***“I have no life and neither do the ones watching me suffer”*: Women’s Lived Experiences of Transvaginal Mesh Implant Surgery**

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Declaration

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Literature Review

Abstract

Pelvic floor disorders, notably stress urinary incontinence and pelvic organ prolapse, impact on women’s quality of life. A common surgical treatment method known as transvaginal mesh implant surgery has been used in recent times to rectify these impacts. Although successful for many women, this procedure has led to controversy due to growing accounts of adverse complications, leading to a recent Parliament of Australia Senate Inquiry. This paper will discuss these issues, provide context for the complications through the biopsychosocial model, and provide recommendations for future research.

Overview

As the prevalence of pelvic floor disorders increases among women, surgical procedures and materials have been modified to provide more efficient and safe treatment methods. This paper describes pelvic floor disorders often experienced by women as they age and treatment methods for these disorders. Transvaginal mesh implant surgery, a controversial surgical treatment method for pelvic floor disorders in recent years is discussed. This discussion highlights areas of successful application along with multi-faceted complications arising from this treatment. Additionally, this paper discusses a recent Parliament of Australia Senate Inquiry regarding the mesh controversy and explores current support in Australia and abroad for women suffering complications of transvaginal mesh surgery. This paper then reviews a theoretical framework, the biopsychosocial model, and its relevance to women’s experiences of transvaginal mesh surgery. Finally, since transvaginal mesh surgery remains a novel and controversial area of exploration, both academically and in practice, suggestions for possible future research are provided.

Pelvic Floor Disorders

Pelvic floor disorders are a global health problem, estimated to affect up to 50% of older-aged women (Memon & Handa, 2013). The pelvic floor consists of ligaments, muscles, connective tissues, and nerves that provide support to internal organs including the uterus, vagina, bladder, bowel, and rectum (Raizada & Mittal, 2008). The most common pelvic floor disorders include stress urinary incontinence, pelvic organ prolapse, and faecal incontinence (Chen et al., 2019). Stress urinary incontinence is characterised by weakened tissues and muscles surrounding the bladder neck, urethra, and rectum, resulting in pressure on the bladder and consequential involuntary loss of urine upon exertion (from exercise, sneezing, coughing or laughing), and pelvic organ prolapse as a result of the bladder and the bowel herniating inside and outside of vaginal walls (Better Health Channel, 2018; Geller et al., 2017). Faecal incontinence is the least common disorder, characterised by a lack of bowel control resulting in an involuntary loss of faecal liquid or stools (Better Health Channel, 2017).

As women’s life expectancy increases, pelvic floor disorders are likely to become increasingly more prevalent (Chen et al., 2019; Zeleke et al., 2016). The most common risk factors for developing a pelvic floor disorder are increasing age and vaginal childbirth that results in weakening of organs and connective tissue in the pelvic floor (Niu et al., 2016). Other risk factors include previous pelvic floor surgery, hysterectomy, chronic cough, chronic constipation, and lifestyle factors such as heavy lifting, obesity and diabetes (Kawaguchi et al., 2018; Stothers & Friedman, 2011; Vergeldt et al., 2015). Diagnosing a pelvic floor disorder is based on prior history (e.g., risk factors like vaginal childbirth), physical and clinical examination (e.g., observing or feeling a bulge indicating prolapse), and a discussion of symptoms with a healthcare professional (National Institute of Child Health and Human Development, 2016).

Pelvic floor disorders impact on many aspects of women’s lives, including physically, psychologically, socially, sexually, and occupationally (Karmakar & Hayward, 2019; Souza et al., 2011). Physical symptoms are most frequently discussed in the literature, with the most common symptom being pain - in the back, pelvis, abdomen, and rectum (often while emptying bowels) - commonly interfering with sexual intercourse (Hyland et al., 2014). Additionally, it is well-known that physical symptoms are connected to women’s psychological well-being, with a recent case-control study finding a correlation between physical pain and depression (Mazi et al., 2019). Furthermore, a study that qualitatively assessed emotional experiences in 44 women with pelvic floor disorders found women described feelings of loneliness, isolation, anxiety, depression, embarrassment and shame (Ghetti et al., 2015). Other research supports these findings with women also reporting a loss of confidence (Shen et al., 2011) and body image issues (Lowder et al., 2011; Zielinski et al., 2009), contributing to a change in or avoidance of sexual relations (Zielinski et al., 2009). These factors impact women's social functioning, and in turn, their overall health-related quality of life, with the most common impacts on social functioning reported to be social isolation, requiring sick leave and loss of employment (Shen et al., 2011).

Despite the physical, psychological and social burden of pelvic floor disorders, research has indicated that many women do not seek care for their symptoms (Abhyankar et al., 2019; Chen et al., 2019; Kawaguchi et al., 2018). This may be partly attributable to a large portion of women perceiving negative or painful pelvic floor symptoms as a normal part of childbirth and ageing, thus minimising their likelihood of seeking intervention (Chen et al., 2019). A qualitative study by Abhyankar et al. (2019) investigated women's experiences of seeking care for pelvic organ prolapse and found that embarrassment, stigma, and a lack of awareness regarding their symptoms were among the most common barriers for seeking care. Findings also indicated that general practitioners were dismissive of women's symptoms until they became severe enough for intervention, and women's autonomy was not respected in regards to knowledge of their condition and treatment decisions. These findings align with research identifying the significant impact that healthcare professionals can have, as poor understanding of diagnoses and treatments can elicit fear and confusion about the appropriate treatment pathway (Kiyosaki et al., 2012; Souza et al., 2011). Thus, these studies highlighted the importance of healthcare professional communication during the assessment and diagnosis of pelvic floor disorders. As such, researchers have stated that patient-centred care can increase positive collaboration between a healthcare professional and patient and that increased knowledge of the procedure can enhance compliance with recommended treatments (Abhyankar et al., 2019; Chen et al., 2019; Kiyosaki et al., 2012).

Treatments for Pelvic Floor Disorders

Surgery for pelvic floor disorders is a last-resort due to the risks associated with surgical procedures, such as an increased risk of injury, pain, and infection (Powers et al., 2019). As such, first-line treatment options, often recommended in combination, can include pelvic floor physiotherapy - strengthening pelvic floor muscles with a specialist physiotherapist (Labrie et al., 2013), continence therapy - involving inserting devices into the vagina to control leakage from the bladder, bladder and bowel training - involving passing urine or faeces at particular intervals to break the cycle of frequent toilet use, medication, and lifestyle changes such as weight management and avoidance of heavy lifting (Hyland et al., 2014; Kawaguchi et al., 2018). In addition, pessaries (a silicone or latex object placed and fitted in the vagina) are recommended as an effective non-surgical treatment to hold organs in place and relieve pressure on pelvic structures, and in conjunction with pelvic exercises has proven useful (Cheung et al., 2016). However, complications such as discomfort, vaginal discharge, difficulties with insertion and removal, and continued urinary incontinence led to speculation that surgical procedures may be more effective for treating pelvic floor disorders (Powers et al., 2019).

Surgical methods are required when non-surgical treatment methods, such as physiotherapy, are ineffective (Labrie et al., 2013). Surgery for pelvic floor disorders, such as the use of sutures to hold pelvic tissue in place or using women’s native tissue to support the weakened tissues in the pelvic floor, was considered expensive and invasive (Powers et al., 2019). Among this, common occurrences were short-lived anatomical corrections, and complications and high reoperation rates. These results led to the development of other surgical procedures and materials to treat pelvic floor disorders (Powers et al., 2019).

Transvaginal Mesh Implant Surgery

Due to the desire to provide a minimally invasive, safe, and time-efficient surgical procedure for pelvic floor disorders, in recent years, prosthetic materials, such as transvaginal mesh, have been used (Li et al., 2020; Luo et al., 2018; Mangir et al., 2019). Transvaginal mesh, a woven synthetic netting made from polypropylene, is inserted through a surgical incision in the vagina through to the pelvis to provide permanent structural support to weakened organs and to repair damaged tissue in the pelvic floor (Better Health Channel, 2018; Mangir et al., 2019). Such mesh is primarily used for stress urinary incontinence and pelvic organ prolapse (Geller et al., 2017). Since the introduction of transvaginal mesh in the 1970s, and its use in transvaginal procedures for stress urinary incontinence in 1998 (Craig et al., 2019; Rubin, 2019), and for pelvic organ prolapse from 2004 (King, 2020), there has been no single registry collating data about the number of women who have received the surgery and their outcomes post-surgery. Thus, it is estimated that 151,000 women in Australia have received a transvaginal mesh implant (Craig et al., 2019; Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2017).

The use and method of delivery of polypropylene mesh transvaginally is thought to reduce the risk of recurrent pelvic organ prolapse, lower intraoperative and post-operative complications (and thus reoperation rates), and increase durability (Powers et al., 2019; Ward & Hilton, 2004). For example, a study examining 159 women that underwent transvaginal mesh surgery for pelvic organ prolapse found that 156 (98%) did not suffer any intraoperative complications, and demonstrated a significant improvement in vaginal symptoms, such as pain (Balchandra et al., 2015). To support this, Luo et al. (2018) examined 175 patients and concluded a cure rate of 99.1%, with nil post-operative discomfort and only a small percentage of women reporting mesh exposure into surrounding organs (1.1%). Other research aligns with these findings by concluding women experience significant improvements in urinary symptoms (Buca et al., 2018), and quality of life post-surgery for pelvic organ prolapse (Chang et al., 2015). In addition, a retrospective study found at three and a half years follow-up, all 32 patients who received transvaginal mesh surgery for pelvic organ prolapse had subjective symptomatic relief, with none reporting persistence of original symptoms, or requiring re-corrective surgery (Chaturvedi et al., 2012). However, there were several methodological flaws in the research, such as an invalid questionnaire and a small sample size - which is a common finding among the literature (Powers et al., 2019). Among this, there is an increasing rate of complications reported, resulting in controversy surrounding its safety and efficacy for pelvic organ prolapse (Dyer, 2019; Powers et al., 2019). Despite this, studies have found many benefits of the use of transvaginal mesh for the treatment of stress urinary incontinence - with high patient satisfaction reported (Mangir et al., 2019; Powers et al., 2019).

Mesh used for stress urinary incontinence, commonly termed a mid-urethral sling, is the most frequently studied surgical treatment and is considered the gold standard intervention (King, 2020; Perkins et al., 2015; Shah & Badlani, 2012). This is because there is a reduced risk of complications such as infections and erosion due to a smaller portion of mesh lying near vaginal skin, and a greater evidence-base regarding the optimal targets and locations for surgical correction (Mangir et al., 2019; Powers et al., 2019; Shah & Badlani, 2012). Documented benefits of this procedure have included short operating time, briefer hospitalisation, quicker recovery rates, reduced voiding dysfunction post-surgery, and lower reoperation rates (King, 2020; Ward & Hilton, 2004). Additionally, studies have assessed the long-term effectiveness of mid-urethral sling surgery, with one study reporting statistically significant improvements persisting for four years across domains of health-related quality of life, such as social, physical, interpersonal and emotional (Chung et al., 2010). Similarly, Liapis et al. (2008) demonstrated the efficacy of mesh over seven years among 60 women, with 80% of women cured of stress urinary incontinence. However, 13% of women reported worsening symptoms, such as mixed incontinence (3.2%) and urge stress urinary incontinence (9.8%). Despite these rates of complications seven years post-surgery, the study concluded that the procedure is safe and minimally invasive as the initial problem (stress urinary incontinence) was treated. Similarly, Saidan et al. (2019) reported successful outcomes following re-correction of mesh perforation into the bladder or urethra for nearly half of their study population (n = 45). However, reviews have argued that women under-report complications, as it is common for pain to occur years following mesh implant or re-correction (Keltie et al., 2017; Mangir et al., 2019). Further, reviews have stated that there remains a lack of high-quality evidence, among mixed evidence, associated with mid-urethral sling safety and associated complications (Ashok & Petri, 2012; Blaivas et al., 2015; Rubin, 2019).

Transvaginal Mesh Complications

Despite the success of transvaginal mesh for many women, the procedure has been a subject of controversy due to accounts of adverse complications (Mangir et al., 2019). These complications are often long-term, although rates vary among the literature, with limited exploration of their severity and duration (de Vries et al., 2018). Reported complications are multi-faceted, although physical pain is the most common reason for women seeking additional treatment (Bergersen et al., 2019; Powers et al., 2019). The first physical concern was reported to the Therapeutic Goods Administration (TGA) in 2006, and with concerns on the rise, the TGA closely monitored complications and clinical evidence from 2008 (TGA, 2019). Since that time, mesh procedures have gradually become a public health issue and gained widespread media attention (Mangir et al., 2019; TGA, 2019). Complications are reported immediately following and/or years post-surgery, with the most common including mesh exposure and erosion into the bladder and bowel - commonly resulting in reoperations, bladder infections, urinary tract infections, blood in the urine, abnormal vaginal bleeding or discharge, urge incontinence (rushing to the toilet), and acute and chronic pain - such as dyspareunia (pain during sexual intercourse) (Australian Commission on Safety and Quality in Health Care, 2018; Chughtai et al., 2020; Keltie et al., 2017; Mangir et al., 2019; Manonai et al., 2016; SA Health, 2020).

Supporting the existence of physical complications as mentioned above, a retrospective study conducted pelvic organ ultrasounds on 79 women who experienced mesh complications between 2010 and 2012 (Manonai et al., 2016). The most common complications described were pain during intercourse (82.2%) and vaginal and pelvic pain (51.9%). Following ultrasounds, 54 patients required surgical correction of the mesh, with the most common reason being mesh exposure (81.1%). Ten patients (19%) reported the same or exacerbated pain post-surgery. These findings align with recent systematic reviews detailing the most common complications are mesh exposure, dyspareunia, and vaginal pain (Bergersen et al., 2019; Carter et al., 2019). A prospective cohort study also assessed transvaginal mesh outcomes using a questionnaire among 159 women. Of the 51 women that completed the questionnaire at three-month follow-up, 21 (41%) complained of vaginal pain, describing it as a 'dragging' sensation, and 25 (49%) reported vaginal soreness (Balchandra et al., 2015). These definitions of vaginal pain are common and often result in sexual health difficulties, with one study finding frequent pain during sexual intercourse following surgery for pelvic organ prolapse (Shen et al., 2011). Of the 116 women in the study, 22 (18.9%) did not regain usual sexual activity post-surgery.

As pain can significantly affect women's sexual health, along with their physical functioning, women that seek care for complications are recommended various treatment options. Although there is a lack of quality evidence of how complications should be effectively managed (Carter et al., 2019), common recommendations are physiotherapy, pain management (specialists), and medications (for pain, incontinence, mood, and sleep) (Australian Commission on Safety and Quality in Health Care, 2018). However, women that continue to have chronic disabling pain following interventions using non-surgical methods can require reoperation - being partial or full mesh removal (Chughtai et al., 2020; Marcus-Braun & Theobald, 2010).

The permanency of mesh (due to its non-absorbable form and resulting scar tissue formation) places women that require removal at an increased risk of further physical complications - such as damage to internal organs, nerves and blood vessels, contributing to pain and ongoing urinary incontinence (Australian Commission on Safety and Quality in Health Care, 2018). Some argue that complications occur regardless of receiving mesh surgery for stress urinary incontinence or pelvic organ prolapse (Chien, 2019). However, others argue there are more dire complications for women treated for pelvic organ prolapse, due to the larger portions of mesh used, its positioning and the increased risk of infection if exposed (Australian Commission on Safety and Quality in Health Care, 2018; Lee & Zimmern, 2019). For women that have undergone mesh removal, longitudinal studies have reported that two-years following reoperation, infections and pain were a common finding upon clinical examination (Marcus-Braun & Theobald, 2010). In light of these findings, there is an absence of high-quality controlled studies demonstrating the clear benefits of total mesh removal for pain reduction (Wolff et al., 2016). Although reoperation may correct mesh exposure and erosion, underlying pain often remains, with research suggesting this is due to the development of chronic pain (Geller et al., 2017). This may be attributable to mesh removal occurring years following the original mesh implant, thus pain not being managed adequately and developing into a chronic condition (Australian Commission on Safety and Quality in Health Care, 2018).

Physical complications of transvaginal mesh surgery are well-documented throughout the literature (Carter et al., 2019), although there are limited reports of associated psychological and social complications. This is surprising given the extensive literature examining the association between physical pain, psychological functioning, and quality of life (Vadivelu et al., 2017). From the minimal literature available, Welk et al. (2019) found that women who received a mid-urethral sling were at a significantly increased risk of depression and self-harm when requiring surgical correction. To support this, 31 women (most having received mid-urethral slings) wrote to an Australian forum about their experiences, with most women enduring varying degrees of emotional and psychological distress, influenced by the loss of sexual function and chronic pain (Australian Commission on Safety and Quality in Health Care, 2019). Further, a recent online survey assessed women's levels of catastrophising following mesh complications, finding that women who engaged in higher catastrophising post-surgery experienced greater psychological distress as well as pain - such as pain in the vagina, and poorer pain-related quality of life (Moradzadeh et al., 2019). This aligns with several qualitative studies investigating women's emotional experiences that found distress, anxiety, hopelessness and unhappiness were evident in women years post-surgery, due to belief about a loss of control over their health and poorer health than before surgery (Dunn et al., 2014; Huntington et al., 2019). These experiences influence social functioning such as disruption to or broken relationships (Brown, 2020; Huntington et al., 2019), and employment levels with many women reporting unemployment (Australian Commission on Safety and Quality in Health Care, 2018; Huntington et al., 2019). However, detailed experiences and perspectives such as those of a qualitative nature remain limited in the literature (Australian Commission on Safety and Quality in Health Care, 2018; Huntington et al., 2019).

Women’s physical and psychological health outcomes appear to be highly influenced by their relationship with their treating healthcare professional (Kiyosaki et al., 2012). Appropriate and tailored support and communication by healthcare professionals during the assessment, diagnosis, and treatment of pelvic floor disorders and post-mesh surgery is vital (Abhyankar et al., 2019). For example, a systematic review highlighted the importance of preoperative education as a means of reducing post-operative pain and associated anxiety (Powell et al., 2016). However, research has identified that many women do not feel adequately informed before mesh surgery, nor do they feel they were educated on the potential major risks associated or the limited robust information on the efficacy and safety of transvaginal mesh products (Huntington et al., 2019; Perkins et al., 2015). These findings highlight the importance of clear and sufficient explanations by healthcare professionals to fully inform and prepare women for this form of surgery (Dessie et al., 2015). In addition, women that suffer complications from mesh surgery, have reported difficulties in accessing appropriate care, mostly concerned with a lack of belief by the healthcare professional that physical symptoms are due to the mesh, which may be explained by many women reporting symptoms years post-surgery (Australian Commission on Safety and Quality Health Care, 2018; Huntington et al., 2019). The complications experienced are argued to be partly attributable to surgeons not having appropriate knowledge, training and experience to deliver the mesh procedure (American Urogynecologic Society’s Guidelines Development Committee, 2012; Barski et al., 2014). Receiving inappropriate care and doubting the healthcare professional’s ability to deliver safe and effective treatment can adversely impact women’s psychological and physical well-being, in turn affecting their quality of life (Abhyankar et al., 2019).

Discontinuation of Transvaginal Mesh for Pelvic Organ Prolapse

Due to research identifying adverse complications from transvaginal mesh procedures, and unfavourable accounts reported to the TGA since 2008, in 2016, mesh products were regarded as high risk by the Food and Drug Administration; requiring a stringent review process (Nguyen & Burchette, 2008; TGA, 2019). This decision was guided by little evidence of its safety and efficacy for pelvic organ prolapse, mainly due to the first randomised controlled trial (RCT) being published six years following its first use, with inadequate follow-up of participants common across studies (Dyer, 2019; Lee & Zimmern, 2019; Nguyen & Burchette, 2008; Shah & Badlani, 2012). Data regarding the original efficacy and credibility of mesh were reliant on the success of hernia repair and mid-urethral mesh slings used for stress urinary incontinence (Mangir et al., 2019; Mowat & Maher, 2017; Ward & Hilton, 2004). However, upon growing research, findings indicate that treatment of pelvic organ prolapse carries the risk of greater complications (such as mesh exposure) and reoperations than slings and original surgical procedures such as native tissue repair (Ashok & Petri, 2012; Geller et al., 2017; Li et al., 2020; Powers et al., 2019). As such, due to much speculation of its efficacy and safety, in 2017, transvaginal mesh used to treat pelvic organ prolapse in Australia was discontinued from the Australian Register of Therapeutic Goods (SA Health, 2020; TGA, 2019). Despite the discontinuation, there remained complaints of adverse effects which led to more thorough investigations of the widespread impacts of transvaginal mesh.

Australian Parliament Senate Inquiry

The serious and adverse long-term complications reported through clinical trials and to the TGA from mesh-related procedures led to a recent Parliament of Australia Senate Inquiry titled 'Number of women in Australia who have received transvaginal mesh and related matters' (Australia Parliament Senate Community Affairs References Committee, 2018). The purpose of the Inquiry was to investigate how many women have received the mesh and attempts at mesh removal in Australia or elsewhere, the information provided before surgery about possible complications and side effects, complications experienced, the impacts these complications have had on women's lives, and the role of the TGA in approving and monitoring mesh devices for use in Australia. These questions were addressed in 555 written submissions (received from the 15th of February to the 30th of June 2017) by women who have received the surgery, their loved ones, and governmental bodies and health professionals (Australia Parliament Senate Community Affairs References Committee, 2018). Based on the majority of submissions detailing adverse personal experiences, the Senate Committee developed thirteen recommendations for the Australian Government to re-evaluate and implement appropriate measures for the safe and effective marketing and delivery of transvaginal mesh, intending to reduce the occurrence of adverse complications (Australia Parliament Senate Community Affairs References Committee, 2018).

Due to thousands of women suffering from transvaginal mesh procedures, Shine Lawyers (2020) led a class action against the manufacturers of mesh and tape implants - Johnson and Johnson Medical Pty Ltd in July 2017. This was the largest women's health class action in Australian history, with Shine Lawyers (2020) alleging the following: Johnson and Johnson were negligent in their conduct, misleading patients and doctors regarding the safety and efficacy of mesh - thus women were not adequately provided with information of all possible risks and the implants should not have been distributed, and the complications were too severe. The class action settled favourably in November 2019; women can now seek financial compensation for their adverse life-altering complications of transvaginal mesh (Dyer, 2019; Shine Lawyers, 2020).

Pelvic Mesh Clinic

The Senate Inquiry and class action led to the development of a variety of support services across Australia for women suffering adverse complications from transvaginal mesh. As there is no urogynaecological unit in South Australia able to provide full mesh removal, a multidisciplinary Pelvic Mesh Clinic has opened at the Royal Adelaide Hospital in Adelaide (SA Health, 2020). The clinic assists women who have experienced adverse physical complications, and assists in the management of associated psychological and social complications (Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2019; SA Health, 2020). Among this, the clinic educates doctors and surgeons regarding mesh procedures to deliver safe care and be better able to inform patients of all realistic benefits and risks before mesh correction or removal (SA Health, 2020). In addition to the clinic, consumer resources, which include a ‘Pelvic Mesh Consumer Support Line’, support groups such as the ‘Australian Pelvic Mesh Support Group’, websites including personal stories, information and patient resources, and a ‘Mesh Awareness Day’ in May, are available (Australian Commission on Safety and Quality in Health Care, 2018; SA Health, 2020).

Class action lawsuits are rapidly occurring worldwide against companies distributing transvaginal mesh devices (Perkins et al., 2015). Therefore, a growing number of support services have become available to women outside of Australia (Lee & Zimmern, 2019). Support groups in the form of websites and Facebook groups are prevalent across New Zealand, parts of Europe, Canada and the United States of America, offering women information on campaigns, mesh insertion and removal, personal stories, and social and peer support (Mesh Injured Australia, 2019). However, it is evident throughout the literature that there remains a lack of clinics outside of Australia dedicated to offering face to face psychological and emotional support for women having undergone transvaginal mesh surgery.

Theoretical Framework - Biopsychosocial Model

Understanding the theoretical context is important when talking about health issues. One such theoretical framework that offers valuable insights in health contexts is Engels' (1977) biopsychosocial model. This is a holistic model characterised by complex bi-directional influences between biological (e.g., genetics, age, physical health, biochemistry, immunology), psychological (e.g., mental health, thoughts, beliefs, expectations, habits), and social (e.g., family relationships, cultural context, socioeconomic status, environmental stressors, finances) factors on health and illness (Lehman et al., 2017). No researchers to date have explored this model in the context of transvaginal mesh; however, this model is commonly applied to chronic pain - a highly prevalent and complex condition with associated psychological and social factors (Darnall et al., 2016; Meints & Edwards, 2018; Souza et al., 2011). This aligns with women's adverse experiences of transvaginal mesh, as women have reported chronic physical pain and associated psychological, emotional and social distress (such as isolation and loss of employment) that greatly interfere with their quality of life (Huntington et al., 2019). To address these factors, women often require long-term multidisciplinary care (Lee & Zimmern, 2019). The application of the biopsychosocial model to women's experiences of transvaginal mesh implant surgery is illustrated in Figure 1.

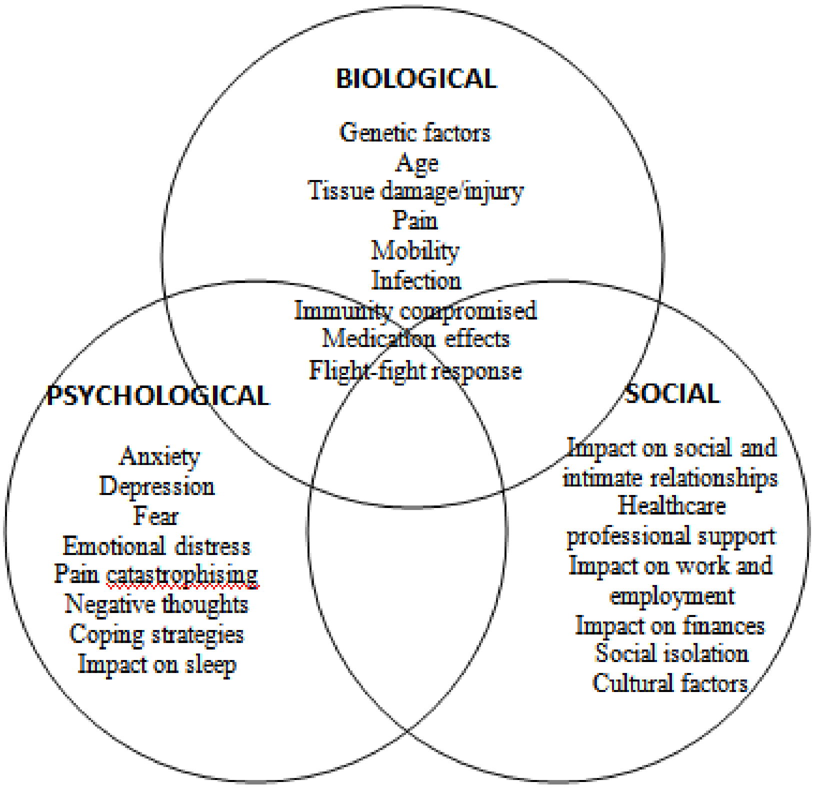

Figure 1. *Biopsychosocial Model - Women's Experiences of Transvaginal Mesh Implant Surgery.*

Future Research

Research has extensively explored physical complications of transvaginal mesh and also acknowledges that there are associated psychological and social implications that affect women's quality of life (Brown, 2020; Dunn et al., 2014; Huntington et al., 2019). However, there remains limited exploration and detailed accounts of these psychological and social impacts on women's lives, particularly through qualitative methods. Thus, further qualitative research is essential to understand women's emotional experiences following transvaginal mesh surgery and their outcomes following reoperation. This research could include examinations of psychological well being, social impacts, including the impact on intimate relationships, social interactions, and employment as well as protective factors and factors associated with poorer psychological and social outcomes. Qualitative research could be combined with quantitative methodologies (such as surveys and RCT’s) to triangulate the data as a mixed-methods analysis and provide healthcare professionals with an adequate understanding of women’s experiences to guide their practice. Due to the chronic nature of women’s experiences post-surgery, and associated psychological distress (Huntington et al., 2019; Moradzadeh et al., 2019), developing guidelines would be particularly useful for psychologists. Such guidelines may assist psychologists’ with their understanding and aid their chosen psychological interventions - tailored to women who are experiencing multi-faceted complications from mesh surgery.

There is limited research investigating women’s experiences with their healthcare professional before mesh surgery, and when they have developed complications post-surgery (Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2016). This interaction is an important area for future research to investigate women’s attitudes and experiences surrounding their care, as patient-practitioner interactions are likely to impact patient physical and psychological functioning. Thus, future research could develop guidelines for healthcare professionals, particularly doctors, urogynaecologists and surgeons, to influence appropriate clinical decisions such as information to share with women related to the procedure, its evidence-base, and associated risks.

As there is no available mesh registry, and thus no record of the number of women who have received mesh or the scope of complications experienced, developing and maintaining a nationwide registry is vital. A registry would aid in providing a detailed analysis of the safety and efficacy of mesh implants, available treatments if unsuccessful, and provide an accurate evaluation of patient-reported short and long-term outcomes, such as the number of adverse complications and mesh removals. In addition, a registry would provide information about the implanting surgeon, which would assist in understanding their level of expertise in regards to mesh procedures and their success rates (Chungtai et al., 2020).

Developing a registry could occur in conjunction with high-quality longitudinal cohort studies, given many women present with complications years following their initial surgery (Chapple et al., 2013). Overall, future research is crucial to understand the impacts of transvaginal mesh surgery on women’s lives and identify how health professionals can best assist women who have suffered mesh-related complications.

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"I have no life and neither do the ones watching me suffer": Women's Lived Experiences of Transvaginal Mesh Implant Surgery

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ABSTRACT

Objectives: Pelvic floor disorders, such as stress urinary incontinence and pelvic organ prolapse, affect up to 50% of older-aged women. Due to the high prevalence and impacts on quality of life, surgical treatment methods, such as transvaginal mesh implant surgery, have been used in recent years to treat these disorders. Despite the rise of adverse complications, there remains little research exploring women's lived experiences of this procedure. Much of what is known comes from quantitative methodologies and focusses on physical complications. Therefore, this study aimed to explore women's lived experiences of transvaginal mesh implant surgery through the biopsychosocial lens of physical, psychological and social health.

Design: A qualitative deductive thematic analysis design was employed.

Methods: One-hundred and fifty-three women's submissions detailing their experiences of transvaginal mesh implant surgery to an Australian Parliament Senate Inquiry were thematically analysed as per Braun and Clarkes' six-step approach. Submissions contained both adverse and positive accounts.

Results: Ten themes were identified under three categories: Physical Health, comprising three themes, Psychological Health, comprising two themes, and Social Wellbeing, comprising five themes.

Conclusions: Transvaginal mesh implant surgery resulted in devastating impacts on most women's physical, psychological and social wellbeing. Early access to psychological care is crucial to reduce long-term psychosocial harm for women with adverse mesh-related outcomes. Further research could explore women's long-term lived experiences and impacts on quality of life, such as relationships with healthcare professionals.

Keywords:

Transvaginal Mesh, Qualitative, Biopsychosocial, Physical Health, Psychosocial Health

Data availability statement:

The data that supports the findings of this study are available from the Parliament of Australia Website at https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Submissions

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Pelvic floor disorders are a significant public health issue estimated to affect up to 50% of older-aged women, with the two most common disorders being stress urinary incontinence and pelvic organ prolapse (Chen et al., 2019; Memon & Handa, 2013). Women experience pelvic floor disorders for a range of reasons, such as older age, vaginal childbirth, chronic cough, obesity, or heavy lifting (Memon & Handa, 2013; Niu et al., 2016). Due to the myriad of challenges with such disorders that can significantly affect quality of life, women have attempted to rectify these challenges through treatments such as physiotherapy, and when often unsuccessful, through surgical methods (Kawaguchi et al., 2018; Labrie et al., 2013; Powers et al., 2019). In recent times, a surgical procedure involving the use of transvaginal mesh implants has been offered to women to support the weakened or damaged tissues in their pelvis. This procedure is considered a minimally invasive and safe alternative to traditional surgical methods, such as native tissue repair (Mangir et al., 2019).

Despite positive reports regarding the use of transvaginal mesh for many women, including improvements in their original symptoms and health-related quality of life (Balchandra et al., 2015; Buca et al., 2018; Chang et al., 2015; Chaturvedi et al., 2012; Chung et al., 2010; Luo et al., 2018; Powers et al., 2019; Ward & Hilton, 2004), this treatment has increasingly appeared to lead to a multitude of problems (Therapeutic Goods Administration, 2019). These problems are typically physical complications, such as pain, erosion, and infection, which are often co-morbid and thus severely impact women's physical functioning (Bergersen et al., 2019; Huntington et al., 2019; Karmakar & Hayward, 2019; Mangir et al., 2019; SA Health, 2020; Therapeutic Goods Administration, 2019). Additionally, these complications, particularly erosion, often require surgical treatment, further deteriorating women's physical health (Keltie et al., 2017). Researchers, typically through quantitative methodologies, have extensively addressed the above physical complications among women who have received transvaginal mesh (Carter et al., 2019; Hyland et al., 2014). However, there has been little investigation into the associated psychological and social experiences, which are widely known to affect quality of life and the pain experience (Australian Commission on Safety and Quality in Health Care, 2018; Brown, 2020; Dunn et al., 2014; Moradzadeh et al., 2019; Vadivelu et al., 2017). For example, the biopsychosocial model of pain posits that psychological distress, such as depression and anxiety, increases the risk of developing and maintaining chronic pain (Engel, 1977; Meints & Edwards, 2018).

The importance of exploring experiences using a biopsychosocial approach is supported by qualitative research findings that have addressed how mesh-related complications impact women's lives (Brown, 2020; Dunn et al., 2014; Huntington et al., 2019; Wailling et al., 2019). Researchers have noted that common long-term complications such as pain exacerbate psychological distress and interfere with social wellbeing (Dunn et al., 2014). For example, Huntington et al. (2019) found that women experienced anxiety and hopelessness as a result of the mesh diminishing their health-related quality of life. This resulted in the women grieving their past lives before the insertion of the mesh, exacerbating their depression and social isolation, concurring with other findings (Brown, 2020; Dunn et al., 2014). Other researchers have stated that mesh-related complications often interfere with women's social and intimate relationships (Brown, 2020; Huntington et al., 2019; Karmaker & Hayward, 2019; Wailling et al., 2019). Dunn et al. (2014) found that women experienced shame over their pain and deteriorating bodily functions, contributing to social isolation and leading to significant issues with sexual intimacy. This resulted in guilt and a loss of dignity and identity as a partner, aligning with other findings (Brown, 2020; Huntington et al., 2019; Wailling et al., 2019).

Moreover, multiple surgical treatments are common for women who experience mesh-related complications (Keltie et al., 2017; Wailling et al., 2019), with multiple complex surgeries resulting in trauma and suicidality (Brown, 2020; Wailling et al., 2019). For example, several studies have found women were fearful of possible damage that the mesh is doing to their bodies, in addition to the uncertainty associated with future surgical treatments to manage these complications. This fear and uncertainty contributed to anxiety, despair, and suicidal thoughts, greatly impacting women's quality of life (Brown, 2020; Dunn et al., 2014).

In light of these findings, further exploration of women's psychological and social experiences is essential to understand the full extent of their challenges beyond their physical functioning and to identify how care can best be delivered to these women (Wailling et al., 2019). Although a small body of literature has investigated these often co-morbid experiences, there remains a paucity of research that gives voice to women's experiences of transvaginal mesh (Brown, 2020; Ducey et al., 2020; Dunn et al., 2014; Huntington et al., 2019).

A useful insight into women's lived experiences of transvaginal mesh is provided by a recent Australian Parliament Senate Inquiry (Australia Parliament Senate Community Affairs References Committee, 2018). This Inquiry highlighted the need for work such as the present study, as it is evident in the academic literature that women have had very few opportunities to share their experiences of transvaginal mesh (Australian Commission on Safety and Quality in Health Care, 2018; Keltie et al., 2017; Mangir et al., 2019). This lack of expression could have dire consequences for women's health-related quality of life, particularly when demonstrating surgical and/or post-surgical complications, as mentioned above. Therefore, this study aims to add to the limited knowledge in this area by exploring how mesh impacts women's lives through the biopsychosocial lens of physical, psychological, and social health.

Method

Participants

The sample comprised 399 women who had received transvaginal mesh implant surgery and had provided written submissions to an Australian Parliament Senate Inquiry entitled "Number of women in Australia who have had transvaginal mesh implants and related matters" (Australia Parliament Senate Community Affairs References Committee, 2018), between the 15th of February 2017 and the 30th of June 2017. Specific demographic details cannot be provided as women did not report them in their submissions.

Procedure

Data were obtained by reviewing 555 publically available written submissions made to the above Australian Senate Inquiry. The 555 submissions comprised accounts from women who had received transvaginal mesh (n = 399), women's loved ones (n = 6), women who had not received transvaginal mesh (n = 6), and government and healthcare professional bodies (n = 61). There were also 83 confidential, inaccessible submissions. As previous literature has indicated that women experience adverse and positive experiences of mesh (Powers et al., 2019), both views were eligible for inclusion in the study; 359 submissions reported adverse experiences, while 40 reported positive experiences. Submissions were reviewed until saturation, meaning no new themes relevant to the research question were evident (Fusch & Ness, 2015). Adverse experiences, defined as women reporting negative symptoms (such as complications from mesh), reached saturation at 138 submissions. Whereas, positive experiences were defined as women documenting successful outcomes of mesh, notably without complications extending beyond recovery time, reached saturation at 15. Only submissions written by women who had received transvaginal mesh implant surgery were included in the analysis as the focus of the current research is women's physical, psychological and social experiences of this medical procedure.

All submissions were downloaded as submitted and used verbatim. Due to the information contributors chose to share, it was not possible to obtain specific demographic data. Males and females and people who had and had not undergone mesh surgery made submissions to the Inquiry from which data were collected. As the current study sought to explore the experiences of women who had undergone mesh surgery, information about contributors’ gender was gathered through direct self-identification, use of gendered language (i.e., explicit references to being female), and references in submissions to gendered roles (i.e., wife, mother, daughter). Information about mesh status was gathered by explicit references to having undergone mesh surgery. Submissions made by individuals who could not be identified as female and who did not undergo mesh surgery were excluded.

In following recommendations for best practice in qualitative research (Tracy, 2010), to enhance the credibility and sincerity of research findings, the researcher maintained a reflexive stance by documenting personal influence and bias during data analysis in an audit trail. The researcher is a young woman who has not had a pelvic floor disorder or transvaginal mesh surgery. Given this, the researcher was able to undertake analysis with a greater level of objectivity. Additionally, bias was mitigated through discussion with the research supervisor at each stage of data collection and analysis.

Ethical Considerations

Data used in this research were freely available in the public domain via the Parliament of Australia website. All submissions except those deemed confidential were accessible without need for a password; confidential submissions could not be accessed. Therefore, in accordance with the Ethics Guidelines for Internet-Mediated Research (British Psychological Society, 2017), it was not necessary to seek informed consent from contributors. In place of pseudonyms, to protect the privacy of individuals who made submissions, each woman was referred to as a contributor with an assigned contributor number. Further, possible identifying features were removed from the submissions before analysis. The University of Adelaide School of Psychology Research Ethics Sub-Committee approved this study (19/81).

Data Analysis

Data were analysed using the thematic analysis method of Braun and Clarke (2006, 2013). A deductive approach to analysis was undertaken, seeking to understand women's lived experiences of transvaginal mesh surgery through the lens of the biopsychosocial model - identifying women's physical, psychological and social experiences.

The researcher analysed the data in six steps, as recommended by Braun and Clarke (2006, 2013). First, data familiarisation involved multiple readings of submissions to become acquainted with the data and record initial ideas of interest. Next, initial codes were generated in the form of succinct labels by systematically working through the entire data set. The third step involved organising and collating codes to form themes and sub-themes. The research supervisor validated the themes to aid the credibility of the research. Subsequently, themes were reviewed and refined against codes and extracts across the entire data set. A thematic map, guided by the biopsychosocial model, was created to illustrate relationships between themes (See Figure 1). The themes were then defined and named, with the most relevant themes and illustrative extracts relevant to the research question selected. Data analysis ceased when saturation was reached (n = 153).

Results

Aligned with the biopsychosocial model of health, the results are presented in three categories, themes related to women's Physical Health, comprising three themes, Psychological Health, comprising two themes, and Social Wellbeing, comprising five themes (See Figure 1).

Physical Health

Three themes, 'Mesh-related pain is pain like no other', 'The constant battle with infections' and 'Bladder and bowels: Dysfunctional for some, no longer a worry for others', were identified. Within these themes, most experiences were adverse, although for one theme a minority of women reported positive experiences.

Mesh-related pain is pain like no other

Most women expressed the shocking and constant physical pain they have endured - days, months, and years following transvaginal mesh surgery, with common descriptions being *"severe"*, *"unbearable"*, *"excruciating"*, *"debilitating"*, and *"crippling"*. Many women had a lengthy recovery period post-implant, referring to their pain as a *"burning"*, *"stabbing"* and *"pulling"* sensation, spreading through their body. More specifically, pain in the abdomen and pelvic regions, such as the vagina and buttocks, back, and legs, were described as restricting movement and making it challenging to sit down. Further, recovery took much longer than expected:

> *"It would take be a good 14 weeks, NOT 10 days post implant, before I could get out of bed and walk again. I can only describe my pain as being cut open and set alight - a deep burning, searing ache that intensifies with any movement, that is nerve pain for you." (Contributor 75)*

Additionally, many women spoke of new extreme stabbing pain that they had not previously experienced when urinating or evacuating their bowels:

> *"Prior to the implant, I had never had that excruciating urethral pain where you are in so much pain you cry every time you urinate!!!" (Contributor 94)*

Due to the constant and unrelenting pain, sleep deprivation was a common occurrence for many women. One woman spoke of pain so severe that she spent the evening vomiting:

> *"The bladder spasms were so severe and painful that I would vomit from the pain - it was common to spend all night on the toilet with a pillow against the wall."(Contributor 111)*

In order to find some relief from the pain, women frequently sought remedies, such as wheat packs, hot showers and regular bed rest, as well as consuming a variety of medications. As such, some women had to go to extreme measures to get some sleep:

> *"I would tie a strap tightly around my foot to relieve the pain there. That's how I would sleep and I'd wake up with a crushed foot."* (Contributor 60)

When referencing their pain women described the adverse impact of the mesh on their physical functioning, genital anatomy, and sexual functioning, as illustrated in the three sub-themes below.

Pain affecting physical function

Many women described how mesh-related complications, including pain, erosion, infection and incontinence, restricted their ability to resume normal and simple activities, such as housework and physical activity. For example, movement of any kind, notably bending and lifting, created a painful razor-like sensation for many women, identified by Contributor 53 as *"fish hooks in my buttocks".* Consequently, restrictive and painful movement reduced women's physical health and psychological wellbeing, preventing them from doing previously enjoyed activities and creating resentment about having the mesh implanted:

> *"To say this filthy mesh has changed my life is an understatement. Before it was implanted, I was walking 5 kms a day. This is now not possible. I have chronic leg pain that renders me crippled after sitting or laying down. Swollen feet, abdomen and hands, and a horrendous lethargy, makes most mundane jobs difficult." (Contributor 71)*

Lack of physical activity and restricted mobility contributed to weight gain and associated health co-morbidities for many women. Additionally, having to adapt to a more restrictive way of living created grief over the loss of the active lifestyles they had before transvaginal mesh surgery:

> *"I'm left with a life of pain daily, my ability to function as before taken from me and having to live with such pain and suffering is incomprehensible. I am no longer the active happy woman I was before." (Contributor 125)*

My whole pubic area is mutilated

Mesh erosion and exposure through the vaginal wall and into surrounding organs such as the bladder or bowel was a common occurrence for women. Some women associated the process of erosion with *"cheese through a grater"* (Contributor 112), resulting in significant scarring and pain - defined by Contributor 61 as like *"sitting on barbed wire".* For most women, erosion occurred multiple times, over many years, requiring numerous painful and confronting surgical procedures to extract the mesh:

> *"After some time I had sharp pains from pieces of mesh poking through my flesh, inside my vagina, having Dr's trying to find the pieces was painful, also having the dr use a lunar caustic silver nitrate, which was fused into sticks which was formerly used in cauterizing. This was very painful, torture." (Contributor 97)*

Many surgical attempts aimed to remove the mesh entirely, referred to as full removal. However, most often mesh could only be partially removed, due to the difficulty and danger of removing mesh entangled in organs, increasing the risk of further complications that could be fatal. With each attempt at full removal, many women experienced worsening complications, primarily related to nerve damage and pain, scarring, infection and incontinence, resulting in general ill-health and a reduction in quality of life:

> *"Extremely dangerous first surgery, - massive blood loss, nightmare dissection of the mesh "mess" entangled in major organs. 2nd operation to try and "fix" the first one. It ruined my life as I knew it. It did not repair the bladder prolapse and caused damage to more body parts and my mental health." (Contributor 13)*

For some women who had full removal, a multitude of long-term complications ensued, some being nerve damage and chronic pain, poor mobility, recurrent prolapses, chronic fatigue, and incontinence:

> *"I am still having extreme hip and back pain and nerve entrapment issues, as well as becoming more and more incontinent as the months progress." (Contributor 47)*

Unsurprisingly, the pain associated with mesh erosion complications contributed to adverse impacts on sexual functioning as described below.

Sex = pain, so no sex for me

Most women described difficulties with sexual intercourse due to experiencing distressing sharp, burning pain and spasms in the vagina, abdomen and at times bladder, during and often days following sex. Pain occurred despite the use of aids, such as lubricants, and the changing of sexual positions:

> *"Sex became impossible. Severe pains progressively increased in and around the vagina, movement of any kind produced sharp pain in the general area." (Contributor 129)*

Among pain, women noted issues with discharge and *"offensive"* odour due to infections and protruding mesh (Contributor 47). These complications, resulting in repeated experiences of pain and displeasure, led to a loss of libido and contributed to the avoidance of sexual intimacy with their current or potential future partners:

> *"I have never had intercourse without pain since my first surgery in 2007....10 years and counting. I expect to never have intercourse again." (Contributor 54)*

The constant battle with infections

Frequent urinary tract infections, notably of the bladder, occurred for most women post-mesh surgery. Infections resulted in difficulties in urinating and emptying the bladder, at times requiring hospitalisation for the use of a catheter and intravenous antibiotics. For many women, extensive and long-term use of antibiotics was required to combat the reoccurring infections:

> *"Many infections every 4-6 weeks. Am on permanent antibiotics for the last 18 months and when I get an infection stop taking those to take stronger medications for 10 days and start over again." (Contributor 109)*

Infections caused severe abdominal pain, and discharge with odour, requiring daily use of sanitary pads. Some women that experienced infection with erosion for the first time highlighted embarrassing and distressing public incidents:

> *"Whilst in a public place I experienced extreme pain & felt nauseous then noticed a putrid brown discharge running down my legs." (Contributor 69)*

Women expressed how ongoing infections and pain adversely affected their immune systems, with many in a constant, vicious cycle of pain and ill-health. Lethargy, fatigue, headaches, and constant unwellness were noted as a daily battle:

> *"Perhaps the most exhausting of all is the constant temperature as the body uses autoimmune responses and fights to rid itself of this putrid mesh." (Contributor 71)*

Bladder and bowels: Dysfunctional for some, no longer a worry for others

Within this theme, two subthemes, described below, were identified.

My bladder and bowels are controlling my life

Bladder and bowel dysfunction, namely urinary and faecal incontinence, significantly worsened for many women post-mesh surgery. For example, many women expressed difficulty with voiding, requiring carefully timed bathroom visits and daily monitoring of their bladder and bowel function. Women also expressed how intervention is often required to void, with some describing how they must use a catheter or press on their bladder to urinate, and others going to more extreme measures to evacuate their bowels, as expressed by Contributor 21: *"Having to manually manipulate the rectum externally to have a bowel motion."*

Incontinence meant frequent toilet use for most women, impacting sleep and requiring them to remain close to toilets at all times, resulting in very carefully planned outings. As such, many women stated they bring a spare pair of underwear and pants, and wear a pad anytime they leave the house. However, even when making use of incontinence aids, women are left with concerns, particularly about their hygiene:

> *"I have urinary incontinence wear incontinence aids I always feel I smell and use wipes to maintain my hygiene and a little dignity." (Contributor 103)*

Also, despite high levels of preparation, women experienced confronting and embarrassing incidents, exacerbating their anxiety and decreasing their confidence in their bodily functions. The lack of control of such functions further contributed to symptoms of psychological distress:

> *"There have been numerous times I have been out socially and I get a sudden urge to urinate. If a toilet is not available straight away I let my bladder just empty where I'm standing then have to go home." (Contributor 107)*

Several women highlighted other forms of preparation for social settings to counteract frequent toilet use, such as restricting their fluid intake, which results in dehydration:

> *"I have had problems with dehydration because I deliberately don't drink a lot of water when I'm out due to urge incontinence." (Contributor 64)*

Bladder and bowels no longer a constant worry

In contrast, for a small number of women, the insertion of mesh provided them with a greater quality of life due to complete improvement in incontinence, control in voiding and reduced infections. For example, improvements in their sexual relations and intimacy with their partner, and in their confidence to enjoy activities without worrying about the implications of frequent toilet use:

> *"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 carry a spare set of clothes with me, I can enjoy an intimate relationship with my husband. " (Contributor 141)*

The successful outcome of surgery, such as the return of normal bladder and bowel function, and the absence of pain and adverse complications, led women to recommend transvaginal mesh to their friends:

> *"I couldn't be happier with the result. So much so that a good friend of mine was experiencing bladder problems and I recommended her to the same doctor and she is also very pleased. She has had no pain and experienced no problems as well!" (Contributor 147)*

Psychological Health

Two themes, concerning psychological health, 'Living in darkness', and 'Ticking time bomb' were identified. Many women articulated the intense emotional anguish they experienced following transvaginal mesh surgery due to the devastating impact of symptoms and complications:

> *"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." (Contributor 53)*

As several women stated, the multi-faceted physical, psychological and social consequences of mesh led to a *"complete nervous breakdown."* (Contributor 92)

Living in darkness

For many women, adverse experiences with mesh led to loneliness and depression. Women felt an overwhelming sense of hopelessness due to the unbearable pain experienced, along with the prospect of having to live with pain for the rest of their lives and endure further surgical procedures to fix complications. The pain, coupled with pain and anti-depressant medications, restricted their ability to function and consequently resulted in social isolation and suicidal thoughts:

> *"My life has changed to the degree where I have had suicidal thoughts because I do not believe that I can continue to live my life this way. Constant pain, depression and days when I feel too exhausted to even get out of my pyjamas and face the world. It is no way to live a life." (Contributor 94)*

The experience of hopelessness and suicidal thoughts was in part attributed to not receiving answers or guidance from health professionals regarding future treatment options. Women also reported the significant impact of being dismissed without hope of further treatment:

> *"I went to another gynaecologist. I was so sick that I could not even sit down in the waiting room. He just turned me away, saying 'there isn't anything I can do for you'. That day, as I walked out of his rooms, if my husband wasn't*

> *with me, I would have jumped under the first car that came along. That is how helpless I felt, like I didn’t want to live through it anymore.” (Contributor 44)*

The pain, depression, and lack of support for treatment options contributed to desperation, loneliness and isolation, resulting in a downward spiral of adverse health behaviours and coping mechanisms for some women:

> *“I developed Apathy Syndrome and didn’t care if I lived or died. My husband said it was like I was flatlining. I increased my alcohol consumption and put on 15 kilos due to depression and then was diagnosed with fatty liver disease.” (Contributor 60)*

Ticking time bomb

Many women expressed worry and fear about the mesh causing further painful complications, notably pain, and mesh erosion into other organs, necessitating further surgery. The idea of further surgery, particularly, mesh removal, was a fear for most women due to their traumatic surgical experiences, with some diagnosed with post-traumatic stress disorder as a result. As such, some women expressed their high levels of anxiety when thinking about their previous surgeries and the pain they experienced, indicating they felt incapable of undertaking further surgery:

> *“I honestly don’t think that I could ever go through any further surgery, but I am scared of what the future holds, as the mesh has broken through, worse than ever now and is continuing to breakdown and god only knows what it is doing. I am nervous, scared and fed up with all that I have gone through and continue to go through.”(Contributor 40)*

The physical and emotional impacts of mesh, such as pain, sleep deprivation, constant stress, and the fear and uncertainty of never being able to remove the mesh entirely, contributed to women’s frequent difficulties in coping with and managing their emotions and anxiety:

> *"It has left me feeling lost, extremely anxious and I feel like an emotional wreck. I lash out at people, my hands shake, and I constantly cry, meaning every day." (Contributor 75)*

Social Wellbeing

Five themes, concerning social wellbeing, 'The strain of losing sexual intimacy', 'Failure as a friend, partner, mother, grandmother', 'Mesh = no fun for me', 'My employment has suffered' and 'The financial burden of mesh complications', were identified. The themes encapsulate the adverse experiences of women who received transvaginal mesh surgery.

The strain of losing sexual intimacy

Many women described how their traumatic and painful experiences of attempting sexual intercourse impacted not only them but also their partner. For example, many women commented on their partners suffering injuries due to protruding mesh, as reported by Contributor 2: *"The first time my husband and I tried to have sex, my husband was stabbed in the penis, grazing it, and frightening the heck out of him."* These experiences led to anxiety, guilt, grief and depression, and adversely altered women's sexual and emotional relationship with their partner. It took a toll on both members of the couple:

> *"We found ourselves apologising to each other every time we had intercourse, he offering to stop and saying sorry; with me apologising and saying I did not want to stop whilst biting my fingers as hard as I could to take the focus of the pain away from my vagina." (Contributor 53)*

The lack of sexual intercourse, and for many, sexual relations or intimacy of any kind, contributed to a complete relationship breakdown for some women:

> *"My relationship with my partner at that time ended, due to the anguish, stress and the inability for sexual relations." (Contributor 55)*

Additionally, women described that due to the extent of their complications, and the *"fear of being touched inside my vaginal area"* (Contributor 56), they did not envision themselves in a sexual or intimate relationship in the future.

Some women expressed that despite a lack of sexual intimacy, their partner was supportive and understanding, although they still emphasised the importance of sex for sexual and emotional fulfilment in an intimate relationship:

> *"I am very fortunate to have a very loving and understanding husband but emotionally this is not at all satisfying for either of us." (Contributor 88)*

Failure as a friend, partner, mother, grandmother

Many women expressed how their relationships with friends and family had been strained, due to the inability to attend social events and their emotional difficulties adversely impacting on how they interact, making them feel like a burden:

> *"These health problems with my bladder and bowel cause me frustration and create mood swings and which makes me snap at family and friends and I just want to crawl in bed and cry." (Contributor 12)*

Additionally, most women described overwhelming guilt and sadness over not being the partner, mother or grandmother they envisioned to be. These feelings were largely due to the inability to partake in family and social activities, do household chores, and provide emotional and financial support to their family. As such, women felt time with their children and grandchildren had been *"stolen"* due to complications experienced (Contributor 13). In saying this, women stated they felt like a burden having to rely on their partner to care for them and be the main caregiver for their family - affecting their independence and sense of self:

> *"The time without my children is irreplaceable.*
> *The emotional pain I've caused my family is unforgivable.*

> *The tolerance my husband has had to have has unnecessarily robbed him. The despair it has caused him and me is overwhelming." (Contributor 77)*

As Contributor 45 states: *"I have no life and neither do the ones watching me suffer."*

Mesh = no fun for me

The insertion of mesh prevented most women from resuming previously enjoyed hobbies and activities, such as exercise, gardening, and holidays, due to fatigue, ill-health, and the inability to sit or stand for long periods:

> *"Activities I once enjoyed like road trips, reading, knitting and many more are no longer possible with my inability to sit for long periods." (Contributor 59)*

Due to the myriad of complications, for example, pain and incontinence, many women indicated they did not feel comfortable leaving their house, resulting in isolation, loneliness, and reduced quality of life:

> *"...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." (Contributor 46)*

As such, women reported not wanting to plan social activities or tasks due to uncertainty of symptoms such as pain *"flare-ups"* (Contributor 16). For several women, psychological distress associated with prior experiences of mesh-related complications prevented them from committing to social events:

> *"I am constantly anxious if I have not opened my bowels for two days or more as this often indicates a bowel obstruction or twisting of the bowel. Therefore, I can't plan, and don't plan more than a week in advance." (Contributor 113)*

My employment has suffered

Taking time off work for surgical procedures and recovery times, often well beyond the recommended six-week recovery period, significantly impacted women's employment:

> *"Due to ongoing pain, it was 10 months after the operation before I returned to work." (Contributor 124)*

Upon return to work, women expressed challenges of resuming work duties, due to ongoing pain and the nature of their job requiring bending, lifting, standing or sitting for long periods. Therefore, many women had to make modifications to their work environment and reduce their hours:

> *"Work breaks were spent lying on my office floor. My employer purchased a stand-up desk, as sitting was almost impossible. Work had become increasingly difficult and I had to cut my hours down." (Contributor 23)*

Due to the nature of symptoms, such as constant pain, infections and incontinence issues, many women were unable to meet work demands, resulting in unemployment:

> *"I have had to work and wear a catheter carrying around a bag of urine, this is very undignified and embarrassing. This has caused unemployment, loss of jobs..." (Contributor 87)*

The reduction and or loss of employment led to grief, isolation, and lowered self-esteem, with an additional burden of grief described below.

The financial burden of mesh complications

Related to the above theme, most women described the financial burden of having to take time off work and exhausting all of their sick and annual leave to recover from surgeries and complications. Medical needs necessitated many periods of leave without pay, resulting in difficulties in managing household income and providing for their families:

> *"Financially ruining us in the long run.. nearly lost the house because I couldn't make house repayments etc." (Contributor 134)*

Women who could no longer work due to complications and symptoms expressed how life-changing it was, with some no longer able to afford the cost of treatments due to only just being able to afford the cost of living:

> *"We are drawing down on what is left in our meagre superannuation accounts to survive." (Contributor 62)*

Despite the use of health insurance, many women had out of pocket expenses, notably for surgeries, pain medication and antibiotics, sanitary pads, appointments with health professionals and associated travel expenses, and paying for household assistance such as a gardener and cleaner:

> *"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." (Contributor 16)*

Discussion

Employing a thematic analysis of 153 submissions to an Australian Senate Inquiry, this study explored women's lived experiences of transvaginal mesh implant surgery. The findings show that most women reported adverse experiences; a minority of women described positive experiences. Ten themes, in the three categories of physical health, psychological health, and social wellbeing, were identified relating to these experiences and will be discussed below.

It is evident from the findings that most women who made submissions to the Inquiry experienced life-changing and long-term physical, psychological and social distress. The multi-faceted complications reported by women in the current study are consistent with the literature (Huntington et al., 2019; Keltie et al., 2017). For example, extreme and debilitating pain upon any kind of movement was a common occurrence for women, with the pain experienced being more significant than their original pelvic floor dysfunction. Experiencing pain, particularly chronic pain, dramatically interferes with quality of life, and contributes to and results from psychological distress such as anxiety and depression, creating a vicious cycle of pain and ill-health (Meints & Edwards, 2018; Vadivelu et al., 2017; Welk et al., 2019). As such, women in the present study felt that pain severely limited their day-to-day activities, including employment, hobbies and social interactions. This created psychological distress for women due to diminished finances, being socially isolated and the inability to be the person they were before the mesh surgery. These results concur with qualitative research findings of the grief and mourning women feel over the loss of their past, active lives before the mesh was inserted (Brown, 2020; Dunn et al., 2014; Huntington et al., 2019).

The overwhelming and constant complications experienced led women to feel a disruption in their sense of self. This disruption was evident from the impacts of incontinence, such as embarrassing incidents, and the loss of employment, contributing to a loss of dignity and self-esteem. Also, women's identity as a partner, mother, and grandmother was severely disrupted, and they felt responsible for the negative impacts of mesh on those close to them, particularly their children and partner. These findings are evident in other research documenting the overwhelming grief, guilt, humiliation and shame experienced by women with mesh complications (Brown, 2020; Dunn et al., 2014; Huntington et al., 2019; Wailling et al., 2019).

Sexuality is considered an integral part of one's quality of life (Karmakar & Hayward, 2019), which is intrinsically expressed by women in the present study. The insertion of mesh shattered many women's sexual relationships with their partner, with their partner sharing the emotional trauma of the pain experienced. Psychological distress is a common finding among the literature for those who experience sexual dysfunction associated with severe pain

(Australian Commission on Safety and Quality in Health Care, 2019; Karmaker & Hayward, 2019; Wailling et al., 2019).

Along with the impacts of pain and sexual functioning changes, consistent with Keltie et al. (2017), psychological functioning was severely affected for many women who endured multiple surgeries. Many women in the current study experienced severe fear, anxiety and suicidality related to complications from attempting to extract the mesh and the thought of having to endure further pain and surgery. This finding is similar to those of past research (Brown, 2020; Dunn et al., 2014). Enduring surgical complications contribute to prolonged recovery and fear of lifelong disability, increasing psychological distress, including anxiety, depression, and trauma (Pinto et al., 2016). As such, research has found that women are at a heightened risk of depression and suicidal thoughts when requiring surgeries to recorrect complications such as erosion (Welk et al., 2019).

Despite most women who made submissions experiencing adverse outcomes of mesh, a minority of women experienced positive or successful outcomes. Improvements in overall quality of life were expressed due to no pain or complications, a return of normal bladder and bowel functioning, and improvements in sexual intimacy. These findings align with studies documenting the significant improvements in these domains following surgery and recovery time, concluding the effectiveness of mesh to recorrect stress urinary incontinence and pelvic organ prolapse (Buca et al., 2018; Chaturvedi et al., 2012; Chung et al., 2010). However, most of the studies report quantitative findings, with small sample sizes, methodological limitations, a focus on short-term outcomes, and a sole focus on the anatomical success of mesh as opposed to patient self-reports, creating complexity in understanding the actual experiences of women having received mesh and the impact on their lives (Ashok & Petri, 2012; Blaivas et al., 2015; Ducey et al., 2020; Milani et al., 2018; Powers et al., 2019; Rubin, 2019).

Methodological Considerations

This study adds to the minimal academic literature regarding women's lived experiences of mesh surgery by exploring women's perspectives of their physical, psychological and social experiences. To date, qualitative researchers have primarily focussed on adverse experiences such as mesh-related complications (Brown, 2020; Dunn et al., 2014; Huntington et al., 2019; Wailling et al., 2019), whereas this study also sheds light on women's positive experiences of mesh.

However, the study also has limitations. The terms of reference of the Senate Inquiry (i.e., investigating the number of women impacted by mesh) may have attracted women who suffered adverse and life-altering mesh-related complications who were motivated to share their experiences (Australia Parliament Senate Community Affairs References Committee, 2018). This avenue of self-selection to participate in the Inquiry could have resulted in selection bias. As such, the focus of the Inquiry may have meant that women with more positive experiences did not make submissions. Therefore, the Inquiry and the findings may not be reflective of the full range of women's experiences. However, this limitation may be mitigated by the present study analysing and reporting submissions that described both positive and negative accounts.

Moreover, the study could not obtain demographic information such as age, place of residence, socio-economic status, level of access to health care, and the dates of mesh surgery and the dates and number of subsequent re-corrective surgeries. Such information, including that regarding the length of time between the initial implant and subsequent surgeries (i.e., partial or full removal) would provide insight into which women are most affected by mesh complications, the time women spent living with adverse symptoms, and how multiple surgeries may influence psychosocial-related outcomes.

Implications of Findings

Research Implications

Although the literature is growing in its investigations of women’s experiences of mesh (Brown, 2020; Dunn et al., 2014; Huntington et al., 2019; Wailling et al., 2019), there remains a consensus that further research of a qualitative nature is essential (Brown, 2020; Huntington et al., 2019; Wailling et al., 2019). The need for qualitative research may partially explain the mismatch between the adverse submissions presented to the Inquiry, and the academic literature documenting many positive outcomes (Balchandra et al., 2015; Chang et al., 2015; Chaturvedi et al., 2012; Powers et al., 2019; Ward & Hilton, 2004). For example, positive outcomes may be attributable to the focus on anatomical success rather than patient experience (Ducey et al., 2020; Milani et al., 2018). Therefore, the current study supports the widespread notion that women’s voices and their accounts of adverse experiences remain underreported in the academic literature (Keltie et al., 2017; Mangir et al., 2019).

This study aimed to give women a voice from a biopsychosocial perspective. It is clear from the findings that physical, psychological and social experiences greatly interconnect to impact quality of life. Additionally, the submissions were extremely comprehensive, with a large amount of data documenting women’s interactions with healthcare professionals and how this has impacted their lives (Australia Parliament Senate Community Affairs References Committee, 2018). This research is important as patient-healthcare professional relationships influence patients’ physical and psychosocial outcomes following a surgical procedure (Kiyosaki et al., 2012). Therefore, it is recommended that research continues to explore women’s submissions further to investigate the relationship dynamics with their healthcare professionals before and after mesh surgery and its overall impact on quality of life. Further research could also seek to interview women about their relationships with healthcare professionals to understand these relationships, access to care and level of support. In addition, interviewing healthcare professionals who directly assist these women would provide an interesting insight into how they administer care and support and allow triangulation of the data to gain a more comprehensive understanding of experiences of mesh surgery.

Moreover, in a systematic review, Carter et al. (2019) concluded that there is minimal evidence and guidance on how to manage mesh-related complications, creating further complexity for how health professionals can aid in the management and treatment of the often co-morbid complications experienced. A lack of guidance may be due to the number and nature of surgeries resulting in further complications (Keltie et al., 2017), and limited literature investigating severity and duration of complications (de Vries et al., 2018). Further research is required to explore women’s long-term experiences of mesh to understand how healthcare professionals can optimally care for women, notably when surgical and or post-surgical complications arise.

Clinical Implications

Looking through the lens of the biopsychosocial model, it is evident from the current findings that physical, psychological and social wellbeing are inter-related. Therefore, based on the complexity of psychosocial experiences, it is important to provide recommendations to psychologists on how to best assist women who have experienced adverse mesh-related outcomes. This suggestion is further supported by a deficiency in recommendations in the Australia Parliament Senate Community Affairs References Committee (2018) report related to psychological care, combined with no recommendations provided within the academic literature, apart from several non-specific suggestions of providing counselling (Huntington et al., 2019; Moradzadeh et al., 2019). Therefore, it is crucial to guide psychologists on how to deliver optimal care to women affected by mesh, with early intervention essential to mitigate the severity of psychosocial impacts (Dunn et al., 2014). Recommendations for psychologists based on the findings of this study are provided in Table 1.

Table 1.

Recommendations for Psychologists to Assist Women who Have Experienced Adverse Mesh-related Outcomes

→ Validate, acknowledge and empathise with the myriad of women’s adverse experiences from transvaginal mesh implant surgery and how this has impacted their life. A holistic, biopsychosocial lens is essential.

→ Assist women with the emotional and physical adjustment of mesh-related complications. Educate women about pain and pain management and the interconnection with psychosocial functioning such as mood and emotions, and how this can adversely impact other facets of their lives (e.g., relationships). A focus on the psychosocial components rather than the pain itself is most beneficial, to enhance self-management and autonomy.

→ Provide counselling related to sexual health and intimacy, and how this impacts on intimate relationships. Educate women on how they may foster intimacy with their partner or husband in other ways.

→ Work collaboratively with health professionals and propose that health professionals, namely surgeons and doctors, facilitate early-access to psychological services, particularly in the case of mesh-related complications.

→ Aid in the development of psychological resources to assist with women’s psychosocial functioning. Optimally, these resources would be co-designed with women with lived experience of mesh-related complications (Wailling et al., 2019).

→ Obtain current evidence-based information and support so women are adequately informed of how they can access safe and supportive care outside of their psychology sessions (e.g., 'Pelvic Mesh Consumer Support Line') (SA Health, 2020).

→ Undertake professional development training surrounding pain and pain management, particularly concerning pelvic floor dysfunction.

Conclusions

The findings from the current study provide further insight into women’s lived experiences of transvaginal mesh implant surgery. The results reveal that most women who submitted to the Inquiry experienced adverse mesh-related outcomes, with severe disruptions to their physical, psychological and social wellbeing. The findings and lack of recommendations among the literature highlighted the need to provide recommendations to psychologists to assist these women, intending to provide early intervention to mitigate the severity of psychosocial impacts. Further research could explore women’s long-term lived experiences, impacts on quality of life, and their relationships with health professionals to understand how this influences their level of care and support before and after mesh surgery.

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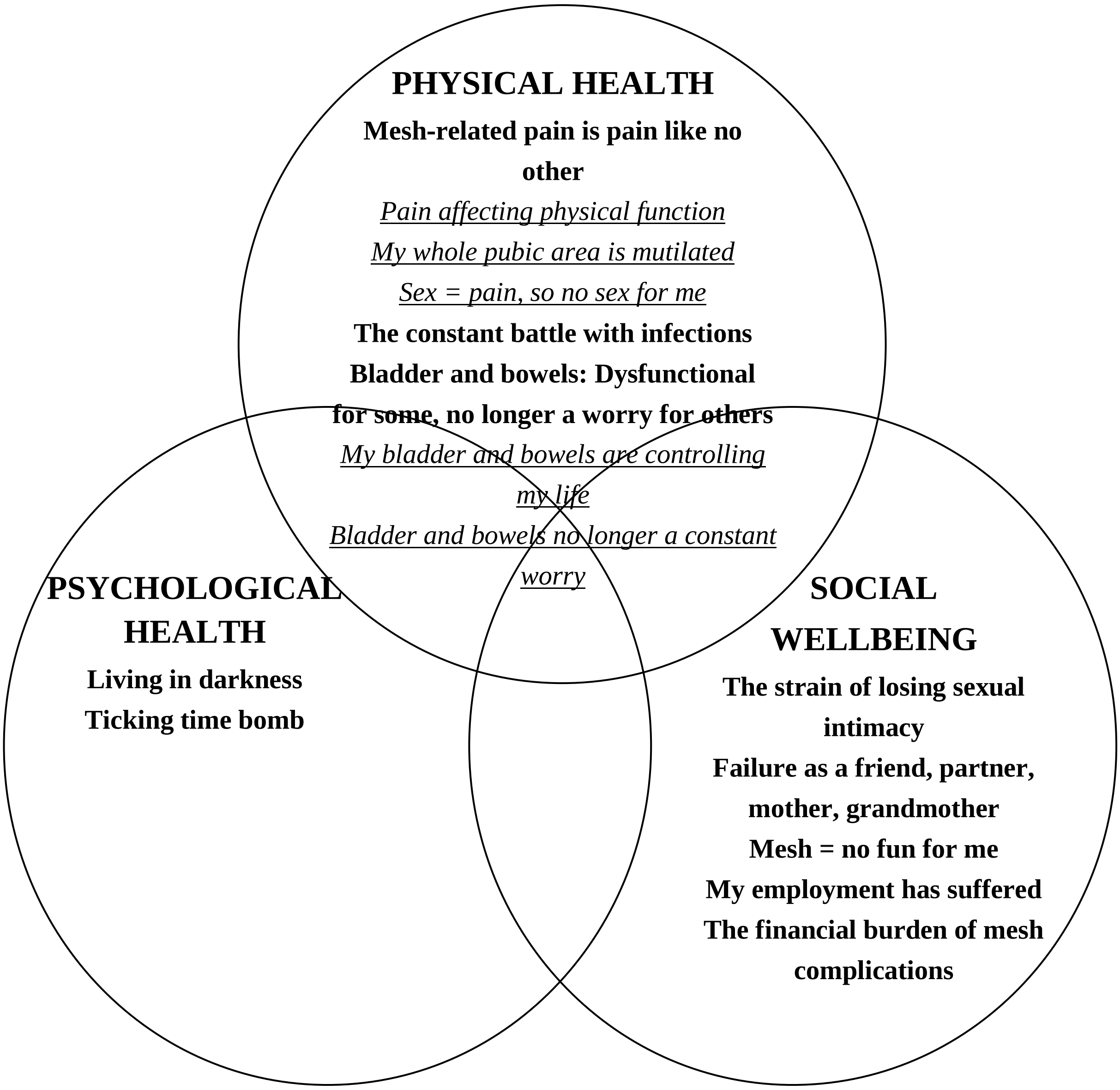

Figure 1. *Biopsychosocial Model - Women's Physical, Psychological and Social Experiences of Transvaginal Mesh Implant Surgery.*

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