BRAY GROUP LTD

# Portia by Bray

## Vaginal Pessaries Overview

Clinical Review by Bray Group Ltd

Portia by Bray Pessaries

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|---|---|
| **Indication** | Conservative management of pelvic organ prolapse (POP) |
| **Device Type (Portia)** | CE-marked Class IIb medical device (intravaginal pessary) |
| **Document Type** | Internal Content & Communications Approval Document |
| **Prepared by** | Bray Group — Product Management |
| **Regulatory Status** | CE-Marked, compliant with Directive 93/42/EEC |
| **Manufacturing** | Designed and manufactured in Britain under controlled conditions |
| **Clinical Guidelines** | NICE NG123 · RCOG · BSUG · IUGA |
| **Classification** | Confidential – For Healthcare Professional Use Only |

## 1. What is Pelvic Organ Prolapse (POP)?

Pelvic organ prolapse (POP) is a common condition characterised by the descent of one or more pelvic organs — including the bladder, uterus, vaginal vault, small bowel, or rectum — into or beyond the vaginal canal. This occurs secondary to weakness or disruption of the pelvic floor support structures.

POP is common, with some degree of prolapse seen in up to 50% of parous women. Its prevalence increases with age and parity. While not life-threatening, POP can cause significant pain, discomfort, and functional impairment.

### 1.1 What Causes Pelvic Organ Prolapse?

Anything that puts increased or sustained pressure in the abdomen can lead to POP. Common causes include:

- Pregnancy, labour, and vaginal childbirth — the most common causes
- Obesity
- Respiratory problems with a chronic, long-term cough
- Constipation
- Pelvic organ cancers
- Surgical removal of the uterus (hysterectomy)
- Genetics — connective tissue weakness may place some women at increased risk

### 1.2 What are the Symptoms of Pelvic Organ Prolapse?

Some women notice nothing at all. Others may experience:

- A feeling of pressure or fullness in the pelvic area
- A low backache
- Painful intercourse
- A feeling that something is falling out of the vagina
- Urinary problems such as leaking of urine or a chronic urge to urinate
- Constipation or loss of bowel control
- Spotting or bleeding from the vagina

Symptoms depend on which organ is affected. Bladder prolapse may cause urinary leakage; rectal prolapse may cause constipation and uncomfortable intercourse; uterine prolapse is often accompanied by backache and discomfort during intercourse.

### 1.3 How is POP Diagnosed?

Diagnosis is typically made through a medical history and pelvic examination. POP may also be discovered incidentally during a routine pelvic exam (e.g., cervical smear). Additional investigations may be ordered to assess the severity of prolapse and the involvement of multiple organs.

> *Vaginal pessaries are a long-established and proven solution for symptoms associated with pelvic organ prolapse. A healthcare professional will assess the correct size following medical examination. Successful patient fitting rates are high.*

## 2. Clinical Classification of Pelvic Organ Prolapse

### 2.1 POP-Q Classification System

The Pelvic Organ Prolapse Quantification (POP-Q) system is an internationally recognised and standardised method for describing and staging pelvic organ prolapse. It is endorsed and utilised by organisations such as the International Urogynaecology Association and American Urogynaecology Society and is widely adopted in clinical practice and research.

The system provides an objective and reproducible assessment based on specific vaginal landmarks measured in centimetres relative to the hymen.

#### Key Measurement Points

- Aa, Ba — Anterior vaginal wall
- Ap, Bp — Posterior vaginal wall
- C — Cervix or vaginal cuff (post-hysterectomy)
- D — Posterior fornix (if uterus present)

- gh — Genital hiatus
- pb — Perineal body
- tvl — Total vaginal length

### POP-Q Staging

| Stage | Description |
|---|---|
| Stage 0 | No prolapse |
| Stage I | Leading edge remains >1 cm above hymen |
| Stage II | Leading edge within ±1 cm of hymen |
| Stage III | >1 cm below hymen but not complete eversion |
| Stage IV | Complete vaginal eversion |

#### Clinical Relevance

- Supports treatment planning (e.g., conservative management such as pessary use versus surgical options)
- Enables standardised communication across multi-disciplinary teams
- Facilitates consistent outcome reporting in research and audit

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## 2.2 Compartment-Based Classification of Prolapse

Pelvic organ prolapse is also clinically described according to the vaginal compartment involved, a framework widely used in urogynaecology practice and supported by organisations such as International Urogynaecology Association and American Urogynaecology Society.

### Code IIa: Anterior Compartment Prolapse

- Involves the bladder and anterior vaginal wall
- Commonly referred to as cystocele
- May be associated with urinary symptoms (e.g., stress urinary incontinence, voiding dysfunction)
- Continuous use less than and up to 30 days (short term use)

### Code IIb: Posterior Compartment Prolapse

- Involves the rectum and posterior vaginal wall
- Includes rectocele and sometimes enterocele
- Associated with defecatory dysfunction (e.g., incomplete evacuation, need for digital support)
- Continuous use for up to 6 months (long term use)

### Code IIc: Apical Compartment Prolapse

- Involves the uterus, cervix, or vaginal vault (post-hysterectomy)
- Often contributes significantly to overall prolapse severity

- May coexist with anterior and /or posterior compartment defects

> *Clinical Application: Compartment classification helps guide pessary selection (e.g., ring with support for anterior defects; Gehrung or Gellhorn for multi-compartment or apical prolapse) and supports targeted assessment of symptoms and functional impact.*

## 3. Clinical Indications for Pessary Use

Vaginal pessaries represent a first-line, conservative management strategy for POP. They are intravaginal devices, most composed of medical-grade silicone or polymer, designed to restore pelvic anatomy and alleviate symptoms by providing mechanical support to prolapsed structures.

Pessary use is indicated for:

- Symptomatic POP (all stages, depending on device type and fit)
- Patients wishing to avoid, defer, or who are unfit for surgery
- Women in the preoperative period or awaiting surgical intervention
- Postpartum or future pregnancy considerations
- Coexisting stress urinary incontinence (in selected pessary types)

### 3.1 Guideline Recommendations

- National Institute for Health and Care Excellence guideline NG123: Urinary incontinence and pelvic organ prolapse in women (2019) recommends offering vaginal pessaries as a non-surgical option for women with symptomatic POP, with appropriate counselling, fitting, and regular follow-up.
- Royal College of Obstetricians and Gynaecologists (RCOG) and British Society of Urogynaecology (BSUG) support pessary use as part of conservative management, emphasising individualised assessment, correct fitting, and structured ongoing review.
- International Urogynaecology Association (IUGA) highlights vaginal pessaries as a safe and effective management option, including for long-term use, particularly in women who wish to avoid surgery or have significant comorbidities. option, particularly in women with comorbidities or.
- American Urogynaecology Society also recognises pessaries as an evidence-based treatment for pelvic organ prolapse, supporting their role across a range of prolapse stage and patient preferences.

### Key Principles Across Guidelines:

- Individualised fitting by appropriate trained clinicians
- Clear patient education, including self-management where appropriate
- Regular follow-up to assess fit, symptom relief, and complications (e.g., vaginal ulceration, discharge, bleeding)
- Shared decision-making, considering patient preference, comorbidities, and prolapse severity

> *The vaginal ring pessary is prescribed by a Healthcare Professional (HCP) only after consultation and a simple, painless internal procedure. In most cases fitting is performed by an HCP. In some cases, self-management programmes are conducted by medical professionals and operate under their supervision.*

# 4. Types of Pessaries

Pessaries are broadly categorised into support pessaries and space-occupying pessaries, based on their mechanism of action. Pessary selection should be guided by POP-Q stage, compartment involvement, vaginal anatomy and tissue quality, and patient preference, dexterity, and sexual activity.

## 4.1 Support Pessaries

#### FIRST LINE

### Ring Pessary (± Support)

- First-line device in most cases
- Suitable for Stage I–II prolapse
- Variants include ring with support (membrane) for additional apical support
- Favoured due to ease of insertion, removal, and patient self-management

#### MODERATE PROLAPSE

### Shaatz Pessary

- Dish-shaped with central support
- Used for moderate prolapse, particularly when ring pessary is insufficient
- Offers greater structural support while maintaining relative ease of use

#### SELECTED CASES

### Hodge Pessary

- Historically significant but now less commonly utilised
- May be considered in selected cases (e.g., uterine retroversion)

## 4.2 Space-Occupying Pessaries

#### ADVANCED PROLAPSE

### Gellhorn Pessary

- Indicated for advanced (Stage III–IV) prolapse
- Provides strong apical support via suction and mechanical positioning
- Typically requires clinician-led management due to removal difficulty

#### ADVANCED / MULTI-COMPARTMENT

### Cube Pessary

- Uses suction to maintain position
- Effective in advanced or multi-compartment prolapse
- Requires daily removal to minimise risk of vaginal epithelial damage

#### SEVERE PROLAPSE

### Donut Pessary

- Suitable for severe prolapse
- Bulky design provides substantial support
- Less commonly used due to insertion and removal challenges

#### COMPLEX / SPECIALIST

### Gehrung Pessary

- Adjustable, U-shaped device
- Useful in complex or compartment-specific prolapse
- Requires specialist expertise for fitting

## 4.3 Pessary Type Comparison

| Pessary Type | Stage / Indication | Self-Management | Evidence Strength |
|---|---|---|---|
| Ring (± support) | Stage I–II (first-line) | Yes — suitable for self-management | Strongest — RCT & observational data |
| Gellhorn | Stage III–IV (second line) | Difficult — usually clinician-managed | Strong — RCT comparison with ring |
| Shaatz | Moderate prolapse | Moderate | Moderate — observational studies |
| Cube | Advanced / multi-compartment | Daily removal required | Weak — limited comparative trials |
| Donut | Severe prolapse | Challenging | Weak — limited high-quality data |
| Gehrung | Complex / compartment-specific | Specialist only | Weak — specialist use cases |

> *Key Takeaway: There is no single 'best' pessary type supported by strong evidence. Successful use depends on individualised fitting and patient tolerance, with ring pessaries typically used first and other types introduced as needed.*

# 5. Portia by Bray Vaginal Ring Pessaries

Portia by Bray vaginal ring pessaries are support pessaries indicated for the conservative management of pelvic organ prolapse (POP), particularly in women with mild to moderate prolapse

(POP-Q Stage I–II). They provide mechanical support to the vaginal walls and pelvic organs and are widely used due to their tolerability, ease of fitting, and suitability for self-management in selected patients.

## 5.1 Device Description & Regulatory Status

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|---|---|
| **Device Description** | White, smooth, symmetrical, torus-shaped (ring) intravaginal pessary |
| **Regulatory Status** | CE-marked medical device, compliant with Directive 93/42/EEC |
| **Classification** | Class IIb medical device |
| **Materials Available** | Flexible PVC (Polyvinyl Chloride) and Rigid Polythene (LDPE) |
| **Latex Status** | Latex-free |
| **Supplied** | Non-sterile, individually packaged |
| **Manufacturing** | Designed and manufactured in the United Kingdom under controlled conditions |
| **Prescription** | Prescribed by a Healthcare Professional (HCP) following clinical assessment |
| **Replacement** | Recommended maximum in situ period of 6 months |

## 5.2 Materials & Design

| Material | Properties | Wall Thickness |
|---|---|---|
| Flexible PVC (Polyvinyl Chloride) | Softer, more flexible construction. Preferred for patient comfort and ease of self-management. | 12.5 mm |
| Rigid Polythene (LDPE) | More rigid with a narrower wall profile. May provide more secure positioning in some patients. | 7.5 mm |

*Material selection is based on HCP assessment of patient comfort, retention, and clinical need.*

## 5.3 Sizing & Selection

| | |
|---|---|
| **PVC Pessaries** | 16 sizes available — 50 mm to 110 mm diameter |
| **Polythene Pessaries** | 15 sizes available — 50 mm to 100 mm diameter |
| **Size Selection** | Determined by HCP following clinical examination, considering vaginal dimensions, POP-Q stage, and patient-specific factors |
| **Sizing Guide** | A pessary sizing guide is typically used by the HCP to select the most appropriate size |

## 5.4 Clinical Considerations

- Fitting is a simple, non-surgical procedure performed by an HCP
- The vaginal ring pessary is prescribed following clinical assessment and a painless internal examination
- In most cases fitting is performed by an HCP
- Ongoing follow-up should be conducted in line with local clinical protocols
- Self-management may be appropriate for selected patients within structured, HCP-led programmes

> *Unsuitable or requiring caution in cases of vaginal discomfort or poor fit; vaginal bleeding or ulceration; active infection (e.g., vaginitis); pelvic inflammation; inability to comply with follow-up or self-management.*

# 6. Regulatory Classification & Guidance

## 6.1 Class IIb Medical Device Classification

Portia by Bray vaginal ring pessaries are classified as Class IIb medical devices under the MHRA framework, in accordance with the UK Medical Devices Regulations (derived from EU Directive 93/42/EEC and now aligned with the UKCA marking system).

| Classification | Definition & Rationale |
|---|---|
| Class IIa (medium risk) | Devices intended for short- to medium-term use within a body orifice. Invasive devices for continuous or repeated use that do not interact with vital organs in a high-risk manner. |
| Class IIb (higher medium risk) | Devices intended for long-term use (typically >30 days continuous) or those with greater potential physiological impact. Pessaries are classified IIb as they are used over long periods, though they are removed and replaced at regular intervals. |

## 6.2 Duration of Use & Replacement Guidance

UK clinical practice standards:

- Vaginal pessaries may be used long-term provided appropriate follow-up and monitoring are in place
- They should not typically remain in situ continuously without review

| Patient Group | Recommended Management Interval |
|---|---|
| Self-managing | Only through HCP-led programmes for selected patients |
| Clinician-managed patients | Review, removal, and dispose typically every 3–6 months |
| Device replacement | Portia by Bray recommend replacement at a maximum of 6 months. Earlier replacement may be required based on wear, patient symptoms, or clinical findings. The pessary is intended for single-patient use, single use and should |

| Patient Group | Recommended Management Interval |
|---|---|
| | be discarded and replaced with a new device at each replacement interval or if removed for clinical reasons. |

### 6.3 Safety Considerations

Regular removal and inspection are essential to minimise risks associated with long-term pessary use, including:

- Vaginal ulceration or erosion
- Infection (e.g., bacterial vaginosis, vaginitis)
- Bleeding or abnormal discharge

Guidance emphasises the importance of:

- Documented follow-up schedules
- Patient education, particularly around device awareness and care
- Timely review in cases of non-compliance or new symptoms

> *Adjunctive use of topical oestrogen is often recommended in postmenopausal women to maintain vaginal mucosal integrity and reduce complication rates.*

## 7. Follow-Up & Complications Management

### 7.1 Follow-Up Schedule

Regular follow-up (typically every 3–6 months for clinician-managed patients) is recommended to monitor for complications and assess ongoing suitability.

At each review, the clinician should assess:

- Vaginal tissue integrity — signs of ulceration, erosion, or mucosal changes
- Pessary fit — appropriate positioning, comfort, and no evidence of pressure damage
- Symptom control — ongoing relief from prolapse symptoms
- Patient satisfaction and self-management ability
- Need for pessary replacement or change in device type/size

### 7.2 Complications

| Complication | Description | Management |
|---|---|---|
| Vaginal discharge | Most reported side effect; often related to altered vaginal flora | Review for infection; consider topical oestrogen |
| Vaginal ulceration / erosion | Pressure damage to vaginal epithelium | Remove pessary; allow healing; reassess fit; topical oestrogen |

| Complication | Description | Management |
|---|---|---|
| Infection | Bacterial vaginosis, vaginitis | Treat infection; review hygiene practices; consider alternative device |
| Bleeding | May indicate mucosal damage or infection | Urgent assessment; remove pessary; investigate as appropriate |
| Expulsion | Pessary falls out, particularly with increased abdominal pressure | Reassess sizing; consider different device type |
| Urinary symptoms | New or worsened incontinence, voiding difficulties | Reassess pessary position and fit; consider specialist referral |

*Serious complications (e.g., fistula, bowel obstruction, impaction, vaginal cancer) are rare and typically associated with neglected care, prolonged in situ use without review, and poor follow-up compliance.*

## 8. Clinical Evidence — Study Review

The following peer-reviewed clinical studies provide evidence for the safety and efficacy of vaginal pessaries across their principal clinical indications. All studies are PubMed-indexed unless otherwise stated.

| | | | |
|---|---|---|---|
| **82.8%** Successful pessary fitting in Stage IV POP patients (Zhou et al., 2024, n=157) | **>90%** Patient satisfaction following successful fitting (Zhou et al., 2024) | **76%** Achieved continence following pessary use for SUI (Klein et al., 2022, n=376) | **60%** Continuation rate at 12 months for POP (Ontario HTA, 2021) |

### Study 8.1 — Health Technology Assessment: Pessaries for POP and SUI

#### Vaginal Pessaries for Pelvic Organ Prolapse or Stress Urinary Incontinence: A Health Technology Assessment

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|---|---|
| **Publication** | Ontario Health Technology Assessment Series. 2021 May 6;21(3):1–155 |
| **Source** | National Library of Medicine / PubMed / NCBI |
| **PMID** | 34055111 · PMCID: PMC8129636 |
| **Study Type** | Health technology assessment incorporating systematic review of 15 studies |

**Background:**

POP is the descent of pelvic organs into the vagina, often causing vaginal bulging. Stress urinary incontinence (SUI) is urine leakage during activities such as coughing or exertion. This assessment evaluated the effectiveness, safety, cost-effectiveness, budget impact, and patient preferences for vaginal pessaries.

**Results & Conclusion:**

- For SUI: pessaries showed short-term symptom improvement versus no treatment, but no clear long-term advantage over pelvic floor muscle training (PFMT)
- For POP: pessaries improved symptoms and sexual function compared with PFMT-based interventions
- Continuation rates at 12 months were approximately 60%
- Economic analysis suggested pessaries are likely cost-effective for both POP and SUI, particularly for POP
- Patient interviews showed generally positive experiences, with many reporting symptom relief and improved daily functioning
- Barriers included long wait times for fitting and out-of-pocket costs in some healthcare systems

> *Clinical Relevance: Evidence suggests pessaries may provide symptom relief and represent a cost-effective, non-surgical option for POP and SUI, with high patient satisfaction when barriers to access are addressed.*

## Study 8.2 — Pessary Fitting Outcomes in Stage IV POP

### Outcomes of Pessary Fitting Trials for Patients with Stage IV Pelvic Organ Prolapse: A Prospective Study

| | |
|---|---|
| **Publication** | International Urogynaecology Journal. 2024 Jan;35(1):59–67 |
| **Authors** | Ying Zhou, Tianzhu Sun, Aijing Ju, Lan Zhu |
| **DOI** | 10.1007/s00192-023-05594-2 |
| **PMID** | 37542565 · PMCID: PMC10810943 |
| **Study Type** | Prospective study (n=157 patients with Stage IV POP) |

**Methods:**

157 patients with symptomatic Stage IV POP underwent pessary fitting in a hospital setting. Successful fitting was defined as initial placement of a pessary with continued use after two weeks. Outcomes assessed included fitting success rates, patient satisfaction, and improvement in prolapse and urinary symptoms.

**Results & Conclusion:**

- Successful pessary fitting achieved in 130 patients (82.8%)
- Patient satisfaction exceeded 90% for both pessary types used
- Ring pessaries had a fitting success rate of 44.6%; 84.3% of ring pessary patients were able to manage independently
- Prolapse symptoms improved in 90% of patients
- Urinary symptoms improved in 58–93% of patients compared with baseline
- Predictors of unsuccessful fitting: higher number of vaginal deliveries, prior hysterectomy, and increased vaginal introitus/TVL ratio

*Clinical Relevance: High success rates (over 80%) in Stage IV POP patients directly supports the clinical value of ring pessaries as a viable first-line option even in advanced prolapse, with excellent self-management rates.*

## Study 8.3 — Pessaries for Stress Urinary Incontinence: Systematic Review & Meta-Analysis

### The Role of Pessaries in the Treatment of Women with Stress Urinary Incontinence

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|---|---|
| **Publication** | Female Pelvic Medicine & Reconstructive Surgery. 2022 Jun 1;28(6): e171–e178 |
| **Authors** | Klein J, Stoddard M, Rardin C, Menefee S, Sedrakyan A, Sansone S, Chughtai B |
| **DOI** | 10.1097/SPV.0000000000001180 |
| **Study Type** | Systematic review and meta-analysis (10 studies, 376 patients) |
| **Source** | American Urogynaecology Society / PubMed / NCBI |

**Results & Conclusion:**

- 76% of 72 patients reported continence following pessary use, compared with 0% of 86 patients prior to treatment (p<0.0001)
- Urinary Distress Inventory scores decreased by 46.7% (p<0.0001)
- Incontinence Impact Questionnaire scores decreased by 67.8% (p<0.0001)
- Objective measures showed increased urethral closure pressure and reduced pad weight following pessary use
- Adverse events generally decreased with longer-term use (>6 months)
- Conclusion: Pessaries are an effective conservative treatment for SUI, though further large-scale studies are needed

*Clinical Relevance: Significant improvements in both subjective and objective measures of SUI confirm pessaries as an effective non-surgical option with a favourable safety profile that improves over time.*

## Study 8.4 — Pessary Use in SUI: Advantages, Complications, Patient Satisfaction & QoL

### Pessary Use in Stress Urinary Incontinence: A Review of Advantages, Complications, Patient Satisfaction, and Quality of Life

| | |
|---|---|
| **Publication** | International Journal of Women's Health. 2018 Apr 17; 10:195–201 |
| **Authors** | Al-Shaikh G, Syed S, Osman S, Bogis A, Al-Badr A |
| **DOI** | 10.2147/IJWH.S152616 |
| **Study Type** | Literature review — 192 original research articles, reviews, and clinical trials (2000–2016) |

| | |
|---|---|
| **Source** | PubMed / National Library of Medicine / NCBI |

**Results & Conclusion:**

- Evidence supports vaginal pessaries as an effective non-surgical treatment option for SUI
- High reported patient satisfaction rates across the reviewed literature
- Complications are generally minor — vaginal discharge is the most reported issue
- Pessaries provide good symptom control when appropriately fitted and maintained through regular follow-up
- Conclusion: Vaginal pessaries represent an effective and well-tolerated conservative treatment for SUI and should be considered a first-line option

> *Clinical Relevance: High patient satisfaction and a minor complication profile across a substantial evidence base reinforce pessaries as a first-line conservative option for SUI, with complications manageable through good follow-up practice.*

## Study 8.5 — International Urogynaecology Consultation: Pessary Management

### International Urogynaecology Consultation Chapter 3 Committee 1 – Pessary Management

| | |
|---|---|
| **Publication** | International Urogynaecology Journal. Published 28 January 2025. Volume 36, pages 533–550 |
| **Authors** | Rantell A, Abdool Z, Fullerton ME, Gedefaw A, Lough K, Miotla P, et al. |
| **Study Type** | Narrative review by international multidisciplinary group — 540 articles screened, 313 included |
| **Source** | American Urogynaecology Society / International Urogynaecology Journal |

**Results & Conclusion:**

- Pessary fitting success ranged from 41% to 96.6%; continuation rates from 21% to 97.7%
- Predictors of unsuccessful fitting: prior POP surgery or hysterectomy, short vaginal length, wide genital hiatus, and posterior compartment involvement
- Following successful fitting, over 90% reported resolution of vaginal bulge and pressure
- Improvements noted in obstructive voiding (40–97%), urinary urgency (38%), urgency urinary incontinence (29–77%), and SUI (9–45%)
- Serious complications (e.g., fistula, vaginal cancer) were rare and associated with neglected care
- Evidence gaps remain regarding device selection, clinician training, and patient education for safe and effective use

> *Clinical Relevance: The largest and most recent international review confirms pessary use as effective across a wide range of patients, with over 90% symptom resolution. Emphasises the importance of structured follow-up and patient education.*

## Study 8.6 — RCT: Vaginal Pessary vs Pelvic Floor Muscle Training Alone

### Vaginal Pessary in Women with Symptomatic Pelvic Organ Prolapse: A Randomized Controlled Trial

| | |
|---|---|
| **Publication** | Obstetrics & Gynaecology. 2016 Jul;128(1):73–80 |
| **Authors** | Cheung RYK, Lee JHS, Lee LL, Chung TKH, Chan SSC |
| **DOI** | 10.1097/AOG.0000000000001489 |
| **Study Type** | Parallel-group, single-blind, randomised controlled trial (n=276, 12-month follow-up) |
| **Source** | PubMed / National Library of Medicine / NCBI |

**Method:**

Women with symptomatic Stage I–III POP were randomised to pelvic floor muscle training alone (n=137) or pelvic floor muscle training plus a vaginal pessary (n=139). Primary outcomes: changes in prolapse symptoms and quality of life assessed using PFDI and PFIQ questionnaires.

| Outcome Measure | Pessary + PFMT Group | PFMT Alone (Control) |
|---|---|---|
| PFDI score change (POP domain) | −29.7 | −4.7 (p<0.01) |
| PFIQ score change (POP impact) | −29.0 | +3.5 (p<0.01) |
| Study completion rate | 95.0% (132/139) | 93.4% (128/137) |
| Complication rates | Low | Comparable |

**Conclusion:**

Women who used a vaginal pessary in addition to pelvic floor exercises experienced much greater symptom relief and better quality of life improvement, with statistically significant differences and similarly low complication rates. This provides further evidence supporting non-surgical management of POP.

> *Clinical Relevance: This RCT directly validates that adding a vaginal pessary to pelvic floor muscle training produces significantly greater improvement in prolapse symptoms and quality of life — supporting pessaries as a meaningful addition to conservative POP management.*

## Studies 8.7 & 8.8 — Ring vs Gellhorn Pessary Comparison

### Study 8.7: Symptom Relief Outcomes of a Randomized Crossover Trial of the Ring and Gellhorn Pessaries

| | |
|---|---|
| **Publication** | American Journal of Obstetrics & Gynaecology. 2007 Apr;196(4): 405.e1–405.e8 |
| **Authors** | Cundiff GW, Amundsen CL, Bent AE, Coates KW, Schaffer JI, Strohbehn K, Handa VL |
| **DOI** | 10.1016/j.ajog.2007.02.018 |
| **Study Type** | Randomised crossover trial — 134 women, 3 months per pessary type |

### Study 8.8: Ring and Gellhorn Pessaries in POP: A Retrospective Study of 8 Years

| | |
|---|---|
| **Authors** | Jun fang Yang, Jin song Han, Fuli Zhu, Yu Wang |
| **PMCID** | PMC6096563 · PMID: 29978415 |
| **Study Type** | Retrospective observational study — 8-year data on ring and Gellhorn use |

**Combined Results & Conclusion:**

- Both ring (with support) and Gellhorn pessaries were associated with statistically and clinically significant improvements across most PFDI and PFIQ domains
- No clinically significant differences were observed between the two pessary types
- Ring pessaries: most used, easier self-management, first-line choice
- Gellhorn pessaries: used for more advanced prolapse or where ring pessary fitting has been unsuccessful
- Choice between pessary types should be based on patient fit, anatomy, comfort, and preference rather than superiority of one type

| Evidence Type | Key Finding | Clinical Interpretation |
|---|---|---|
| Randomised crossover trial | Both types of pessaries significantly improved symptoms and quality of life. No significant difference between groups. | Both equally effective; choice based on comfort, anatomy, and patient preference |
| Observational / cohort studies | Ring: most used, easier self-management. Gellhorn: used in more advanced prolapse or after ring failure. | Supports clinical practice: ring = first-line, Gellhorn = second line |
| Limited evidence (cube, donut, etc.) | Cube may provide stronger support in severe prolapse. Higher maintenance. Limited comparative trials. | Evidence weak; used when other pessaries are unsuitable rather than proven superior |

> *Clinical Relevance: Ring and Gellhorn pessaries are similarly effective, and clinical decision-making should be driven by individual fit, severity, and patient preference rather than by any claimed superiority of one device type.*

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