30 years as a result of being disembowelled by a swimming-pool filter at the age of two. In her submission, Ms Hutson described her feelings of desperation prior to her surgery and the dramatic and life changing impact that a procedure using urogynaecological mesh has had in her case.<sup>118</sup>

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112 Name withheld, *Submission 473*, p. 1.

113 *Submission 473*, p. 1.

114 UGSA, *Submission 32, Attachment 15*.

115 See, for example: Dr Jenny King, Urogynaecological Society of Australasia, *Photographs: prolapse*, (tabled 18 September 2017).

116 See, for example: Dr Caroline Dowling, Urologist, USANZ, *Committee Hansard*, 3 August 2017, p. 22; Dr Gary Swift, President, National Association of Specialist Obstetricians and Gynaecologists, 3 August 2017, p. 22.

117 *Committee Hansard*, 18 September 2017, p. 57.

118 Ms Sunny Hutson, *Submission 151*.

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### ***The complexity of treating pelvic floor disorders***

2.85 Medical practitioners stressed that pelvic floor disorders can be very complex to treat and that surgeons who manage advanced and/or recurrent prolapse must be able to offer patients a complete range of non-surgical surgical and surgical options.<sup>119</sup>

2.86 UGSA submitted that '[n]o one procedure is appropriate for all patients and for some women a transvaginal mesh procedure may be the most effective and durable treatment.<sup>120</sup> UGSA went on to explain that clinicians must try to balance the benefits of a treatment against the possibility of uncommon events:

Even without mesh, pelvic floor reconstructive procedures can be complicated by pain, vaginal scarring, bladder symptoms and difficulties with intercourse. For example, a recent large randomised trial demonstrated no significant difference in serious adverse events including dyspareunia between those with native tissue and those with mesh repair (15). And the rate of all intra and post-operative complications is increased if repeat surgery is required due to failure. So for some women, for example those with significant comorbidities or at high risk of recurrence, the smaller risk of a mesh complication may outweigh the risks of redo surgery which is them more likely to need mesh implants.<sup>121</sup>

### ***Mid-urethral slings***

2.87 As noted earlier, while submitters generally acknowledged a higher level of risk associated with transvaginal mesh procedures for the treatment of POP, a number of specialist medical practitioners emphasised the positive outcomes associated with the use of MUS in the treatment of SUI. Dr Alison De Souza, a Urogynaecologist with the Mercy Hospital for Women told the committee

The mid-urethral sling has been life-changing for many thousands of Australian women by correcting their urinary leakage. We feel that the silent majority of women who are happy with the outcome of their mesh procedure also need to be heard and taken into account.<sup>122</sup>

2.88 UGSA submitted that there is extensive data, including data from multiple, high quality randomised controlled trials and long term follow up over 17 years, to support the 'excellent safety and efficacy' of MUS. UGSA stated that procedures using MUS have been performed up to 20 times more frequently than previous abdominal procedures with immense quality of life benefits for women of all ages.<sup>123</sup>

2.89 USANZ, submitted that the results of an Australian study on the frequency of side effects from MUS had demonstrated that health related quality of life improvement at three months after retropubic MUS predicts persistence of

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119 See, for example: RWH, *Submission 34*, p. 6.

120 UGSA, *Submission 32*, p. 1.

121 *Submission 32*, p. 3.

122 Dr De Souza, *Committee Hansard*, 3 August 2017, p. 31.

123 *Submission 32*, p. 2.

improvement at four years. USANZ stated '[a]lthough patient numbers are modest, these data contribute to the scarce longer term HRQL [Health-Related Quality of Life] data on the MUS, which is a safe and durable procedure with a minimal complication profile.'<sup>124</sup> USANZ provided the following breakdown of the incidence of complications associated with MUS requiring surgery:

a 3.2% rate for slings that obstruct (too tight), 2% for mesh erosion or exposure, 0.3% for fistulas (connection between one organ system and another) and 0.1% for bowel injury. Further analysis of complications that were defined as life altering, demonstrated chronic pain in 4.3% of which 0.5% was refractory [resistant] to treatment, 11% of patients had new urgency symptoms (over active bladder) and 3.9% of these were refractory to treatment and 5.3% of patients had persistent or recurrent stress urinary incontinence.<sup>125</sup>

2.90 The committee notes evidence that suggests further research is required to validate claims regarding the high rate of successful outcomes for transvaginal procedures using MUS for SUI.<sup>126</sup> Information provided by the APMG indicates that of 101 incidences of complications reported by its members, involving 176 mesh devices, 70 involved mesh for the treatment of SUI using either TVT or TVT-O compared to 43 involving mesh for the treatment of POP. 27 instances were reported by women who had transvaginal mesh surgery to address both SUI and POP.<sup>127</sup>

### ***The evolution of mesh products***

2.91 As noted earlier, a number of practitioners drew a distinction between the use of devices constructed of large sheets of urogynaecological mesh and devices using tape. Dr Darren Gold told the committee that sheets of mesh positioned to hold up organs have never been shown to improve POP symptoms.<sup>128</sup> The International Society for Pelviperineology (ISP) submitted that the rate of complication associated with mesh sheets as compared to tape is much greater and that mesh sheets tend to shrink creating tension in the tissues which in turn contributes to nerve pain.<sup>129</sup> The ISP stated that complications, including pain, are less with MUS and that most involve 'surfacing of a small segment of mesh which can be dealt with by snipping, usually as an outpatient.'<sup>130</sup>

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124 USANZ, *Submission 42*, p. 3.

125 *Submission 42*, p. 3.

126 See, for example: Mr Danny Vadasz, Chief Executive Officer, Health Issues Centre, *Committee Hansard*, 3 August 2017, p. 19.

127 APMG, Number of complications involving stress urinary incontinence vs pelvic organ prolapse mesh procedures within the group's membership, received, additional information received 5 February 2018.

128 *Submission 145*, p. 4.

129 International Society for Pelviperineology (ISP), *Submission 48*, pp. 1- 2.

130 *Submission 48*, p. 2.

2.92 The committee heard that overtime mesh devices have evolved. Dr Gary Swift, President of the National Association of Specialist Obstetricians and Gynaecologists, told the committee:

In the very early days of mesh usage we knew that there were design flaws in the very early meshes. They became obvious when the rates of erosions were much higher...There has certainly been an evolution. In the early meshes, no-one will deny that mesh erosions were much higher in the earlier generations. We have certainly seen those. Those products, I understand, were voluntarily recalled once there was clear evidence that there was potentially a design flaw in the product itself.<sup>131</sup>

2.93 Dr Caroline Dowling, from the Urological Society of Australia and New Zealand, told the committee

There is absolutely no contention that the meshes that predated polypropylene were high risk, and they were withdrawn from the market. There has not been a polypropylene mesh product withdrawn from the market that I am aware of apart from a mini-sling called TVT-Secur.<sup>132</sup>

2.94 At the same time, the evidence base for transvaginal mesh has been evolving. Professor John Skerritt, representing the Therapeutic Goods Association, noted that the evidence base for transvaginal mesh has evolved:

We are all older and wiser and as medical experience with surgery and with particular products evolves you know more at a particular point of time than you would have two, five, 10, 12 or 15 years ago. And this is particularly true with mesh devices. The evidence base for meshes has evolved.<sup>133</sup>

2.95 However, the committee notes that, while many of the personal accounts received from individual women during the inquiry relate to transvaginal mesh surgery performed more than five years ago, a number of the accounts relate to surgery performed in the last two years. Information provided by the APMSG indicates that of the 101 women who have reported complications to the APMSG, 16 of these women have had transvaginal mesh surgery in the last two years and 52 have had transvaginal mesh surgery in the last five years.<sup>134</sup>

### ***Committee view***

2.96 The committee does not discount the successful outcomes experienced by many women. Nor does the committee underestimate the complexity of treating SUI and POP. However, the committee is concerned that the plight of those women who

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131 Dr Swift, *Committee Hansard*, 3 August 2017, p. 27.

132 *Committee Hansard*, 3 August 2017, p. 28.

133 Professor John Skerritt, Deputy Secretary, Health Products Regulation Group, Department of Health, *Committee Hansard*, 8 August 2017, p. 46.

134 APMSG, Number of complications involving stress urinary incontinence vs pelvic organ prolapse mesh procedures within the group's membership, received, additional information received 5 February 2018.

have experienced devastating impacts on their health and quality of life not be downplayed, simply because they are in the minority. Rather the committee intends that greater focus be placed on understanding why some women experience positive life changing outcomes and other experience catastrophe.

2.97 In the next two chapters, the committee will consider the extent of usage of transvaginal mesh implants in Australia and the provision of information, clinical care and support to women who present with symptoms of SUI and POP.