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Contents

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The *Australian and New Zealand Continence Journal* seeks articles and original research papers from people practising and researching the management and treatment of incontinence and continence health promotion.

Do you need topic ideas? A variety of topics are possible and include, but are not limited to: outcome studies, aged care, paediatrics, pregnancy and childbirth, novel drug therapies, reviews of devices, either surgical or non-surgical, assessment articles, literature reviews of continence-related topics, home and community care issues and successes, men's health, nursing management, physiotherapy management, support by other allied health disciplines (including occupational therapy and social workers), the psychological impact of living with incontinence, ethical issues, cultural issues and collaborative approaches to care.

Articles may be papers for peer review, clinical updates, case studies or evaluation of programs.

To discuss topics or for assistance in the preparation of papers and articles, please email journal@continence.org.au

EDITORIAL

For referencing Moro C. Editorial. Australian and New Zealand Continence Journal 2023; 29(3):52.

DOI https://doi.org/10.33235/anzcj.29.3.52

We are excited to present this current edition of the *Australian and New Zealand Continence Journal.* In this edition we present three papers that we feel will be of great interest to readers. In the first article, Homewood, Silagy, Ip, Yao, Plagakis, Tse, Chan, Gani and O'Connell[1] provide clinical outcomes from using Onabotulinumtoxin A injections in the treatment of primary bladder neck obstruction. In the second paper, Tuffnell[2] outlines a four-year follow-up from a 2018 study, providing unique insights from collected data, as well as from the broader literature, surrounding the lived experience of women with pelvic surgical mesh complications. In the third article, Franks and Krause[3] provide a review of clinical practice and Australian medical device regulations regarding pessary management for pelvic organ prolapse, a highly topical area.

It was fantastic to meet so many members of our community in Adelaide at the 31st National Conference on Incontinence and 4th Functional Urology Symposium in June. I would like to extend an invitation to any presenters from the conference to consider publishing their data in the *Australian and New Zealand Continence Journal.* We work hard to ensure visibility of published works in the journal and, to facilitate this, all publications are available online as full Diamond Open Access, with no cost to authors or readers. Each article is also allocated an individual Digital Object Identifier (DOI) to assist with referencing and tracking, and is listed across several databases. These features help our journal stand out and present it as an excellent outlet for the submission and publication of quality works. Also, if you are a first-time author, our reviewing and editorial teams offer feedback and support to assist. Performing and publishing research not only helps our community with increased knowledge and insights, but also advances the mission of the Continence Foundation of Australia and Continence New Zealand to promote bladder and bowel health and eliminate the stigma and restrictions of all aspects of incontinence.

We receive positive support from the community, and I very much appreciate the contribution of our reviewers and the editorial committee. Please contact us at journal@continence.org.au if you would like to be included on our team of reviewers.

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1. Homewood DCT, Silagy AW, Ip CCK, et al. Outcomes of bladder neck Onabotulinumtoxin A injection in the treatment of men and women with primary bladder neck obstruction. ANZ Continence J 2023;29(3):53–58.
2. Tuffnell J. The experience of six women living with pelvic surgical mesh complications – interventions and adaptions: a phenomenological inquiry. ANZ Continence J 2023;29(3):59–66.
3. Franks Z & Krause HG. Pessary management for pelvic organ prolapse: a review of clinical practice and Australian medical device regulations. ANZ Continence J 2023;29(3):67–73.

Christian Moro
Editor-In-Chief and Chair
Australian and New Zealand
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Outcomes of bladder neck Onabotulinumtoxin A injection in the treatment of men and women with primary bladder neck obstruction

For referencing Homewood DCT, Silagy AW, Ip CCK, et al. Outcomes of bladder neck Onabotulinumtoxin A injection in the treatment of men and women with primary bladder neck obstruction. Australian and New Zealand Continence Journal 2023; 29(3):53-58.

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ABSTRACT

Objectives This study aims to determine the clinical outcomes of bladder neck injection of Onabotulinumtoxin A as treatment for adult men and women with primary bladder neck obstruction (PBNO).

Methods Patients at participating institutions who underwent bladder neck injection of Onabotulinumtoxin A for PBNO between May 2011 and May 2018 were included in this retrospective case series study. All patients underwent cystoscopy to exclude anatomical causes and had video urodynamics to diagnose PBNO. Clinico-pathological data were collected from medical records. The primary outcome was subjective improvement in symptoms on clinical follow-up. Proportions were compared using Fisher's exact test.

Results This study had 13 patients with a median age of 40. There were five men and eight women. Nine patients had failed alpha-blocker therapy previously, and none had undergone prior surgery for PBNO. Of the 12 patients who attended at least one follow-up appointment, 75% reported improvement in symptoms. The response rate was significantly higher in men compared with women (100% vs 57.1%, p=0.034). There were no significant complications reported on follow-up. We have subsequently developed a novel practical management algorithm from our clinical experience.

Conclusions Bladder neck injection of Onabotulinumtoxin A for the treatment of PBNO has a good response rate with minimal risk of complications and is a reasonable alternative or precursor to bladder neck incision surgery for patients wishing to avoid complications associated with surgery. Further prospective comparative studies on its use are warranted.

Keywords Onabotulinumtoxin A , bladder outlet obstruction, lower urinary tract symptoms, primary bladder neck obstruction

INTRODUCTION

Primary bladder neck obstruction (PBNO) is a functional cause of bladder outlet obstruction (BOO), where there is inadequate bladder neck opening without an anatomical obstruction such as bladder neck contracture, stricture or sling[1,2]. PBNO symptomatology includes voiding symptoms, storage symptoms, recurrent urinary infections, pelvic discomfort or pain. Video urodynamic studies (VUDS) is required

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Conflict of interest
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to distinguish PBNO from other causes of obstructive voiding such as dysfunctional voiding or Fowler's syndrome[3]. Characteristic features of PBNO include high voiding pressures, normal urethral relaxation, and the absence or delay of bladder neck opening during permitted voiding despite well-sustained detrusor contraction on fluoroscopy[4]. In contrast, absence of proximal urethral dilatation may occur with downstream pathologies such as Fowler's syndrome (obstructive external sphincter). The prevalence of PBNO is unknown, and its incidence has only been reported in patient series with abnormal VUDS. In men younger than 55 years with storage symptoms who undergo VUDS, 33–54% were diagnosed with PBNO[5,6], whilst women with PBNO only account for 4.6–8.7% of women with abnormal VUDS[7,8].

Treatment options for men and women with PBNO include watchful waiting, lifestyle modifications, pharmacotherapy, clean intermittent self-catheterisation (CISC) and surgery. The mainstay of pharmacotherapy has been alpha-blocker therapy. However, unlike benign prostatic hyperplasia in older men, alpha-blockers in younger men with PBNO are less successful[6]. There are also issues regarding tolerance and compliance as only 30% of men with PBNO who responded to alpha-blocker continue treatment for more than 1 year[9]. In females with PBNO, success rates of alpha-blockers have been reported to be 50% at 30 days[10]. Surgery such as bladder neck incision (BNI) for PBNO can have sustained results, although it has to be used judiciously due to the risk of permanent complications[3,10]. In young men undergoing BNI, the risk of developing retrograde ejaculation is the main concern, and has been reported in at least 27% of men after BNI[9]. In females, a study by Zhang et al. reported 15% risk of postoperative complications following BNI, including 5% who had irreversible stress incontinence or vesicovaginal fistula[11].

Onabotulinumtoxin A (BoNTA) blocks acetylcholine transmitter release from pre-synaptic nerves, and has been demonstrated to relax urethral smooth muscle and reduce bladder outflow resistance[12]. BoNTA injection to the bladder neck for men with PBNO has only been studied in one series of 30 patients with disease refractory to alpha-blockers[13]. The study used 200 units of BoNTA, and after two months the reported mean International Prostate Symptom Score (IPSS) decreased from 21.9 to 7.8[13]. The study also reported a high patient satisfaction, with few significant side effects and 86% of patients willing to recommend the treatment to others with PBNO[13]. In women, there has only been a single small pilot study of seven patients treated with bladder neck BoNTA for functional BOO including PBNO, dysfunctional voiding and Fowler's syndrome[14]. The study found a 62% reduction in post-void residual volumes (PVR) and reported effects that lasted an average of 16.8+ weeks[14]. The benefit of BoNTA is its reversibility with time, thus avoiding permanent retrograde ejaculation or incontinence.

Given the limited published literature on the use of bladder neck BoNTA injection for PBNO, especially in female patients, this study aims to determine the success rate of this operation in a case series involving both male and female patients using a dose of 100 units of BoNTA.

METHODS

Patients at participating institutions who underwent bladder neck injection of BoNTA for PBNO between May 2011 and May 2018 were included in this retrospective case series study. All patients underwent cystoscopy to exclude anatomical causes of BOO and had VUDS to diagnose PBNO. Imaging modality for VUDS included both fluoroscopy (Figure 1) and ultrasound. Urethral electromyography (EMG) was performed in select patients and included in the study.

Clinico-pathological data collected included: gender, age, pre-operative urinary retention status, history of medical management of PBNO, history of surgical management of PBNO, dates of BoNTA injections, dose of BoNTA used at each operation, and progression to BNI. Patients who had previously had a sub-urethral sling procedure were excluded. The primary outcome was subjective improvement in symptoms based on clinical notes on follow-up. Complications were identified from examination of medical notes and a significant complication was defined as Clavien-Dindo Class 3 or above.

A total of 13 patients were included in this study. The median age was 40 years (IQR=30–45). There were five men (38.5%) and eight women (61.5%). Five patients had urinary retention pre-operatively (38.5%), four patients were managed with CISC and one managed with suprapubic catheterisation, six patients were not in retention. Nine patients (69.2%) tried and failed medical management with an alpha-blocker prior to bladder neck BoNTA injection. Two of the patients did not trial medical management pre-operatively and there was no data on medical management on the remaining two patients. None of the patients had previous surgery for treatment of their PBNO prior to bladder neck BoNTA injection. On VUDS pre-

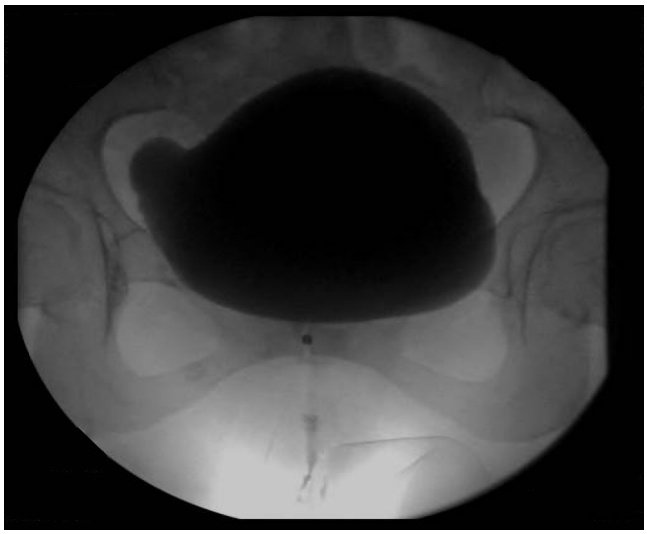

Figure 1. PBNO in a female patient shown on VUDS: note the failure of the bladder neck to open during voiding phase

operatively, two patients were unable to void. Of the remaining 11 patients, the median maximum flow rate (Qmax) was 14ml/s (IQR=5–15) (Table 1).

Bladder neck BoNTA injection technique

A rigid cystoscope was gently inserted into the bladder with the patient in a lithotomy position under general or spinal anaesthesia and prophylactic antibiotic cover. 100 units of BoNTA (Botox®, Allergan PLC, Irvine, CA, USA) made up in 4ml of normal saline (25U/mL) was injected transurethrally at four sites of the bladder neck at 3, 6, 9 and 12 o'clock using a 23-gauge Cystoscopic Williams injection needle (Cook Medical® LLC, Bloomington, IN, USA) or a semi-rigid 4-french, 23-gauge single-use transurethral injection needle (Karl Storz®, Tuttlingen, Germany) through a 20-french operating sheath and working element (Karl Storz®, Tuttlingen, Germany) (Figure 2). The bladder was emptied at the end of the operation. Dose adjustments were made on subsequent injections based on patient response and clinical judgement.

Statistical analyses were performed using Stata Statistical Software: Release 16 (Stata®Corp LLC, Texas, USA). Proportions between groups were compared using Fisher's exact test, with $p<0.05$ being considered statistically significant.

RESULTS

Of the 13 patients, 12 attended follow-up clinic at 4–8 weeks postoperatively. Of these patients, nine (75%) reported improvement in symptoms and three (25%) did not report any improvement. Of the nine patients that reported improvement in symptoms, six provided a subjective improvement rating based on a Likert scale of 1 to 10 (1=no improvement, 10=complete improvement). The median score for subjective improvement in urinary flow symptoms was 8 (range=6–10). Subjective symptom response following bladder neck BoNTA injection for PBNO was significantly higher in men compared with women (100% vs 57.1%, p=0.034, Fisher's exact test) (Table 2).

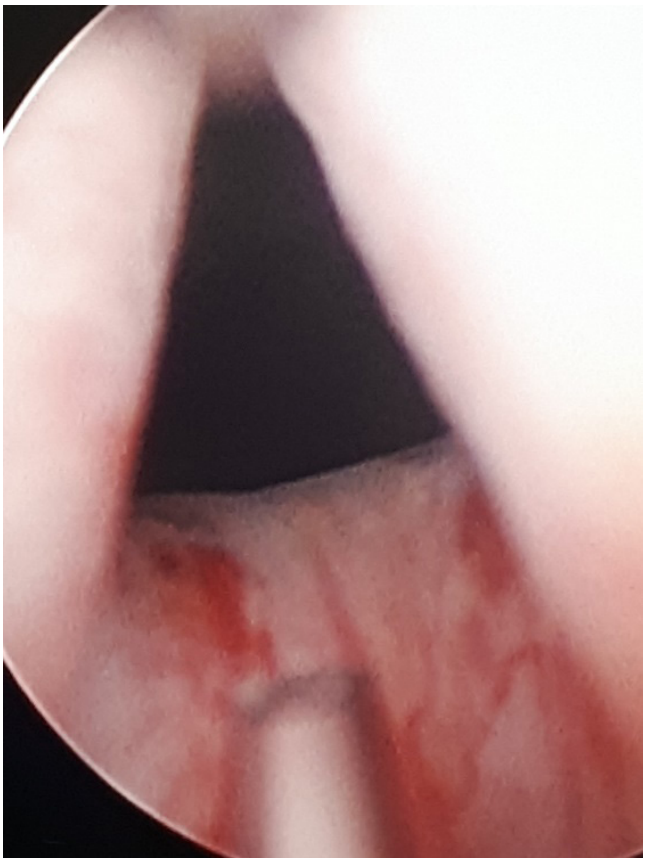

Figure 2. Injection needle at the bladder neck in a male patient

Of the nine patients who responded to bladder neck BoNTA injection, one female patient elected to undergo definitive surgery with BNI, six patients (four men and two women) underwent a second treatment of bladder neck BoNTA injection, and two patients were lost to follow-up (Figure 3). Of the six patients who proceeded to the second treatment of BoNTA, the same dose of 100 units were used in five patients and one patient had a dose escalation to 150 units. The median time between the first and second treatment of BoNTA was 9.4 months.

Of these six patients, four proceeded to the third treatment of BoNTA and two were lost to follow-up. The dose of BoNTA used was 100 units in three patients and the dose was escalated from 150 to 200 units in the remaining patient. The median time between the second and third treatment of BoNTA was 9.2 months.

Of these four patients, one male patient elected to undergo definitive surgery with BNI, two patients proceeded to a fourth treatment of BoNTA after 12 and 17.7 months, and one patient was lost to follow-up. Of the two patients who proceeded to a fourth treatment, there was no dose escalation for either patients, who received 200 unit and 100 units, respectively and both patients underwent a fifth treatment of BoNTA after 9.7 and 10.3 months, respectively.

Table 1. Characteristics of patients with PBNO

Patient characteristics	Total (n=13) (%)	Median
Male	5 (38.5%)	
Female	8 (61.5%)	
Age (years)		40 (IQR=30–45)
Urinary retention	5	
Intermittent self-catheterisation	4	
Alpha-blocker	9	
Previous surgery	0	
Max flow rate (Q_{max}) (mL/s)		14 (IQR=5–15)
Unable to void on VUDS	2	

Table 2. Subjective response after first BoNTA injection

Response	Total (n=12)	Male (n=5)	Female (n=7)	p
Improvement	9	5	4	p=0.034
No improvement	3	0	3	

There were no significant documented complications reported on follow-up. One male patient developed non-bothersome transient retrograde ejaculation which lasted 3–5 days following each injection of BoNTA treatment. Another patient developed a lower urinary tract infection following the procedure which resolved with appropriate antibiotic therapy.

DISCUSSION

This case series indicates that bladder neck injection of BoNTA may have a useful role in the management of PBNO and is well tolerated, with minimal complications. An improvement in symptoms was observed in 75% of cases treated with bladder neck BoNTA injection. The effect of BoNTA wears off after several months and patients may undergo repeated treatments on follow-up with the expectation of a similar response. The median interval between each BoNTA injection was approximately nine months and this is comparable to the 8–11 month duration of action reported in most studies using BoNTA to treat lower urinary tract dysfunction[8,13,15].

We found that bladder neck BoNTA has minimal complications. The most significant complication found in this case series was ejaculatory dysfunction. One patient experienced this for approximately three days that spontaneously resolved.

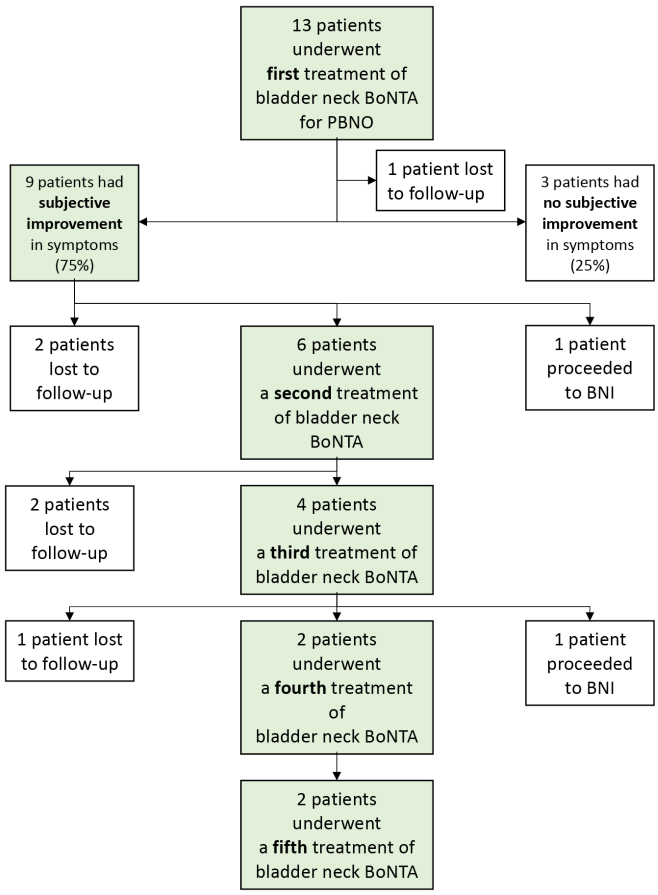

Figure 3. Outcomes of bladder neck injection of BoNTA for treatment of PBNO

Bladder neck BoNTA in men

The only previous study of young men with PBNO treated with 200 units bladder neck BoNTA injection reported subjective satisfaction in 80% of men at two months[13]. A total of 80% of men desired repeated treatment, but the study period was too short to include data for repeat interventions[13]. In this study, all five men with PBNO treated with 100 units of BoNTA injection had improvement of symptoms. Subsequently, one patient was lost to follow-up and the remaining four patients underwent at least two additional rounds of BoNTA injection. Two men went on to have five rounds of bladder BoNTA injection, and one eventually decided to undergo definitive treatment with BNI.

Bladder neck BoNTA in women

There is minimal published literature on women with PBNO treated with bladder neck BoNTA injection. Pradhan et al. previously reported an average 12 point reduction in IPSS with a mean duration of symptom improvement of 16.8 weeks in seven women with functional BOO that was treated with bladder neck BoNTA injection[14]. They assayed a heterogenous group of women with dysfunctional voiding, Fowler's syndrome and PBNO[14]. Importantly, it only included a single patient with PBNO. With seven women included in this study, we present the largest series of women with PBNO treated with bladder neck BoNTA injection to date.

PBNO had a subjective symptom response rate of 57.1% to bladder neck BoNTA injection. Of these women who responded, 50% proceeded to a second round of bladder neck BoNTA injection. Female patients with PBNO were found to have a poorer subjective response rate following BoNTA injection compared with males (inadequately powered for statistical significance). The reason for this is unclear. Perhaps it signifies that the aetiology of PBNO in females is more complex than isolated overactivity of bladder neck muscle fibres. This has practice implications as it could inform targeted BNI for patients whose PBNO is relieved by bladder neck BoNTA. As BNI in females carries higher operative risks, a 5% risk of permanent stress urinary incontinence or vesicovaginal fistula[11], a trial of bladder neck BoNTA improve risk benefit calculations of definitive BNI.

Bladder neck BoNTA as initial interventional management for PBNO

Trial of bladder neck BoNTA prior to a BNI offers an opportunity to stratify patients into separate cohorts based on likely benefit. As BNI is a definitive step that carries significant risk, this could avoid unnecessary patient harm. It ensures that the risk of retrograde ejaculation and sterility in males or stress incontinence from sphincter damage is only taken if maximal benefit is possible. Thus, bladder neck BoNTA offers an exciting initial interventional step and could serve to minimise harm to patients who are unlikely to benefit from a BNI.

Management algorithm for PBNO

From this experience we have developed a management algorithm for intuitive diagnosis and management of PBNO (Figure 4). In patients diagnosed with BOO, an initial clinical assessment including history, examination, flexible cystoscopy and VUDS is to be performed. If anatomical obstruction is identified, it should be promptly managed. To subcategorise functional BOO, we assess voiding pressures, urethral dilatation and bladder neck opening at voiding under VUDS. PBNO is defined by high voiding pressures, normal urethral relaxation and absence or delay of bladder neck opening at voiding. If diagnosed with PBNO, we recommend starting with conservative measures such as appropriate fluid intake, bladder retraining exercises such as timed voiding and double voiding, and avoiding triggers. If these are unsuccessful, devices such as indwelling catheters (IDC), CISC or intra-urethral stents may be trialled. If patients poorly tolerate or fatigue from device use, pharmacological agents such as alpha-blockers may be added. If symptoms are persistent despite this, we recommend bladder neck BoNTA. If there is improvement of symptoms and flow after this, we recommend patient consultation for shared decision making as to whether to pursue repeated bladder neck BoNTA of definitive surgical management. Importantly, if bladder neck BoNTA is unsuccessful, we would recommend avoiding BNI. However, further work needs to be done to validate the significance of this.

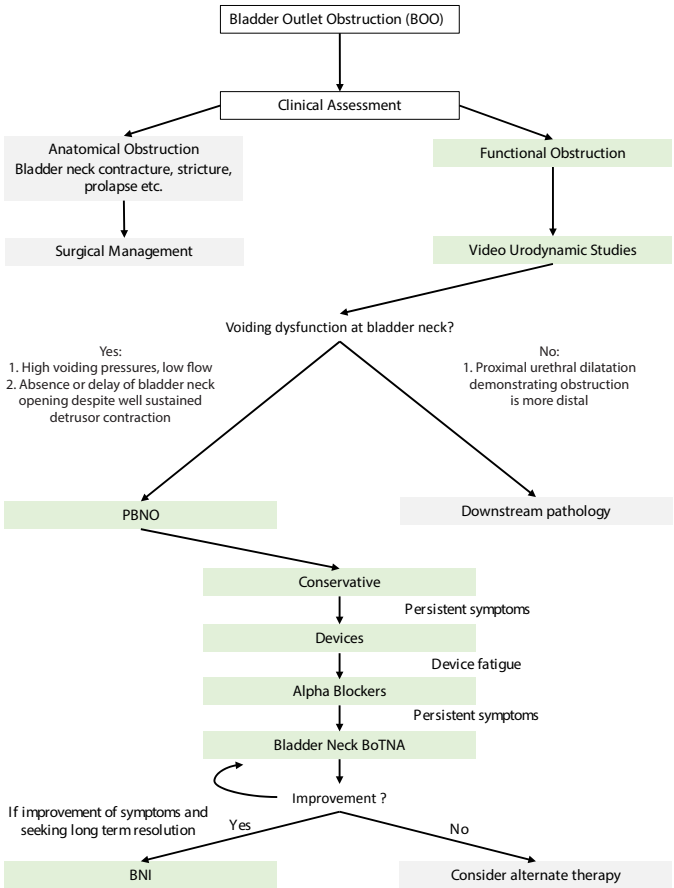

Figure 4. Diagnostic and management algorithm for PBNO

Limitations

There are several limitations of this study. Firstly, due to the retrospective nature of the study, it relies on the accuracy and completeness of medical records. Secondly, this study has a small number of patients. As current clinical practice generally dictates that patients who fail medical management receive BNI, this is expected[13,14]. Thus, small pilot projects like this must be published to allow recruitment of larger patient cohorts. Thirdly, there is no comparison arm and it is difficult to comment on the efficacy of this procedure over other treatment options such as medications or BNI.

CONCLUSION

Bladder neck injection of BoNTA for the treatment of PBNO has a favourable response with minimal risk of complications. For patients who fail or are unable to tolerate alpha-blockers for the treatment of PBNO, bladder neck BoNTA injection is a reasonable off-label alternative to BNI even if they choose to undergo repeat injections. It has a role in patients wishing to avoid the side effects of BNI or as a trial of treatment to provide evidence in support of bladder neck surgery. Further larger, prospective, comparative studies are required to further delineate the role of bladder neck BoNTA injection for treatment of PBNO.

DATA AVAILABILITY STATEMENT

Data used in this publication is available from the corresponding author upon request. These are not publicly available due to privacy and ethical reasons.

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ACKNOWLEDGEMENT STATEMENT

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Dr Andrew W. Silagy (MD)	Western Health	Author	Drafted the manuscript for intellectual content; reviewed literature
Dr Christopher C.K Ip (MD)	Western Health	Co-Author	Revised manuscript for intellectual content
Dr Henry H. Yao (MBBS (Hons) BMedSci PGDipSurgAnat FRACS)	Western Health	Co-Author	Designed study, Revised manuscript for intellectual content,
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Prof Vincent Tse (MBBS, MS, FRACS)	Concord Hospital, Macquarie University Hospital	Co-Author	Revised manuscript for intellectual content, provided data
Prof Lewis Chan (MBBS, FRACS, DDU)	Concord Repatriation Hospital, University of Sydney	Co-Author	Revised manuscript for intellectual content
A/Prof Johan Gani (MBBS, FRACS)	Western Health, University of Melbourne	Co-Author	Revised manuscript for intellectual content, provided data
Prof. Helen E. O'Connell (MD, FRACS, MMed, MBBS, FAICD, President USANZ)	Professor University of Melbourne, Department of Surgery	Co-Author	Conceptualised study, Revised manuscript for intellectual content, Revised algorithm, Provided data

The experience of six women living with pelvic surgical mesh complications – interventions and adaptions: a phenomenological inquiry

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ABSTRACT

This study follows up six women from a 2018 study examining the experience of women living with pelvic surgical mesh complications. Qualitative research relating to women's experience of treatment for mesh complications is limited. Participants had subsequently undergone surgical and non-surgical interventions for their complications. The aim of the current study was to understand the lived experience of these interventions and establish the impact of these interventions on participants' quality of life and wellbeing.

Hermeneutic phenomenology was used with thematic analysis linking findings back to Van Manen's four lifeworld existentials used in the 2018 study – lived space, lived body, lived time and lived other. Participants completed a repeat International Consultation on Incontinence Modular Questionnaire Lower Urinary Tract quality of life (ICIQ-LUTSqol) questionnaire and following this were interviewed via Zoom using a semi-structured approach. During the interview participants self-rated their movement across recovery trajectories. Findings were compared between the 2018 study and the 2022 follow-up.

Comparison of the women's 2018 and 2022 overall ICIQ-LUTSqol scores approached but did not reach statistical significance. However, most participants described some areas of improvement and improved quality of life after surgical and/or non-surgical intervention for mesh complications. These interventions, along with interactions with key health stakeholders, continue to have significant impacts, both positive and negative, on women's lived space, body, time, relationships and recoveries.

Keywords surgical mesh, restorative, mesh complications

INTRODUCTION

Polypropylene mesh commonly used for abdominal repairs was first used in the female pelvis for vault prolapse in 1993. By 1997 polypropylene mesh was being used in urogynaecological surgery in New Zealand. Notifications from the US Food and Drug Administration (FDA) in 2008 and 2011 flagged complications with mesh[1,2] and in 2016 the FDA changed the status of transvaginal mesh for pelvic organ prolapse (POP) from Class II (moderate risk) to Class III (high risk).

In New Zealand high complication rates with pelvic mesh were brought to the attention of the Parliamentary Health Select Committee in 2014 via a petition. The Ministry of Health (MOH) responded to recommendations of the Health Committee by establishing a Surgical Mesh Roundtable in 2017 with all stakeholders, including consumers, to begin work on implementing the Committee's recommendations.

In 2018, in response to one of the recommendations, the New Zealand government asked people injured by surgical mesh to share their experiences to improve future patient safety as part of a restorative process. More than 600 consumers, family members and health professionals shared their stories. As a result of the report and recommendations of this process, four key workstreams evolved – credentialling, education and harm prevention, specialist mesh services and a registry workstream[3]. It is against this background that insider research in 2018 reported the lived experience of seven New Zealand women with pelvic surgical mesh complications[4].

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LITERATURE OVERVIEW

The pool of literature focusing on clinical aspects of surgical mesh complications continues to grow[5–8]. Writing about best practice in diagnosis and treatment, Bueno Garcia Reyes and Hashim describe the symptoms of patients with mesh complications saying that they can be "catastrophic" with a huge impact on health and quality of life[9]. There is now some international consensus on the management of mesh complications[10]. However, there remains limited qualitative research from the women's lived perspective.

Dunn et al. undertook one of the first qualitative studies in 2014, interviewing 84 women experiencing surgical mesh complications. They identified three recovery trajectories, finding that only a small number of women fell into the third category, returning to health. Most continued to have ongoing challenges with their recoveries. The authors compared their findings with their previous study of women awaiting surgery for POP and noted that the difference was "the sustained, emotional, and life-changing trajectory of women who experience repair of mesh complications" along with the amplification of "the severe pain, despair and permanent loss of physical and socioemotional health"[11].

A qualitative systematic review in 2021[12] examined women's experiences of and perspectives on surgical mesh for stress urinary incontinence (SUI) and POP and suggested that women's agency in managing complications should be recognised. Medical professionals, they suggested, had a special responsibility towards women who have been unable to adapt to their changed lives. They also highlighted the importance of patient-centred accounts of outcomes[12]. A 2022 study that analysed 153 women's written submissions to the Australian Senate Inquiry gave insight into women's lived experience, highlighting that "impacts rarely affected only one health domain; instead adverse physical, psychological and social experiences interacted resulting in reduced quality of life for women"[13]. A 2023 study acknowledged that women's lives are "irreversibly altered" by mesh complications and noted that some participants demonstrated resilience in the form of acceptance of their situation[14].

Inquiries in Australia, the United Kingdom, Scotland, and New Zealand that have incorporated submissions from large numbers of mesh-injured women have identified problems with device regulation, adverse event monitoring, acknowledging harm, the lack of data due to the absence of registries, inadequate informed consent, and women's loss of trust in the medical profession[3,15–18].

The qualitative report of the New Zealand restorative justice process for surgical mesh harm described multiple physical and psychosocial harms experienced by mesh-injured men and women who shared their stories. The report noted they were left "grieving losses to their physical wellbeing, relationships, identity, employment and financial status"[19].

The current follow-up study aimed to follow up the 2018 study participants' lived experience of interventions for their mesh complications and establish the impact of these interventions on their quality of life and wellbeing. As much of the research on mesh complications is international, a secondary aim was to provide local data to inform the evidence base in New Zealand.

METHODS

Hermeneutic phenomenology asserts that individuals are as unique as their life experiences[20]. This methodology was used to investigate the women's lifeworlds across four domains – impact on day-to-day life (lived space), body and ability to do what you need to (lived body), hopes and plans for the future (lived time), and relationships with others (lived other)[21].

Participants from the 2018 study were contacted by email and asked if they would be willing to participate in a follow-up study. All seven agreed, one later withdrawing for family reasons. All participants were of European ethnicity, their average age was 49 years, ranging from 43–69 years of age. Four of the seven women had SUI and POP combination surgeries, one had POP only, and two had SUI only (Table 1).

An extension of University of Otago Human Ethics Committee Approval No: H17/142 was granted and the participants consented. Following this, they were asked to complete a repeat International Consultation on Incontinence Modular Questionnaire Lower Urinary Tract quality of life (ICIQ-LUTSqol) without referring to their 2018 questionnaire. The researcher re-read each participant's 2018 interview transcript and compared the 2018:2022 ICIQ-LUTSqol questionnaires prior to interview. Participants were then interviewed via Zoom (an online video conferencing software) for up to 1 hour with semi-structured questions across five key areas:

- Events since 2018 in terms of pelvic surgical mesh complications and any subsequent interventions.

Table 1. Participant surgery types

Pseudonym	Age range (years)	Mesh surgery type	Year of implantation
Lisa	50–59	Anterior, posterior, tension-free vaginal tape (TVT)	2006
Julie	50–59	TVT	2014
Ruth	60–69	TVT	2008
Gloria	60–69	TVT-O (Obturator)	2008
Penny	50–59	Anterior, posterior	2008
Donna	50–59	Anterior, posterior, TVT	2008/2010

- Lifeworld changes.
- Where participants felt they sat in terms of Dunn et al.'s recovery trajectories – cascading health problems, settling for a new normal and returning to health[11].
- Sources of strength, comfort and hope.
- Participation in the New Zealand MOH restorative process and its impact.

As part of the interview, Dunn et al.'s recovery trajectory Venn diagram was shown and explained, and women were invited to locate where they felt they were in terms of their recovery[11]. Dunn et al.'s recovery trajectories consist of three interconnecting trajectories:

- Cascading health problems – where women experienced a cascade of health problems and felt their health was out of control.
- Settling for a new normal – where women who once considered themselves healthy now believed they were unhealthy, constantly coping with permanent changes to their health.
- Returning to health – where women described a resolution of most symptoms and issues[11].

Transcripts were returned to participants to validate. This was an intentional act of empowerment to enable them to remain in control of their own story. None of the women requested any changes. Transcripts were themed line by line separately and as a group and annotated as key words, phrases or themes emerged. These were compared with the 2018 transcripts. Likewise, the participants' ICIQ-LUTSqol were compared. Overall themes were extracted and linked to relevant narrative and lifeworld existentials, with the aim of using as much of the women's verbatim narrative as possible. The same pseudonyms were used as in the original research.

FINDINGS

Five of the six participants had undergone assessment and surgical intervention since the 2018 study (Table 2). Two had travelled overseas at their own cost to seek treatment, a further two had full removal in New Zealand, and one had removal of remnant mesh, also in New Zealand.

Table 2. Interventions since 2018

Pseudonym	Intervention	Year
Lisa	No intervention	N/A
Julie	Full removal (US)* + replace neuro-modulator battery and wire (NZ)	2021
Ruth	Full removal (NZ) + neuromodulator	2019
Gloria	Full removal (US). Some mesh strands embedded in nerves remain	2021
Penny	Colonoscopy, cystoscopy, full removal posterior mesh (NZ)	2018
Donna	Cystoscopy, remnant mesh removal (bladder wall/15cm each groin) (NZ)	2020 2021

*Although it was a full removal there was one small piece of Apogee remnant mesh arm that was unsafe to remove.

Choosing to have or not have an intervention, surgical or otherwise, is not always clear cut and the women had to make difficult choices not knowing what the outcome might be. Julie and Gloria took matters into their own hands after being unable to get the help they needed in New Zealand and sought removal of their mesh in the US. The number of women that have travelled overseas for self-funded mesh removal surgery is not known. In Julie's case, the surgeon removed more mesh than she had been told remained. Gloria underwent a 7.5-hour surgery where both the Prolift mesh and TVT-O sling were removed intact.

Both Julie and Gloria experienced improvements postoperatively – Julie with mobility, and Gloria with mental clarity, improved sexual function, and the ability to lead a more active social life. However, both agree that recovery after full removal is a long process, Gloria took 18 months to recover fully, and Julie is still in the recovery phase nine months postoperative at the time of interview.

Assessment of lifeworld themes

The women's lifeworlds across four domains – impact on day-to-day life (lived space), body and ability to do what you need to (lived body), hopes and plans for the future (lived time), and relationships with others (lived other)[21] – are outlined below.

Lived space: day-to-day existence

Postoperatively, most of the women experienced gains, but conversely some disappointment when symptoms that they had hoped would resolve with mesh removal did not. Postoperatively, Ruth's expectation for her day-to day existence was:

> *To get better and that life would return to normal, but that didn't happen. I'm no better off, worse actually... very incontinent, no control whatsoever now, still got groin pain, still get infections, but not as many as I had before. People say that they feel so good after it's out... feel a difference. I didn't.*

As with the 2018 study, narrative relating to the Accident Compensation Corporation (ACC) took up a large part of the women's responses during the interviews. The ACC is a no-fault personal injury insurance scheme that also covers treatment injury as a direct result of medical treatment where the injury is not a normal side effect of treatment. One of the biggest impacts on four of the women's lived space was the sense of loss of control and lack of choices engendered by their contact with the ACC system.

After 13 years of battling, assessments, reviews, appeals and a heart attack that she attributes to the stress, Ruth's claim was finally fully accepted. She said:

> *I got an email after all this fighting for 13 years and I get an email to say we've accepted it and it's all over. And... you're uptight, and you've fought for so long you couldn't just relax and think I've won and now it's finished. It didn't feel any different.*

Julie, who had an approved claim, explained how it felt to be dependent on ACC support on a daily basis:

I am solely reliant on ACC and when you get a new case manager, and they cancel something on you it just throws your whole world into chaos. And unless you live and breathe ACC every day, the fear that you live in… it's horrible. You don't have a choice; you just have to grin and bear it really.

Lisa described the ACC as constantly "on my back" and shared the difficulty of dealing with the ACC while working around pain:

I've got to respond to their emails in a timely manner, but I can't think too much when I am in too much pain. So, effectively, it puts me in danger of losing my services. They are keeping me so damn busy that it's really hard to live.

Describing herself as "broken but healthy", Lisa has engaged a life coach to help her achieve her goals.

Lived body: being bodily in the world

Even non-surgical interventions carry risk. Julie had been offered a nerve block for pain originating from the posterior femoral cutaneous nerve, but the possibility of not being able to lift her leg is a trade-off she was not prepared to risk. Ruth had been offered Botox injections to improve her continence, as the neuromodulator (device which uses electrical stimulation of nerves to modulate bladder and/or bowel function) implanted after her mesh removal had not been as successful as hoped. She explained:

The latest thing is they are going to do Botox, and then if that doesn't work… I will then just have a stoma and a bag.

Options for a further surgery to remove the remaining mesh from her bowel are so daunting for Donna that she has decided to put that surgery "on hold". She said:

So, the options to get that bit out I would either have to have an open wound in the perineum for six months, or they would go in through my abdomen and it would highly likely damage the bowel and have to have some bowel removed. So now I'm pretty much… this is me.

Two women had neuromodulators inserted to help them manage their bowel and bladder incontinence. Both women have experienced complications with these. Ruth had a wire dislodge during physiotherapy, requiring replacement of her neuromodulator. For Julie, using the neuromodulator is a constant trade-off between continence and pain. She explained:

When I didn't have the neuromodulator working when I came back from America, I could sit for up to two hours, so I could actually watch a movie. When [NZ surgeon] put the neuromodulator in, it's in S3 and that posterior femoral cutaneous nerve comes out of S1–S3, it restimulated it, and that's why I can't sit. So, I can turn my neuromodulator off when it's really bad, but the problem is I'm incontinent, and then I have a mess to clean up.

The interventions these women had undergone since 2018 continue to have a significant impact on how they are bodily in the world, requiring constant adaption.

Lived time: past, present and future

Gloria reported substantial improvement in her narrative, but her overall ICIQ-LUTSqol score did not reflect this. Gloria explained that she felt she had been getting her life back and:

… [husband] and I are looking at future plans now rather than worrying I might die.

She described her mesh explant surgery as a "life changer" and while not yet completely recovered, described feeling mentally "on top of it". She is now able to do some volunteer work and gains a sense of purpose from this.

Lisa struggled with not having a sense of purpose and linked this to employability:

It's really hard to get up when you've got nothing to do… Losing your employment you lose part of your confidence… you second-guess yourself. It's also just to be a functional member of society. You don't feel like you are.

Ruth had been working with a psychologist who was supporting her to let go. She said:

I've accepted my lot, and this is it… I've just got to live with the life that I've got now.

Dibb et al. describe this acceptance as a demonstration of resilience[14].

Lived other: social and interpersonal

The importance of the support of significant others as a source of strength is a continuing theme. Two women continued to find strength in their faith in God, while for those that had a spouse, the support of their spouse was vital to their ability to adapt and cope.

Ruth explained:

Without [husband's name] I wouldn't have coped… I would have ended it. I wouldn't have carried on.

Post-surgical intervention, Gloria and Penny had been able to recommence intercourse with their husbands. Sadly, for Ruth, surgical intervention worsened her urinary and faecal continence to the point where it negatively impacted on her ability to have intercourse. The loss of sexual intimacy as a significant cause of grief and loss is well described in the literature[3,4,7,11,15,16].

All the women in this study participated in the MOH restorative process Listening Circles. These were facilitated meetings of between 10–20 participants where those harmed shared their stories with each other and key health stakeholders. Some chose individual conferences or contributed to a story database. This gave them an opportunity to be heard and have their lived experience validated. It took courage to share their vulnerability with a group of people they didn't know, and most were concerned about breaking down while telling their stories. Some women found the experience empowering. Gloria explained:

I wasn't just a complaining old woman. I was a person who mattered. I didn't feel alone anymore. I had the language and a voice thanks to Mesh Down Under [online support group].

All but one of the women found it cathartic to some degree, whether it was just writing their story down, or getting it "off their chest" and most had family/whānau attend to support them and share their perspective. However, all six women had concerns about whether the restorative process has changed anything as they have not observed or experienced significant systemic improvements. An evaluation of the restorative approach[10] highlighted that consumers were largely unaware of progress on the 19 actions recommended by the MOH, and this is reflected in the women's responses.

2018:2022 comparisons

Lifeworld themes 2018:2022

Using Van Manen's Lifeworld existential domains[21] the themes from the current study were compared with those from the 2018 study (Table 3).

There are significant changes and adaptions in the women's lifeworlds. Previously feeling as though they were living in shrinking worlds, the women have leaned into the new normal, despite the additional isolating impacts of COVID-19. The women have expanded their worlds where they can and developed resilience where they cannot. While their bodies still cannot be relied on as they were pre-mesh, the women are confident in their expert knowledge of their own bodies and actively managing their day-to-day symptoms. They balance rest and activity to allow them to participate in the activities that are important to them. They have actively sought treatment and in doing so are faced with difficult choices, risks and benefits to balance, and unknown outcomes. Even small improvements as a result of interventions (surgical and non-surgical) have enabled them to have hope for the future.

Table 3. Comparison of themes 2018:2022 in relation to Van Manen's Lifeworld existential domains[21]

Themes	
2018	**2022**
Lived space: the ways we experience our day-to-day existence	
Feeling powerless in the medical space	Taking back some power The continuing struggle with the ACC
Living in a shrinking world	Leaning into the new normal COVID impacts
Lived body: how we are bodily in the world	
Living with unrelenting pain	Actively managing symptoms, balancing risks and benefits of treatment
Inhabiting a body that can no longer be relied on	
Lived time: how the past, present and future make up the horizons of a person's temporal landscape	
Living in the gap between what was, and what could have been	Having hope for the future
	Acceptance – this is my lot
Lived other: the social world and how we relate to others in the inter-personal space	
Suffering in silence	Being heard, feeling validated
Finding Absolute Other and others a source of strength	Finding Absolute Other and others a source of strength

ICIQ-LUTSqol scores 2018:2022

Although descriptively the ICIQ-LUTSqol 2022 scores were lower than the 2018 scores, they did not reach statistical significance (affect: M2018=9, T2022=8.33, t(5)=1.348, p=0.12; bother: M2018=63.66, M2022=61.0, t=1.38, p=1.11). However, it is worth noting that the sample size was small, and the observed differences were in the predicted direction and approached statistical significance. Had the sample size been larger, the study may have detected a significant effect.

Recovery trajectories

In the 2018 analysis of the interview narratives the researcher determined where participants sat in terms of their recovery trajectories using Dunn et al.'s Venn framework[11]. In the current study the participants were shown the Venn diagram during the interview with an explanation, and asked to rate where they felt they sat. Figure 1 highlights the differences 2018:2022.

Lisa felt that her ongoing struggles with the ACC meant that she was unable to move beyond "settling for a new normal". Julie was still finding her new normal after her surgery. Ruth, experiencing a worsening of her continence post full removal, felt that she was sitting between dealing with the "cascading health problems" related to the surgery, and accepting that that was her new normal. Gloria also selected a midpoint between "settling for a new normal" and "returning to health" that emphasised ongoing physical symptoms. Donna and Penny selected this midpoint as well but with emphasis on the increasing flexibility they now experienced in their lives.

Each surgical intervention required adapting to a "new normal" and sometimes dealing with a range of new or cascading health problems before finally reaching that new normal. The new normal looks different for every woman. The women in this study are unlikely to experience full resolution of their mesh complications because of the severity of their injuries. However, acceptance of their reality, the support of significant others and the active management of physical symptoms giving a sense of control appeared to be a key factor to improving mental and emotional health.

DISCUSSION

The most striking observation during the Zoom interviews was the improvement in mental and emotional wellbeing evident in the women's demeanour during interview. This was despite the acknowledgement in their narratives that for them there will be no return to health that equates with their health pre-mesh implantation.

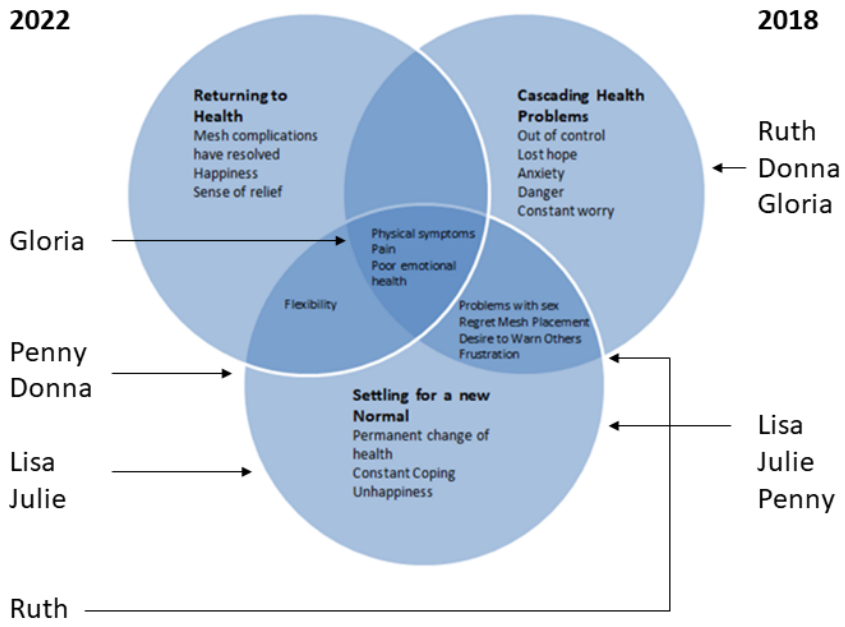

Figure 1. Dunn et al.'s recovery trajectories comparison 2018:2022

This improvement is demonstrated in the contrast in themes, those in 2018 evidencing grief, loss and suffering, the 2022 themes evidencing resilience, acceptance and moving forward. This may be due to a combination of both intrinsic and extrinsic factors. Extrinsically, the increased understanding by the national and international medical community of the harms caused by pelvic surgical mesh and various inquiries have given voice to those injured by mesh. They have laid bare the multi-faceted impacts of the harm and have shattered the 'silence'. While this has improved the women's lived space in a broad sense, they continue to struggle with other factors that limit their agency on a day-to-day basis. Despite high level engagement by the ACC in the restorative process and associated structural improvements in the organisation, participant narratives suggest there is more work to be done at the interface with mesh-injured women.

From a lived body perspective, the women are faced with potentially life-changing decisions about interventions without the benefit of recent clinical studies to guide understanding of risks and benefits.

Intrinsically, acceptance of their changed lives has led to adaptation, moving forward with what is possible with increasing resilience. Edgar and Pattison describe this movement in relation to quality of life, arguing that as patients become used to their condition, they modify their expectations and goals; they re-identify themselves as successful persons with disabilities and may even flourish despite the absence of some material conditions of wellbeing[22]. This is evident with the women in the study in terms of lived time, as they have each engaged with their past mesh injury, made sense of their new normal and have some hope for the future. Surgical and non-surgical interventions have enabled them to regain some quality of life and achieve varying degrees of wellness across bio-psycho-socio-spirito domains.

Mesh complications have a well-documented negative impact on intimate relationships[4,11,15,16,18,23]. In terms of lived other, this study showed the practical and psychological support of others have a reciprocal but positive impact on the wellbeing of the women. For women in this study with partners, their partner was integral to their ability to cope with their mesh complications. For those without partners, the support of children, and the knowledge gained through Listening Circles that they were not alone was significant.

While descriptively the ICIQ-LUTSqol showed improvements in quality of life, the total scores and overall bother levels did not reach statistical significance. However, the ICIQ-LUTSqol provided a holistic framework within which to explore aspects of quality of life, providing consistency between the 2018 study and the present study.

Limitations

A limitation of the study is its small sample size; however, this is not uncommon for qualitative research. Its strengths are that it built on the 2018 study, followed the women over four years, and used the adapted ICIQ-LUTSqol to explore aspects of quality of life. The author's insider status and prolonged engagement in the field allowed access to the women's private stories. Radley and Billig suggest that whether the researcher gets the private or public account depends on the interviewer relationship[24]. This study was conducted on the strength of a four-year relationship with participants. Radley and Dua posit that clinical interview data is prone to inaccuracy

and non-disclosure due to the taboo nature of pelvic floor disorders[25]. Being an insider researcher and using qualitative methods helped counter this. While insider researchers may sacrifice some objectivity, the depth of the information they are able to gather is considered valuable compensation. Kerstetter argues that in fact all researchers fall somewhere on a continuum between complete insiders and complete outsiders[26].

A further limitation is that all the study participants were of European ethnicity. ACC statistics show that there were only a small number of women from Māori, Asian, Pasifica and other ethnicities who experienced mesh complications[27]; however, this may be due to underreporting and inequity of access to health services.

CONCLUSION

Qualitative research related to women's experience of treatment for surgical mesh complications is limited. This follow-up study showed that both surgical and non-surgical interventions can have significant impacts, both positive and negative, on women's lived space, body, time and relationships with others.

Key health stakeholders sharing the power, giving information and options, hearing and responding actively and in a timely manner to the multiple harms caused by surgical mesh is important for women's quality of life and wellbeing. Respecting women's agency and enabling them to self-identify the interventions and resources they need to flourish is critical.

I am hopeful that as specialist mesh clinics begin to provide funded multidisciplinary and holistic wrap-around care for New Zealand women with mesh injury many more women will experience improved quality of life and renewed hope for the future. It is vital that further lived experience research examining the impact of interventions for complications is undertaken. Co-designing outcome measures with mesh-injured women would provide direction for future interventions and service development.

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Pessary management for pelvic organ prolapse: a review of clinical practice and Australian medical device regulations

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ABSTRACT

Pelvic organ prolapse affects up to 50% of women throughout life. Management can be conservative or surgical. Pessaries have become an integral component to management of pelvic organ prolapse, providing symptom improvement and enhancing quality of life. After careful clinical assessment, women choosing pessary management are offered either self-care or clinician-based pessary care. Pessary care can be offered by a range of clinicians, including doctors, nurses and physiotherapists. In this article we review the literature on the historical use of pessaries and how they have changed to be the device manufactured today. We then outline the Australian regulation of vaginal pessaries as per the Therapeutic Goods Administration (TGA). We discuss device classification in relation to clinical practice and guidelines.

The TGA classifies pessary devices as either Class 1: device which is intended for transient use, Class 2A: to be used continuously for at least 60 minutes but not more than 30 days, and Class 2B: continuous use for more than 30 days. The majority of pessaries available in Australia are classified as 2A devices.

The TGA classification of pessaries and commonly accepted standards of care in many Australian centres are not always synergistic. In Australia, varied models of care are offered for pessary management. Recent literature has identified a need for clinician guidelines and training for pessary care. The TGA device classification should be considered in Australian training and guidelines. Information on TGA device classification needs to be discussed with each patient that is offered pessary management. If 2A pessaries are used in conjunction with clinical led care, it is unlikely that the device will be removed every 30 days. Therefore, 2A devices may be used off-label and the patient should be informed of this deviation from the regulation.

Keywords pessary, prolapse, device, regulation, management

INTRODUCTION

Pelvic organ prolapse (POP) affects up to 50% of women[1,3–5]. POP has been defined as the descent of at least one of the vaginal walls to or beyond the hymen with maximal Valsalva, plus the presence of bothersome characteristics such as vaginal bulge or functional compromise. Women with POP describe feelings of vaginal dragging, protrusion into or outside of the vagina, bladder or bowel symptoms, and sexual dysfunction[6].

Management of POP is largely based on symptomatology and bother. It includes both non-surgical and surgical options. Non-surgical management includes pelvic floor muscle training (PFMT) and pessaries to provide support[6]. This paper will discuss pessaries for the management of symptomatic prolapse. We review the evolution in engineering of the current day pessary. We explore the Therapeutic Goods Administration (TGA) regulation of pessary use and consider this in relation to current standards of clinical practice and training. In particular, we apply this to the Australian pessary practitioner[6]. We seek to provide clarity surrounding the TGA regulations on pessaries to all health professionals fitting and managing pessaries.

THE HISTORY OF PESSARY USE

Pessary management for POP has had a variable course throughout history[7]. The word pessary stems from Greek and Latin literature, originating from the Greek word pessós and Latin word pessarium meaning an oval stone used in a checkers-like game[8,9].

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Pessary devices have been used since 400BC; there are reports detailing Hippocrates inserting pomegranates into the vagina to reduce prolapse[9,8]. Further historical literature on POP management from AD1050 describes a "ball pessary" constructed from strips of linen to fill the vagina[9]. German literature from 1559 describes using a sponge tightly rolled and bound with string, dipped in wax, and covered with oil or butter as a pessary[9]. The late 16th century saw developments to pessaries as they became oval-shaped and crafted from hammered brass and waxed cork[8,9].

The vulcanisation of rubber in the 1860s and then polystyrene plastics in the 1950s saw modernisation of pessary design[9]. Currently, pessaries are manufactured using silicone, polyvinyl-chloride, polythene, acetyl-copolymer or latex materials[4,6].

The development and implementation of silicone devices has provided advantageous properties. Silicon is non-absorbent of secretions or odours, it has a long half-life, withstands sterilisation and repeated cleaning processes, and is inert and hypoallergenic[10,11].

Advancements in pessary materials used has allowed for variation in structure to pessary devices. The materials used to manufacture a pessary, although important to improve function, are not likely to affect adverse events. Device shape is more likely to be associated with complications compared to materials used in manufacturing. Evidence shows that complications such as erosions are more common in Gellhorn or donut pessaries rather than ring pessaries[12]. It is important for a practitioner to understand the materials pessaries are made from; however, this is only one aspect that should be considered in practice.

PESSARY USE IN CLINICAL PRACTICE

Pessary devices for POP have a beneficial therapeutic impact on quality of life, sexual function and body image. Pessary use promotes a significant reduction in POP symptoms, with low complication rates[1,4].

Clinical practice is affected by clinical efficacy, risk–benefit profile, patient-reported outcomes and cost. NICE guidelines (2019) report that up to 98% of clinicians managing POP offer pessaries for management[13–15]. They are commonly offered first-line; a multiple disciplinary survey of UK practice published in 2020 found that 75% of clinicians managing pessaries will use them as first-line[16].

High patient acceptability and symptomatic improvement of POP is reported with pessary use[6–7,17]. An observational study found 76% of women newly fitted with a pessary will continue use for at least four weeks. In the same study, 86% of the women continuing with pessary management maintained use for over five years[6,18]. Further to this, medium-term satisfaction rates are high (70–92%), reducing POP-related bother, and improving quality of life and positivity of body image[7,12,19].

Management for prolapse can be either through surgery or pessary use[20]. Evidence supports that pessary management can provide comparable treatment outcomes to surgery in reported symptoms and quality of life[1]. A prospective study comparing pessary management with surgery in women with symptomatic POP reports equivocal outcomes in urinary and bowel symptoms, sexual function and quality of life improvements[21]. A small (n=160) prospective cohort study from the United States[20] compared pessary and surgical management for POP. It showed comparable outcomes between the treatment arms for goal attainment and improvements in physical, social and emotional functioning; only slightly better outcomes were found in surgery[20].

Similar findings are again reported in a recent (2019) observational study comparing pessary and surgery for advanced POP in women with a uterus. It showed similar outcomes in success of pessary and recurrence of prolapse symptoms post-surgery[22]. A prospective study using validated questionnaires compared vaginal pessaries and surgery for POP using the International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS) and Urinary Incontinence (ICIQ-UI) Short Form[18]. Although limited by only one-year follow-up, women with symptomatic POP did report improvement in vaginal, bowel, urinary and quality of life scores in both groups[18].

Pessary management for POP has well documented clinical efficacy and should be considered for patients presenting with symptomatic POP. In addition to improving symptoms, vaginal pessaries are often selected as a cost-effective treatment[6,23,24]. Cost efficacy of pessary management for POP has been supported through cost analysis studies[25].

Complications of pessaries

A 2020 Cochrane review on pessaries for POP includes an analysis of the number of women reporting adverse events from pessary use[6]. The most commonly reported adverse event is vaginal discharge, bleeding and erosions[12]. Increased urinary incontinence, irritation and discomfort during intercourse, vaginal odour and increase in bacterial vaginosis are also reported[6,9].

Common adverse effects are usually straightforward to treat. Vaginal ulcers or erosions can be managed with vaginal oestrogen and removing the pessary for a period of time to allow the ulcer to heal[6,9]. Additional concerns such as spontaneous expulsion, difficulty with defecation and de novo stress incontinence can also require amendments to the size or shape of pessary used[6,9].

If pessaries are left in situ for prolonged periods serious complications can arise[9,26,27]. Poorly fitted devices have resulted in reports of the cervix, uterus or bowel herniating and strangulating through, an impacted or embedded pessary, cervical incarceration and infection[28,29].

Fistulas are rare and result in significant complications for patients. The association between pessary use and fistula formation was described in 1868 by Thomas Addis Emmet[30]. Although infrequent, fistulas have

been well documented throughout the literature with multiple case reports[26,31-33].

When should a pessary review be performed to minimise complications

There is paucity in data to support optimal pessary review to minimise adverse events. A 2020 prospective cohort review assessed efficacy of routine follow-up for pessary cleaning using a measure of visual analogue scale on pain, discharge and irritation one week before and after cleaning at three and nine months. They found there was no difference in outcome pre- or post-cleaning and reported no serious adverse events related to pessary use[34].

A prospective observational study looked at ring pessaries. Patients were reviewed at four weeks then six-monthly until 24 months. In this time pessaries were not removed, rinsed or replaced. They found 91.8% of women continued pessary use at 24 months. Adverse events occurred in 27% of cases. Adverse events were grouped as extrusion of pessary, bleeding, excoriation, pain and increase in vaginal discharge requiring pessary removal[35]. However, there remains a lack of clarity on the optimal timing of pessary review by a clinician to reduce complications. A nine-year longitudinal study in the USA suggests there is a 3% risk of developing a vesicovaginal or rectovaginal fistula and a 5% risk of developing a mechanical genitourinary device complication on follow-up of pessary insertion[36]. When considering optimal timing for pessary review, clinical indications, evidence to support practice and regulation should be considered.

Who regulates pessaries

In Australia, vaginal pessaries for management of prolapse are classified as a medical device and are regulated through the TGA[37]. The TGA has a set of principles including safety requirements, infection and microbial contamination protocols, construction and environmental properties[37]. The current process for TGA classification relies on the submission of evidence on safety of use by Australian device sponsors to the TGA for review[37]. This assessment process is known as a conformity assessment, and it is how a sponsor shows the safety, quality and performance of their medical devices[37].

The regulatory framework comprises pre-market and post-market requirements. Compliance with Australian safety and performance requirements must be met for all medical devices supplied to Australia[37].

What is a medical device?

A medical device (as per the Therapeutic Goods Act 1989) is any instrument, apparatus, appliance, software, implant, reagent, material, or other to be used for human beings for the purpose of one or more of the following[38]:

(i) Diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease.

(ii) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability.

(iii) Investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state.

(iv) Control or support of conception.

(v) In vitro examination of a specimen derived from the human body for a specific medical purpose.

It does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means. Medical devices are classified by the TGA based on risk (Table 1).

The Therapeutic Goods Regulation 2002, schedule 2 classification, details the regulation for invasive medical devices. This applies to an invasive medical device that is intended by the manufacturer to be used to penetrate a body orifice of a patient[2]. Invasive medical devices (not intended to be connected to an active medical device) are classified as Class 1: device is intended for transient use, Class 2A: short-term use ie, to be used continuously for at least 60 minutes but not more than 30 days, and Class 2B: device is intended for long-term use of more than 30 days (Table 2)[2].

A vaginal pessary device is classified as an adaptable medical device. On review of the TGA classification of pessary devices (Class 2A/2B), the TGA classification may not always be in alignment with standard clinical practice in many Australian centres. Table 3 details pessaries commonly used in Australia and registered with the TGA[39-43]. Most of the available pessaries used in Australia are categorised by the TGA as 2A devices. This means the device is approved to use for longer than 60 minutes but not more than 30 days continuously. 2B devices are approved for use longer than 30 days[39,41].

An understanding of the TGA classification of devices is necessary to ensure patients are being counselled

Table 1. Classification of medical devices[37-38]

Risk level	Classification(s)
Low	Class 1: eg surgical retractors
Low to medium	Class 1: supplied sterile eg sterile surgical Class 2A: eg dental drills, ultrasound machines, selected pessaries
Medium to high	Class 2B: eg surgical lasers, diagnostic x-ray, selected pessaries
High	Class 3: eg prosthetic heart valves, absorbable surgical sutures, hip prostheses

Table 2. Classification of vaginal pessary devices[2]

Device classification	Classification definition
Class 1	Intended for transient use
Class 2A	Short-term use, eg to be used continuously for at least 60 minutes but not more than 30 days
Class 2B	Intended for long-term use if the manufacturer intends the device to be used continuously for more than 30 days

Table 3. Commonly used TGA approved pessaries[39-43]

Pessary brand	Pessary type	Material	TGA listing details
TGA Class 2A pessaries (classified for use longer than 60mins but less than or equal 30 days continuously)			
Med Gyn	Ring, Ring with knob, Donut, Modified Cup, Donut, Modified Cup, Donut, Shaatz, Cube, Gellhorn short stem, Cup, Dish, Oval, Hodge, Marland, Gehrung	Silicone	ARTG ID: 368830 Manufacturer: MedGyn Products International Inc and MedGyn Products Inc Sponsor: Sigma Company Limited
Milex by Endotherapeutics	Ring, Ring with knob, Ring with support, Ring with knob & support, Incontinence ring, Hodge, Hodge with support, Hodge with knob, Hodge with knob & support, Risser Smith, Gehrung, Gehrung with knob	Silicone & metal	ARTG ID: 361771 Manufacturers: Cooper Surgical Inc T/a Ackrad Laboratories Prism Healthcare Milex Medscand Wallach Surg Dev SAGE In-Vitro Fertilization and Lone Star Medical Products Sponsor: Endotherapeutics Pty Ltd
Milex by Endotherapeutics	Shaatz, Donut regular, Gellhorn flexible, Incontinence dish, Incontinence dish with support, Cube, Tandem cube	Silicone	ARTG ID: 361771
Milex by Endotherapeutics	Inflatoball	Latex	ARTG ID: 361771
Wallace by Endotherapeutics	Ring pessary, Wallace	Flexible PVC	ARTG ID: 361771
Sayco	Incontinence ring, Hodge, Hodge with support	Silicone with inner metal component	ARTG ID: 399401 Manufacturer: Guangzhou Fame Medical Co Ltd Sponsor: Sayco Pty Ltd
Sayco	Ring with support, Ring without support, Gellhorn with drains soft 30mm/40mm stem, Gellhorn short stem 40mm, Donut, Marland with support, Marland no support, Oval support, Oval no support, Shaatz with drains, Ring with knob no support, Ring with knob support, Donut inflatable, Flexi shelf, Cup with support, Cup no support, Dish no support, Dish with support, Gehrung, Cube with drains, Cube no drains	Silicone	ARTG ID: 399401
Gynaecologic	CPOP, Ring	Silicone	ARTG ID 251215 Manufacturer: Surgi Supplies International Pty Ltd Sponsor: Gynaecologic Pty Ltd
TGA Class 2B pessaries (classified for continuous use longer than 30 days)			
Portia PVC ring by AMA medical products	Portia ring pessary	PVC	ARTG ID: 225317 Manufacturer: Bray Group Ltd Sponsor: AMA Services WA Pty/Ltd AMA Medical Products

appropriately when a pessary is being offered. For example, a silicon ring (classified 2A) is selected as the most appropriate management option for the individual. It is often fitted with the longer-term intent to keep the device in situ for more than 30 days (Table 3). As such, the patient must be counselled that this is common practice but as per the TGA classification this would be considered an off-label use of their pessary[2,29].

Standards in training of pessary practitioners

In contrast to pessary regulation set by the TGA, standards of patient care and responsibility of clinical practice lies with the clinician. This is assisted by relevant professional codes of conduct, guidelines and policies[29,44-48]. A range of healthcare practitioners provide pessary care, including doctors, nurses and physiotherapists[16,45-46]. An Australian cross-sectional study has identified varied training experiences in pessary management across healthcare practitioners[23]. Practitioners report that current practice is largely based on information provided by manufacturers[23].

Recent international literature has highlighted a lack of structured clinical training and guidelines for practitioners providing pessary management for POP[44,47]. Practitioner training in pessary care is needed to ensure appropriate patient selection, correct

pessary fitting, and availability of long-term follow-up to minimise the potential for adverse events[10,2,44]. There is a lack of evidence to correlate complication rates with experience or skill of a practitioner. Yet, to ensure a high level of care is provided to women selecting pessary management and to protect pessary practitioners from liability and litigation, clear guidelines on best practice and clinician training are necessary[44].

Internationally, progress has been made to guide pessary practice[29]. The UK pessary guidelines have created training standards for pessary practitioners[29,39]. A 2022 South Australian Delphi study details the development of a multinational, multidisciplinary competency framework developed for physiotherapy training in pessary management[45].

To further advance pessary care and training, an understanding of pessary regulation with the TGA would be helpful to those considering pessary training. This will help to inform the way pessary practitioners may adequately counsel women to make an informed choice on pessary management.

Guidelines for clinical practice

The UK clinical guidelines for use of vaginal pessaries for POP is a best practice document. It provides an expert opinion on the timeline for review and pessary changes[29]. The document states that good practice for pessary follow-up is 4–6 weeks after initial fitting then six-monthly or longer if the pessary is self-managed successfully[29]. This expert opinion document is widely accepted in practice. As discussed previously, there is paucity of evidence to guide optimal timing of pessary review, with other studies reporting on outcomes from review times ranging from six weeks to 24 months[34–36].

It is widely accepted in practice that there are limited risks related to pessary use. Yet regulation is lacking to support contemporary practice and timing of pessary review. Whilst risk to the patient remains minimal, the clinician needs to have clear documentation that risks have been discussed and understood, and that the patient accepts to use the pessary off -label if follow-up time will vary from TGA regulations. When delivering care, the TGA classification of pessary devices should be considered with the patient. The practitioner should document patient education and consent, the pessary type and size, pessary replacement, exchange or placement of a new device[44].

DISCUSSION

When a patient presents with a symptomatic POP, a detailed assessment and patient-centred discussion must take place prior to arriving at a decision on management. A thorough history should be taken, followed by physical examination. Examination includes assessment and clear documentation of the degree of prolapse of the anterior, posterior and central compartments of the pelvic floor using the POP-Q (Pelvic Organ Prolapse Quantification) system[13]. A careful pelvic exam should contain a bimanual examination to determine if coexisting pelvic pathology is present. Assessment of the pelvic floor muscles and vagina for atrophy or epithelial ulceration should also be performed and cervical screening test collected if indicated[13]. Sphincter tone and presence of rectal prolapse in those with bowel symptoms can be evaluated[13]. A validated pelvic floor symptom questionnaire may be considered to aid assessment and decision making. If obstructed defaecation, faecal incontinence or urinary symptoms are identified on assessment, then further investigations should be considered[13,48].

When discussing treatment, conservative management options include observation, lifestyle intervention, PFMT, topical oestrogen and pessary[13,45]. Some patients may choose to have a pessary if they have not yet completed their family, they have a high risk of recurrence, surgical timing doesn't suit their lifestyle, they want to avoid surgical risks, or they are not fit for surgery[1]. When conservative management is selected, this does not preclude the individual from reconstructive or obliterative surgery in the future[37,48].

Current options for women choosing pessary management for prolapse are either self-care or clinician-based pessary care. Clinician care involves regular review, usually 3–6 monthly, where the pessary is removed and vaginal tissues examined prior to replacing the pessary device[1]. If choosing the self-care option, women are taught to remove, clean and change their pessary regularly[1]. Silicone pessaries are soft and flexible; thus, self-care options are more feasible for this type of device. This enables a TGA class 2A (i.e., ≥60 minutes but ≤30 days) device to be used as per TGA instructions.

When clinician-led care is the chosen model, it is not always feasible for a healthcare practitioner to perform a pessary check every 30 days or less as per the TGA regulations for class 2A devices (eg silicon rings). Class 2B pessaries can be utilised within the current regulatory guidance as they can be left in situ more than 30 days continuously. If 2A devices are being left in situ for more than 30 days continuously they are being used off-label. Evidence and guidelines suggest minimal and acceptable patient risk from having a pessary left in situ for more than 30 days continuously. However, patients need to be informed that this is off-label use and the clinician should clearly document this.

CONCLUSION

The vaginal pessary is an effective management strategy for symptomatic POP. Prior to prolapse management, a patient should always undergo a thorough assessment and discussion on individual risk factors and all available treatment options. When a pessary device is the chosen management strategy, then patient ability to self care or preference of clinician care should guide choice of pessary offered. The TGA device classification needs to be considered and discussed with the patient. If 2A pessaries are used in conjunction with clinician-led care, it is unlikely that a review will be performed every 30 days. Therefore, 2A

devices may be used off-label and the patient should be informed of this deviation from the regulation.

It is likely that future TGA device classifications of commonly used pessaries will change as device suppliers seek amendments to their certifications to align with standard clinical care. For reclassification to be considered by the TGA, the Australian sponsor must submit relevant data to the TGA to increase the length of use. The current TGA regulatory perspective is that the classification of a device reflects the maximum period of use that the manufacturer and sponsor have intended[37].

Currently a large proportion of available pessaries in Australia remain 2A. It is imperative that the clinician providing treatment to the individual has appropriate training in pessary management, adheres to guidelines of clinical practice, and is familiar with the TGA regulations to provide safe and evidenced-based care.

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NEWS

AUSTRALIAN NEWS

As we head into the final quarter of this year, I am proud to report on all we have achieved to date at the Continence Foundation. We run numerous campaigns designed to not only promote awareness and encourage conversations about incontinence but also to remind people where to seek help. The National Continence Helpline (1800 33 00 66) provides a first point of call and is staffed by nurse continence specialists who provide free and confidential advice. Our website (www.continence.org.au) is also an integral source providing extensive resources including fact sheets, videos and bladder and bowel health information for consumers and health professionals.

Joint 31st National Conference on Incontinence and the 4th Functional Urology Symposium

The joint 31st National Conference on Incontinence (NCOI) and the 4th Functional Urology Symposium (FUS) was held at the Adelaide Convention Centre from 14–17 June. Presented by the Continence Foundation of Australia and the Urological Society of Australia and New Zealand, this special joint conference program brought together international and local experts and thought leaders from different disciplines to cover all aspects of the research, assessment and treatment of continence and functional urology related issues, as well as the most current evidence-based best practice.

The conference was a great success, with over 515 delegates attending and so many highlights to share. The 2024 conference will be held in Brisbane from 15–18 May. Details are available on our website.

The Foundation also offered scholarships for rural and remote registered nurses and physiotherapists to attend. Five registered nurses and five physiotherapists were successful, receiving full conference attendance, including networking events, accommodation and flights.

The Great Dunny Hunt

The 2023 Great Dunny Hunt campaign ran from 3 April to 19 June, asking Australians for submissions to find Australia's best public toilets. The public were asked to upload photographs of their favourite public toilet to the National Public Toilet Map (NPTM) website or app, as well as add any updates to any of the facilities, to go into the draw to win one of three $500 Eftpos gift vouchers. This year's hunt attracted over 778 entries, with 1,935 photos and 150 new facilities added, which is an excellent result.

The NPTM is extremely beneficial for the one in four Australians who experience incontinence as well as the 38% of people living with a disability who are experiencing incontinence. The updated map will benefit the thousands of Australians who experience incontinence by identifying nearby toilet facilities that suit their individual needs.

The NPTM currently shows the location of more than 22,000 toilet facilities across Australia. The campaign continues to attract great interest and plays a critical role in raising awareness of the NPTM and incontinence within the community. Please visit www.continence.org.au/great-dunny-hunt and www.toiletmap.gov.au for more information.

World Continence Week (WCW)

World Continence Week (WCW) is an annual international event which aims to raise awareness of continence-related issues. This year, WCW ran from 19–25 June 2023, focussing on the lived experience of incontinence and the impact it can have on people's lives.

One of the highlights of WCW for the Foundation was to have Australian Football League (AFL) icon Robert (Dipper) DiPierdomenico supporting the Foundation by sharing his own lived experience with urinary retention in a video promoting awareness, support and the BINS4Blokes campaign. WCW also heralded the installation of incontinence product disposal bins in 20 of the male public toilets at the Melbourne Cricket Ground (MCG).

The Foundation also hosted a Lived Experience Panel webinar to encourage people to talk about incontinence, raise awareness and understanding, and let people know where to find help and support. A group of panellists discussed their lived experience of incontinence, barriers to seeking help, common misconceptions about incontinence and how to change the narratives around this common condition. Audience members were provided the opportunity to ask questions and provide feedback.

We also launched the first episode of our new podcast series, This is My Story, discussing the lived experience with incontinence. Each episode represents the diverse experiences of five individuals, how their incontinence was identified, how they manage it, the care path they have taken, the value of professional health care, and their tips and strategies for living with incontinence.

National Consumer Continence Survey

The Foundation's annual National Consumer Continence Survey provides valuable feedback that helps the Foundation understand the experience of people who live with incontinence. This includes the extent of public understanding of incontinence and attitudes towards continence health, including preferences for information, treatment and support, as well as health-seeking behaviours and outcomes of interventions. This information can be used to improve products, services and marketing and communication strategies, as well as the Foundation's advocacy activities and government reform.

A recent review of the survey resulted in the decision to spend greater focus on the consumer experience

of living with incontinence and the impacts on carers of people with incontinence. The 2023 survey was undertaken in June, with over 2,000 people participating.

Education

One of our new courses is the Catheterisation Skills Course, a hybrid course designed for registered nurses. The Foundation has been recruiting and training registered nurses around Australia to act as facilitators during the skills workshop. This consists of practice and assessment of indwelling catheters in both male and female mannequins as well as suprapubic catheterisation. Following successful assessment, learners are recommended to undertake supervised catheterisation until their workplace is satisfied with their competency to independently undertake catheterisation.

Specialised Continence Modules for Nurses are 20 stand-alone modules that explore a variety of topics in depth to assist registered and enrolled nurses with their continence care practice. Learners can create their own learning bundle to meet their individualised professional development requirements. Topics include catheterisation, prolapse, the prostate and incontinence, dementia and incontinence and the ageing bladder and bowel. To access the Foundation's online learning system, go to continencelearning.com/login/index.php

Update on the My Continence Care model

In 2019, the Continence Foundation of Australia commissioned the National Ageing Research Institute (NARI) and the lead researcher, Professor Joan Ostaszkiewicz, to develop and test a best practice model of continence care for residential aged care. The purpose of the model is to ensure older people receive evidence-based, person-centred, clinically-informed continence care that is responsive to their individual needs, is safe, is protective of their dignity and optimises their functional abilities. This formed the solid basis of what is now the My Continence Care model.

The My Continence Care model has been developed to enhance governance oversight of continence care, empower individuals receiving continence care, and address gaps in education programs for people providing continence care. The Foundation has been working closely with external stakeholders, including residential aged care providers, to co-design the model. Gaining insight from reference and working group members, consisting of people with lived experience, health professionals and members of the aged care workforce, has afforded the opportunity to make My Continence Care a fit for purpose model for the residential aged care environment.

My Continence Care is a multi-pronged resource program that includes targeted education modules for the multi-faceted aged care workforce, prompts for toolbox talks and corridor conversations in line with the module delivery to promote mentorship amongst My Continence Care champions and peers, and resources to improve reflective practice regarding quality continence care.

Initial piloting at three provider sites commenced in November 2022 and, in keeping with the co-design methodology, was paused following feedback from pilot participants identifying areas that required review and subsequent action. The learnings from this feedback led to work including review and reflection regarding project delivery method, suggestions/additions to the learning modules and an undertaking of further action on the integration of the learning management system to maximise usability.

Re-piloting is scheduled to commence in September 2023. We look forward to sharing the outcomes achieved from the project in the coming months, along with the results from the pilot to support the broader deployment of the program.

Rowan Cockerell
CEO, Continence Foundation of Australia

NEW ZEALAND NEWS

Continence NZ are pleased to be hosting a two-day conference in Auckland on 14–15 September 2023. The conference will cover a range of topics for both adults and children, including managing incontinence in the elderly, recurrent prolapse, bowel management, constipation in children and daytime wetting in children. We are pleased to confirm speakers Dr Giovanni Losco; Liz Childs a pelvic health physiotherapist; Professor Mark Weatherall a geriatrician and more great speakers. A full preliminary programme is available on our website www.continencenzconference.org. We look forward to seeing you there!

World Continence Week 2023

World Continence Week 2023 ran from 19–25 June. This year's campaign focused on bowel health and encouraged a conversation about what 'normal' or healthy bowels look like and when to seek medical advice. Jason Gunn featured in our campaign again this year and it reached almost 45,000 people with tips on how to improve bowel health and information about where to seek support. See the campaign resources at the following link: www.continence.org.nz/pages/World-Continence-Week-2023:-Whats-Your-Number/302

Community and online education

Our popular Toilet Tactic webinar series is running from early August with children's continence nurse Lisa Smith. It covers topics such as bowel and bladder health, toilet training, constipation, bedwetting, daytime wetting, stool withholding, and toilet training for children with additional needs and it's free to register for one or all of our sessions. We will have further webinars for both adults and children running throughout the year. Details of our upcoming webinars are available at www.continence.org.nz/pages/Upcoming-Community-Education/301

With support from the IHC Foundation, Continence NZ has recently developed two new online training modules, Key Continence Training for Schools and Key Continence Training for Disability Support Services. These are free and may be accessed anytime at www.continence.org.nz/pages/Free-Online-Training/295

Research update

Continence NZ is finalising a significant piece of research funded by the New Zealand Lottery Grants Board. The purpose of this project is to make recommendations as to how Continence NZ can most effectively serve those living with incontinence in New Zealand. We have recently completed a series of five focus groups discussing the experiences of our community living with incontinence, the barriers to accessing care and what support is needed for those living with incontinence. We have also gathered further data from those working in continence care in New Zealand, our helpline clients, members and the wider community. We are grateful to all who have contributed to this research, the findings will be released in September 2023.

Laura Fear
CEO, Continence NZ