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

For referencing Franks Z & Krause HG. Pessary management for pelvic organ prolapse: a review of clinical practice and Australian medical device regulations. Australian and New Zealand Continence Journal 2023; 29(3):67-73.

DOI https://doi.org/10.33235/anzcj.29.3.67-73

Submitted 25 March 2023, Accepted 8 August 2023

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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Conflict of interest
The authors declare no conflicts of interest.

Funding
The authors received no funding for this study.

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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