

Biomechanical analysis of the pelvic floor and pessary device design

by

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Author's Declaration

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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Abstract

Pelvic floor disorders (PFD) including pelvic organ prolapse (POP) can significantly impact women's quality of life. Pessaries, removable gynecological prosthetic devices, provide mechanical support for temporary or long-term symptom relief of PFDs like POP. To investigate both PFDs and pessaries this thesis focused on two themes: (1) image-based analysis of dynamic pelvic floor contractions and (2) mechanical characterization of pessaries using a combination of experimental and computational methods.

PFDs are commonly assessed by pelvic floor muscle strength during vaginal contraction, often performed through subjective digital palpation or ultrasound imaging. However, vaginal wall movement can be difficult to interpret. An alternative is colpodynamic imaging (CDI), a novel approach that uses dynamic trans-introital ultrasound combined with intra-vaginal pressure and volume monitoring of vaginal distension achieved with an inflated thin bag, to improve visualization of the vaginal wall during contraction.

The goal of theme (1) was to characterize vaginal contraction biomechanics using a CDI approach. As a first step, 3D Slicer was used to segment the bag shape from 2D CDI ultrasound videos captured during contraction from 19 patients with diagnosed prolapse. The bag shape was defined at common 1cm inferior-superior intervals. Several CDI measurements were extracted during voluntary contraction and averaged using ARCGen in MATLAB. The decrease in average patient bag dimensions exhibited consistent trapezoidal trends, an inverse of the pressure changes observed. This represents the first-time dynamic distended pelvic floor contraction has been evaluated, demonstrating good visibility of the vaginal wall and trends in the contraction pressure and shape change. Next steps include increasing the CDI dataset and evaluating patients without prolapse.

With respect to theme (2), mechanical tests are commonly performed on physical pessary designs to characterize their behaviour under load; however, pessary manufacturing is expensive and time consuming. As an alternative, finite element (FE) modelling can provide detailed numerical insight into the response of a pessary under load but to date has seen limited application, with little data available for pessary silicone materials. The goal of the first study of Theme 1 aimed to identify hyperelastic material models for two silicone materials used in pessary manufacturing towards FE analysis of ring with support (RWS) pessaries. It was hypothesized that hyperelastic material models could be identified to sufficiently capture the force and deformation response of multiple RWS sizes under different

boundary conditions and silicone material types (Shore 60A and 40A). To understand the material characteristics of pessary silicone, uniaxial tension and compression tests were performed using “dog-bone” and cylinder test samples. The uniaxial experimental data was fit with Mooney-Rivlin (MR) material models. To ensure the material models characterize the pessary behaviour, data from mechanical tests representing RWS pessary folding and modified 3-point bending were compared to FE recreations of the same tests with the MR materials applied. The FE model results demonstrated excellent agreement in the force-displacement response for both tests with different pessary sizes and silicones.

A second study within Theme 2 aimed to investigate the use of topology optimization to perform a potential redesign of a generic Gellhorn pessary. The goal of this iterative redesign was to improve pessary insertion and removal while optimizing based on expected boundary conditions within the vaginal canal. To achieve the redesign goals, the Gellhorn cap and knob were recreated in Altair Inspire with an open design space between them, allowing maximum stiffness and minimize mass optimization algorithms to create two optimal stem designs. The parameters for these optimizations included boundary conditions to represent folding for insertion and increased pressures due to a Valsalva maneuver. The results of these optimizations were utilized to redesign the Gellhorn while considering features to improve gripping for insertion and removal. These redesigned features were then analyzed in Altair Inspire to ensure they met the needs of the problem space. This resulted in a tripod stem for directional folding, handles on the stem and cap for gripping as well as a cut-out for releasing pessary suction.

Collectively, the three studies represent novel investigations of pelvic floor contraction and pessary device design. All three studies could result in improved pessary treatment by better understanding pelvic floor biomechanics and improving pessary design. Future work on the CDI technique could expand on the developed approach to better understand different pelvic floor impairments as compared to healthy anatomy. Further, the use of topology optimization design methods could be extended to other pessary types as well as adopting different patient dimensions and potential loading conditions.

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Dedication

Dedicated to my husband, Nick, who has provided endless support throughout every twist and turn.

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Chapter 1

Introduction

Pelvic floor disorders (PFD) will affect 25-50% of all women during their lifetime and are characterized by reduced function of the pelvic organ support structures, such as the levator ani and coccygeus muscles which form the floor of the pelvis [1]–[3]. The reduced function of the pelvic floor muscles may stem from neglect or injury [4], resulting in dysfunction such as incontinence, constipation, obstructive micturition, pelvic pain and sexual dysfunction, pelvic organ prolapse (POP) and/or lower back pain [5]. This dysfunction can be categorized as hypotonic or hypertonic, meaning either too weak or excessive muscle tone and action [5]. Hypotonic pelvic floor muscles can result in POP and urinary incontinence, while symptoms of hypertonic muscles are vaginal pain and backache [5]. Risk factors for developing a PFD include obesity, high parity, advanced age, and lifestyle [5].

An important clinical diagnostic assessment of PFD presence and severity is pelvic floor muscle strength, where pelvic floor contraction strength is evaluated, commonly by digital palpation [6]. Weak or absent voluntary contraction, as well as involuntary relaxation, are indicators of underactive pelvic muscle function [1]. A common pelvic floor strength assessment scale is the Modified Oxford Score (MOS), which rates muscle strength from zero (no contraction) to five (strong contraction) [6]. Digital assessment is based on finger sensitivity, training, and experience, and is thus inherently subjective [7]. As a more objective alternative, vaginal probes can be used to measure pelvic floor contraction [8]–[10]. Medical imaging is also an important tool for visualizing PFDs, this includes use of magnetic resonance imaging (MRI) and several ultrasound imaging modalities [5], [11]–[13]. Ultrasound provides cost-effective, safe, dynamic and objective observation of the pelvic floor in a clinical setting [11]–[13]. Transintroital midsagittal ultrasound imaging allows for consistent visualization of the pubic symphysis (PS), bladder, rectum, uterus, and levator plate by trained professionals. However, this imaging modality does not consistently provide good visibility of the vagina.

Current PFD imaging is limited to the vagina and surrounding structures in their non-distended state. However, the vagina is a collapsed potential space which stretches and distends to fulfill several anatomical functions including supporting surrounding organs, as well as enabling arousal, intercourse, and childbirth [14]–[18]. To better understand the functionality of the vagina at its distended state, colpodynamic imaging (CDI) was developed to combine vaginal distension, intra-vaginal pressure and volume monitoring, as well as vaginal wall visualization using real-time transintroital ultrasound

imaging. CDI has previously been used to evaluate the distended vagina using static ultrasound image metrics, such as shape [19]. However, CDI has not yet been used to observe the dynamic changes of the pelvic floor during contraction while under distention. Understanding dynamic transition periods may provide important information about the vaginal shape and function when performing clinical maneuvers, such as pelvic floor contraction.

POP, one type of PFD, is characterized by the descent of one or more pelvic organs (e.g., uterus, bladder, vaginal walls, rectum), the symptoms of which include vaginal bulging, pelvic pressure or heaviness, pain, and urinary or fecal incontinence (Figure 1) [1], [20]. Treatments for POP include pelvic floor physiotherapy (with limited application), surgery, and use of pessaries [6]. In 1997, 226,000 women in the United States underwent surgery for POP, costing Medicare around \$1 Billion [21], [22]. Alternatively, vaginal pessaries are removable gynecological prosthetic devices for temporary or long-term symptom relief, with a properly fitted pessary providing the same relief as surgical treatment [6], [23]. As a result, reasons such as future plans to conceive, post-operative restrictions, comorbidities, and surgical risk can lead patients to choose pessaries over surgery [6].

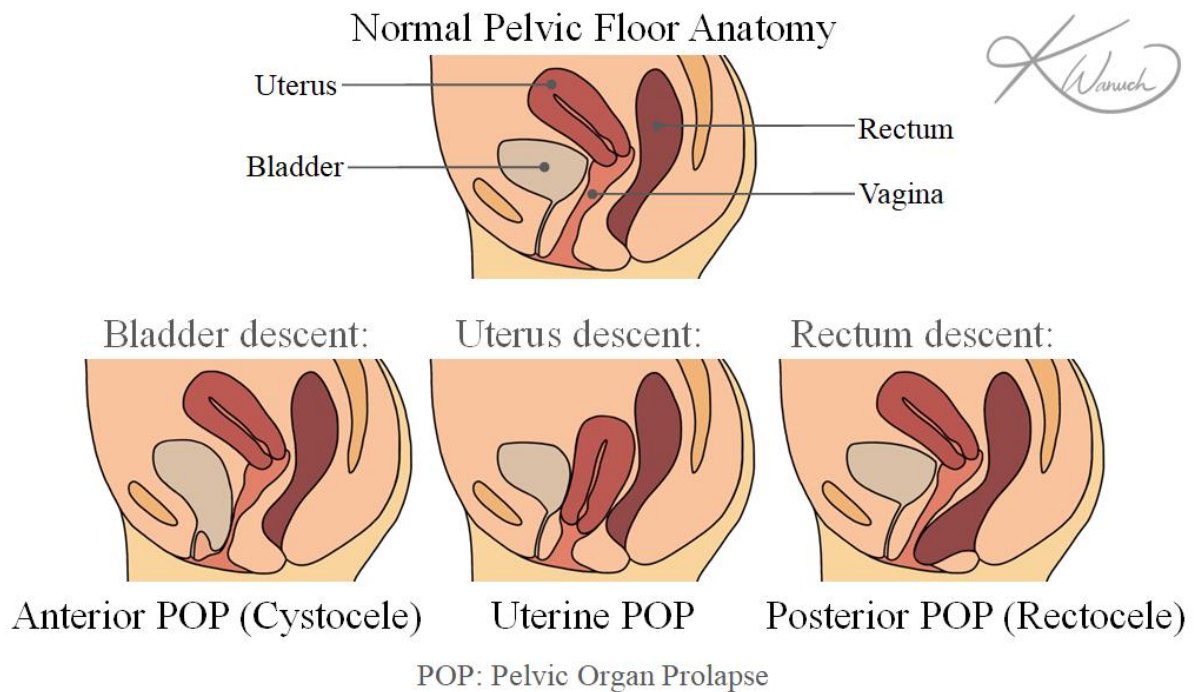


Figure 1: Types of Pelvic organ prolapse (POP); the POP type is characterized by the descent observed, namely bladder descent results in anterior POP (cystocele), uterus descent results in uterine POP, and rectum descent results in posterior POP (rectocele).

Pessaries come in many different shapes and sizes, the most common of which are the ring-with-support (RWS) and Gellhorn (Figure 2); the RWS is often the first line of treatment, only moving to other pessary shapes if a ring cannot be retained [6]. By resting on pelvic floor structures, including the levator ani muscle, obturator internus muscle, and perineal membrane, pessaries counteract gravity, inertial forces, or increased intraabdominal pressure (IAP) during coughing, laughing, sneezing, or heavy lifting [24], [25]. All pessaries are fit through a qualified healthcare provider-performed finger measurement as well as trial and error pessary insertion with Valsalva or bearing down maneuvers to test pessary fallout [6]. This trial and error method is highly clinician dependent and has reported success rates as low as 41% [1]. Improper fitting can be painful for patients, resulting in expulsion, discomfort or complications such as vaginal sores and bleeding [26]–[28]. Complications can be mitigated with a correctly fitted pessary that provides the support required to counteract the pressure on the pelvic muscles; however, there is currently limited understanding of how pessaries respond and provide support to varied loading conditions associated with PFDs. Limited understanding of how pessaries deform under different loading conditions is a barrier for innovation in pessary design.



Figure 2: Ring-with-support (left) and Gellhorn pessary design (right)

Previous work has demonstrated the value of experimental tests to evaluate the mechanical properties of ring pessaries while being folded in half, an important property for patient satisfaction and use. Folding tests can evaluate pessary designs under simulated mechanical forces required for pessary insertion and removal [29]. This is important for RWS pessaries to allow self-management, which can increase patient satisfaction during pessary use, improving quality of life [30]. Another mechanical test to understand pessary behaviour evaluates RWS deformation through modified 3-point bending. This secondary bending scenario represents a variation on well established 3-point bending tests while incorporating sliding between the pessary and test fixtures. This test represents a different method of load application to capture the pessary response to center-applied loads.

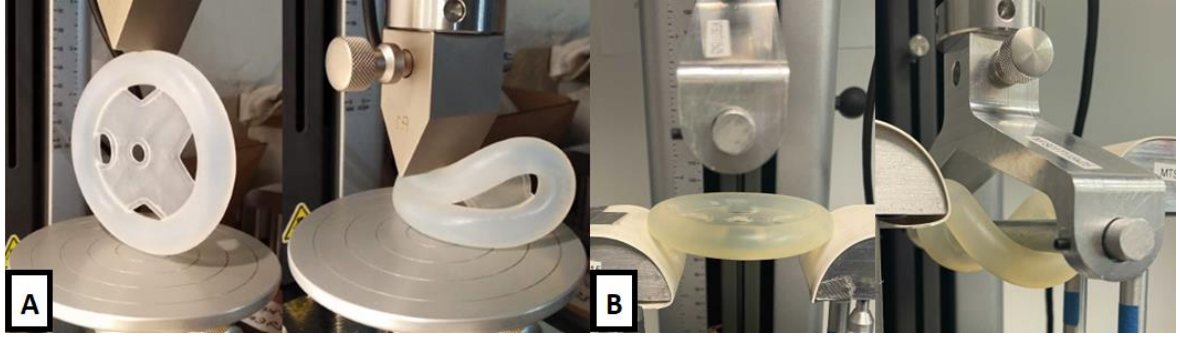


Figure 3: (A) Pessary folding test and (B) Pessary modified 3-point bending test.

Mechanical tests to date have been performed on physical pessaries to characterize their behaviour under load (Figure 3). However, pessary manufacturing can be time consuming and expensive. For example, manufacturing customized pessaries through cocoon moulding requires the manufacture of sacrificial moulds, silicone injection, and time to solidify [31]. Once fully solidified the silicone pessary is removed from the mould and placed into a laboratory oven for material postcuring [31]. All these stages take a significant amount of time. As a result, it is not feasible to manufacture and mechanically test all possible pessary dimensions and design changes during pessary iteration, leading to a need for alternative approaches such as computational finite element (FE) modelling. Simulating the mechanical tests through FE modeling can provide expedited results for pessary parameter and design analysis [32]. Yet, to date, there has been limited application of FE modelling to examine pessary designs and deformation under load.

Evaluating pessary designs using FE modeling has four main requirements: pessary geometry, mesh, material properties, and boundary conditions (BCs) [32]. The pessary geometry and mesh can be created using computer aided design (CAD) software based on the respective pessary design. The material model, defining the silicone material deformation in response to load, however, provides a challenge as the silicones commonly used for pessary manufacturing have not previously been characterized for use in FE models. As such, independent characterization and fitting of the silicone tension-compression material behaviour is needed using mechanical testing. Finally, the boundary conditions can be setup to match the mechanical tests performed for folding and intravaginal pessary conditions, to validate the FE model against the force-deformation response from the physical tests.

Pessary designs have stagnated with legacy designs like the Gellhorn remained relatively consistent since mentions in medical journals as early as 1944 [33]. This stagnation is evidenced by a review of the Gellhorn pessaries commercially available to patients today, all of which exhibit the same legacy

design. These pessaries exhibit weaknesses in their design which could be addressed through a functionally focussed redesign but have been overlooked to date. For example, Gellhorn pessary insertion and removal are challenging if not impossible for patients to perform independently, meaning they must attend frequent appointments for pessary removal, cleaning, and reinsertion by a medical professional [6]. This represents a significant shortcoming as self-management can increase patient satisfaction and quality of life [30]. Current commercially available pessaries are also limited given the finite sizes in which they are produced. Additive manufacturing (AM) presents a valuable opportunity for addressing individual patient needs through customized pessaries [34], [35]. Therefore, a redesign of the Gellhorn pessary which allows for AM could significantly improve patient treatment outcomes.

Topology optimization represents a valuable tool within the engineering design process. The purpose of topology optimization is to determine the optimal structure which fulfills defined design requirements and restrictions [36], [37]. For example, if the optimization goal was to maximize the stiffness of a beam which experiences a known load while minimizing the material mass, the topology optimization would determine the ideal beam shape which would deflect minimally due to the load. This design tool differs from analysis methods, such as FE analysis, because rather than assessing hypothesized designs it allows for design generation. Topology optimization could be a valuable tool for pessary iteration to minimize the required design iterations while ensuring each re-design behaves as intended based on what is known of the pelvic floor environment.

There is a significant knowledge gap surrounding the properties of the distended vaginal canal as well as the material and mechanical properties of pessaries. As a result, this thesis sought to investigate these areas using FE analysis and ultrasound imaging analysis processes to improve the knowledge surrounding vaginal behaviour and pessary properties. This knowledge will serve to better inform pessary development for PFD and POP treatment; therefore, a pilot investigation into redesigning a generic Gellhorn pessary design using topology optimization tools was also performed.

Chapter 2

Background

2.1 Female pelvic floor anatomy

Two hip bones, each composed of an ilium, ischium, and pubis, form the pelvis [2]. These two bones are fused posteriorly to the sacrum and form the pubic symphysis (PS) by being fused to one another anteriorly (Figure 4) [2]. This somewhat circular shape forms an opening known as the inferior pelvic outlet which is closed by the structures of the pelvic floor [2]. The female pelvis has a wider diameter and more circular shape than the male pelvis, allowing for female pelvic function (e.g., coitus, childbirth) but predisposing it to pelvic floor weakness [2]. The primary PFMs are the levator ani and coccygeus muscles which form the pelvic diaphragm [2]. The bulk of the levator ani muscles is the pubococcygeus, the medial portion (pubovisceralis) of which is composed of various subdivisions which attach to the urethra (pubourethralis), vagina (pubovaginalis), anus (puboanalis), and rectum (puborectalis) [2], [38]. One division of interest is the puborectalis, which forms a sling which wraps around and behind the anorectum from the anterior pelvis, forming the levator hiatus [2], [38]. The urethra and vaginal walls while supported by the pelvic floor musculature are also supported by endopelvic fascia [38]. The endopelvic fascia is a fibrous connective tissue that surrounds the vagina and laterally attaches to the arcus tendineus fasciae [38]. The arcus tendineus fasciae pelvis provides support as it is a tensile structure which acts as supportive cables and appears as a sheet of fascia as it fuses with the endopelvic fascia and connects to the levator ani muscles [38].

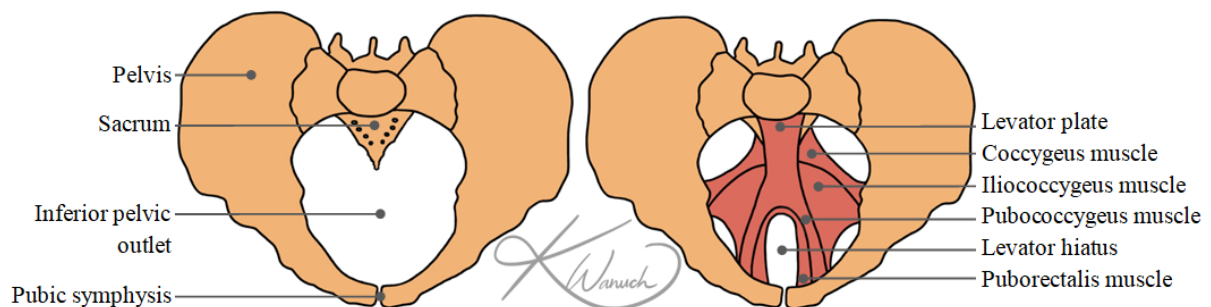


Figure 4: Bony structure and muscles of the female pelvic floor

Just above and supported by the pelvic floor are the bladder, uterus, and rectum [2]. In a standing position the rectum and two thirds of the vagina are supported by the levator plate which is horizontal [2]. Extending from the bladder and uterus respectively are the urethra and vagina which pass through

the levator hiatus to their external introitus, along with the rectum [2]. Moving in an anterior-posterior direction the external female introitus are the urethra, vaginal opening, and anus. The perineal body lies between the vagina and anus, just below the vagina and uterus, and is a fibromuscular structure which contains muscle, elastic fibers, and nerve endings [2].

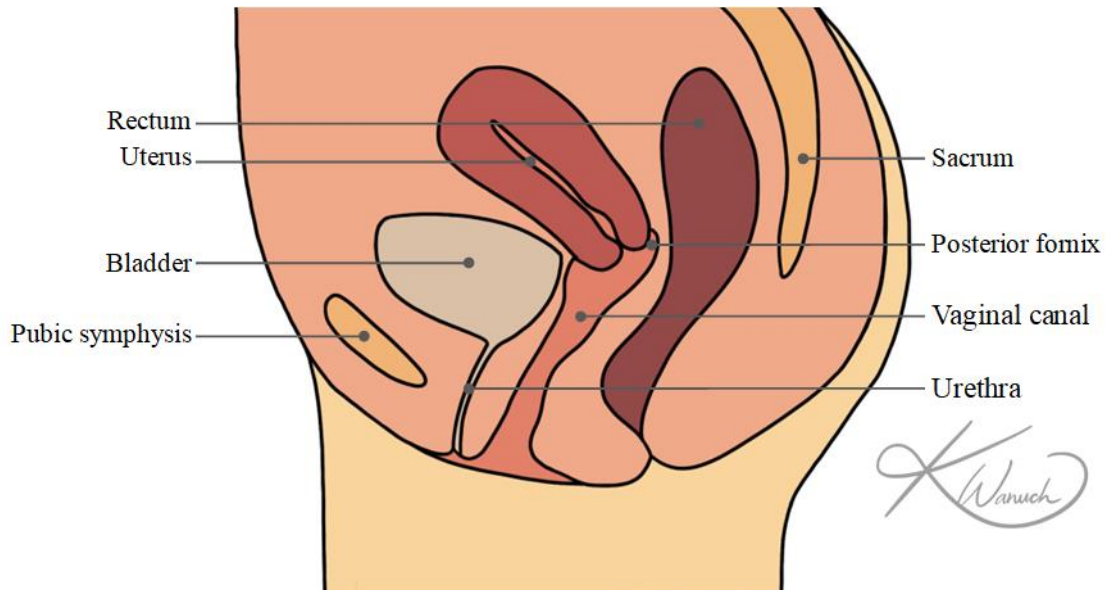


Figure 5: Midsagittal view of female pelvic anatomy

The vagina is a fibromuscular tube which as mentioned extends from the vaginal introitus to the cervix where it attaches to the uterus [39]. Where the cervix and vagina meet the posterior edge of the vagina forms the posterior fornix, a recess behind the cervix [40]. The internal surface of the vaginal canal is covered in an epithelium with folds, known as rugae, atop a loose layer of connective tissue on the vaginal muscles [39]. The shape of the vaginal canal is that of a curve, the anterior portion of which is adjacent to and supports the bladder, while the upper portion lies parallel to the levator plate and connects to the uterus [39]. Overall, the vagina is approximately 8.4 cm long (anterior wall is 7.6 cm and posterior wall is 8.8 cm) with its anterior and posterior sections at 129 degrees from one another [39]. Vaginal shapes are grouped into five types: conical, parallel sides, heart, slug, and pumpkin seed [41]. Vaginal surface area is $87.5 \pm 7.8 \text{ cm}^2$ on average [41]. Among the five shapes, there is no significant difference in surface area and no correlation with parity or the introital diameter [41].

Finally, it is important to recognize the functionality of the vagina. In fact, the vagina is a collapsed potential space which stretches and distends to fulfill several anatomical functions, these include supporting surrounding organs, as well as enabling arousal, intercourse, and childbirth [14]–[18].

During female arousal (without intercourse) the anterior vaginal wall lengthens allowing the uterus to raise [14]. Furthermore, during sexual excitement the vaginal and clitoral length and diameter increase [15]. The vaginal canal must also distend to accommodate intercourse [14], [15]. Distension is also required during vaginal delivery to allow for the baby to pass through the canal and out of the introitus [18], [42]. In fact, pregnancy has been found to result in several changes to the vaginal canal including an increased ability to distend, decreased stiffness, and decreased maximal stress [42].

2.2 Pelvic floor disorders (PFDs)

PFDs represent several conditions including POP, urinary incontinence (UI), and fecal incontinence (FI) [3], [43]. UI is the involuntary loss of urine, and includes subtypes of stress UI, urge UI, mixed UI, and overactive bladder syndrome [43]. FI, sometimes referred to as anal incontinence, results in the involuntary passage of gas, mucus, liquid, or solid stool [43]. Reduced pelvic organ support structure function is characteristic of PFDs, this could include impairment of the levator ani or coccygeus muscles which form the pelvic floor [1], [2]. Reduced function of the PFMs may be caused by neglect or injury, resulting in incontinence, constipation, obstructive micturition, pelvic pain and sexual dysfunction, POP, and/or lower back pain [5]. Muscular dysfunction could be hypotonic or hypertonic, meaning either the muscles are too weak or there is excessive muscle tone and action [5]. Hypotonic PFMs can result in POP and UI, while hypertonic muscles cause vaginal pain and backache [5]. Risk factors of PFD include obesity, high parity (five or more pregnancies), advanced age, and lifestyle [5].

PFDs affect patients' daily activities, sexual function, and exercise, as well as negatively impacting their emotional and psychological state [43]. In fact, these conditions can negatively impact body image and sexuality, as a result delayed diagnosis often occurs as women are embarrassed to discuss their condition [43]. Data from the 2005-2006 National Health and Nutrition Examination Survey (NHANES) allows for estimates of symptomatic PFD prevalence [44]. The overall prevalence of symptomatic PFDs is 23.7%, with the three primary PFDs having individual prevalence of 15.7% for UI, 9.0% for FI, and 2.9% for POP [44]. These statistics represent more symptomatic individuals to capture the population most likely to seek treatment [44]. The estimated cost of urge urinary incontinence and overactive bladder syndrome in the United States was \$65.9 billion in 2007, with a projected increase to \$82.6 billion in 2020, which may further increase with the inclusion of SUI [43].

The prevalence of PFDs significantly increases with age, as well as being correlated with poverty, body-mass-index (BMI), and parity [44]. This is confirmed by a reported UI prevalence from 8.5% to 38% based on age, parity, and condition definition [38]. As the population ages there is an expected

increase in the prevalence of PFDs, especially among the baby boomer generation [4]. However, projections also seem to indicate increases in PFD prevalence independent of baby boomer generation aging [45]. Epidemiological literature supports that UI and FI increase with age [43], [44]. Additionally, anterior, posterior, and apical POP also increase with age [44]. Reason for the age-related increase in PFDs include connective tissue and neuromuscular changes observed during aging, or comorbidities which are common in older adults such as obesity, diabetes, and pulmonary disease [44]. As life expectancy continues to improve the prevalence of PFDs is likely to increase, impacting individuals but also the healthcare system as a whole [43].

2.2.1 Pelvic organ prolapse (POP)

POP is characterized by descent of the anterior or posterior vaginal wall, the vaginal apex, or all three [40]. POP results from the pathological descent of female pelvic organs (i.e., bladder, uterus, small or large bowels, rectum), into the vagina, uterus, or both, and can result in protrusion of the vaginal canal, uterus, or both [4]. Mechanisms, severity, and pattern of prolapse are unique across patients, and understanding these differences could be valuable in improving POP management.

The current understanding of POP pathomechanics is thought to be excessive caudal movement of pelvic organs caused by a loss of support to the vaginal walls [25]. Causes of prolapse include vaginal delivery, trauma to the pelvic floor musculature, hysterectomy, chronic straining, advancing age, menopause, and increased BMI [4]. With loss of support to the vaginal walls due to these factors, the normal caudal forces on pelvic organs such as gravity, and IAP from coughing or laughing cause excessive movement, resulting in reduced pelvic floor functionality [25]. Pelvic viscera support is provided by the levator ani muscle complex which consists of the pubococcygeus, puborectalis, and iliococcygeus muscles. Damage to these muscles or endopelvic fascia can impact muscle tone leading to weakening of the levator plate and eventual prolapse [4].

To quantify pelvic organ support and stage of POP, the Pelvic Organ Prolapse Quantitation (POP-Q) System was developed with indications ranging from stage 0, normal support, to stage IV, a complete inversion of the total vaginal length [4], [46]. This system classifies the amount of prolapse by measuring the descent of segments of the anterior, posterior, and apical portions of the vaginal wall relative to the vaginal hymen during the VM (Figure 6) [4], [46].

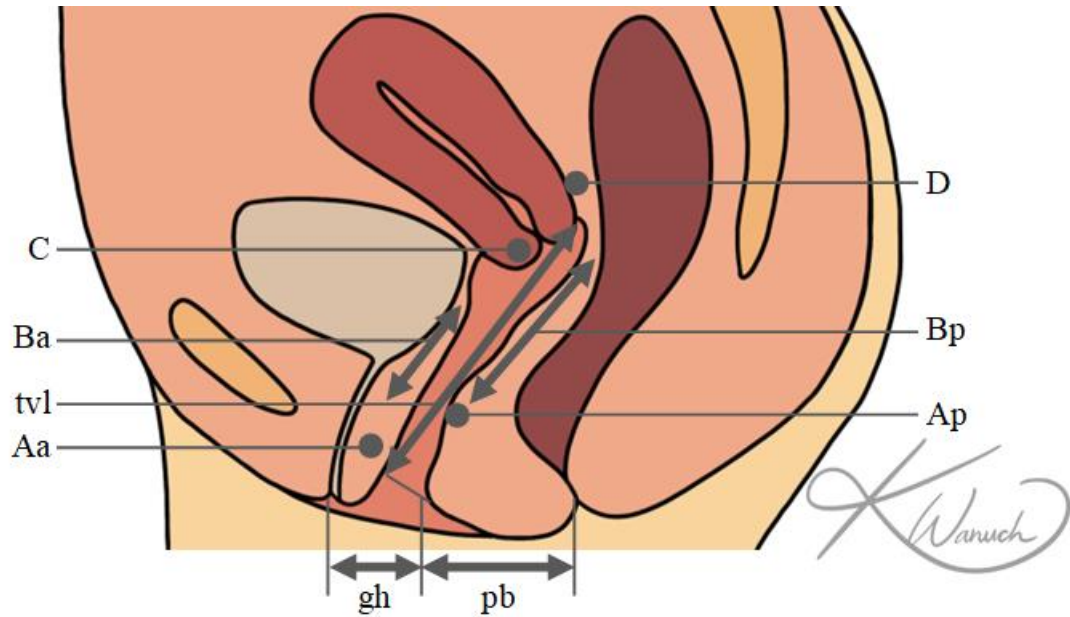


Figure 6: Pelvic Organ Prolapse Quantitation (POP-Q) measures, these indicate anatomic landmarks and measures such as the cervix (C), posterior fornix (D), genital hiatus (gh), perineal body (pd), total vaginal length (tvl), A-anterior (Aa) and A-posterior (Ap) are 3 cm superior to the hymenal ring, B-anterior (Ba) and B-posterior (Bp) are the lowest prolapsed point (between Aa/Ap and cervix) [47].

Symptoms of POP can include vaginal bulging, pelvic pressure or heaviness, pain, and urinary or fecal incontinence [1]. Symptomatic POP is commonly treated using expectant management (observation), pessaries, or surgical repair [4]. In the United States up to 200 thousand surgical repairs are conducted annually [25], [48]. However, recurrence is a major problem in this population, with up to 29% of women requiring re-operation [25], [38]. While surgical correction is common, reasons such as plans to conceive, post-operative restrictions, comorbidities, and surgical risks can lead women to choose nonsurgical interventions or forgo treatment altogether [6]. Alternatives to surgery include pelvic floor physiotherapy and pessaries [6]. Pelvic floor physiotherapy can be employed for minor pelvic floor conditions to achieve limited anatomic and symptomatic improvements [6]. For more severe prolapse pessary prosthetic devices are used for temporary or long-term symptom relief [23]. In fact, if pessary use is successful, successive surgery may only provide marginal improvement [49].

2.3 Pelvic floor assessment

2.3.1 Valsalva

The Valsalva maneuver (VM) is used to assess UI and POP, to evaluate the maximum decent of the pelvic organs with the rise in IAP [50]. The increase in intra-thoracic pressure and IAP occurs due to trunk muscle contraction resulting in the VM, this occurs automatically during coughing, sneezing, defecation, lifting, and parturition [50]. This maneuver is also performed during pessary fitting to assess whether the pessary will remain in place throughout daily activity and automatic IAP increases [6].

2.3.2 Pelvic floor contraction

Contraction consists of a squeeze maneuver where the PFM contract to narrow the genital hiatus. This maneuver is critical for physical examination of the PFM strength and assessing pelvic floor impairment [6], [51]. Contraction is thought to be performed by the shortening of the puborectalis muscle sling, comprised of two limbs, in the dorsoventral-cranial direction, narrowing the genital hiatus, compressing the structures which run through it, and anteriorly lifting the anal canal [52], [53]. From inspection PFM contraction results in muscle fiber shortening in a sagittal direction, in particular the levator muscle [53]. The levator muscle at rest is funnel-shaped then flattens to a plane in contraction, resulting in the ventral-cranial shift of the rectum, vagina, and urethra [53].

Evaluating PFM strength is an important parameter for assessing impairment as well as analyzing pelvic floor training both clinically and scientifically [51]. There are four methods by which PFM contraction can be evaluated: digital assessment, EMG perineometry, pressure perineometry, and perineal ultrasound [51]. The standard method for clinical evaluation of pelvic muscle strength is digital palpation of the muscles [6]. Digital assessment involves instructing the patient to perform a “Kegel contraction” with a physician’s fingers in her vaginal canal [6]. Some coaching may be needed to ensure the maneuver is performed correctly, after which the patient is instructed to squeeze as strongly as possible for as long as the patient is able [6]. The clinician will then assign a score to the contraction on a scale, like the Modified Oxford Score (MOS) where zero means no contraction and five means a very strong contraction [6], [51]. Another assessment method which is often used for pelvic floor training is the use of perineometry, where a specialized device such as a vaginal probe or balloon catheter is inserted in the vaginal canal to objectively measure the contraction strength [51]. Finally, ultrasound can be used to assess changes during contraction, such as the movement of the bladder neck or changes in the 2D levator hiatal AP diameter [12], [51].

2.3.3 Colpodynamic imaging (CDI)

Current PFD assessments and imaging as described are limited to evaluating the vagina and surrounding structures in their non-distended state. However, the vagina stretches and distends to fulfill its anatomic functions: supporting surrounding organs, and enabling arousal, intercourse, and childbirth [14]–[18]. To evaluate the vaginal canal with consideration for its anatomical functionality of distention CDI combines vaginal distension, intra-vaginal pressure, volume monitoring, and real-time ultrasound imaging [19]. These features are combined using a water-filled ultrathin bag in the vaginal canal, which is filled through a catheter and monitored using pressure transducer, and the anatomy is then imaged using transperineal ultrasound [19]. Static measures from 3D transintroital ultrasound of CDI were shown to have excellent reliability, with strong correlation to measures from physical examination, the current gold standard [19]. The benefits of this combined system are that it allows for assessment of the vagina during distention, as well as improving the visibility of the vaginal walls in the ultrasound.

Unfortunately, the current use of the novel CDI system has been limited to static image metrics to evaluate the distended vagina [19]. Use of CDI to characterize static shape and function misses critical dynamic transition periods which may provide important information about the vaginal shape and characteristics when performing clinical maneuvers, such as contraction. As a result, further work is needed to evaluate the CDI system through the capture of 2D ultrasound videos which will provide valuable insight regarding the dynamic motion of the distended vagina during pelvic floor maneuvers, namely VM and pelvic floor contraction.

2.4 Pessaries

Typically, long-term pessary use is chosen by women over the age of 65 and women with significant surgical risks, or both [6]. Pessaries are also used in a clinical setting to simulate post-surgical support to evaluate the optimal patient treatment [6]. While pessaries were previously manufactured using latex and rubber, medical-grade silicone is now used for pessary manufacturing as it results in a durable product that does not produce foul-smelling discharge in the vagina [6]. The most common support pessary is the RWS, while the Gellhorn is the most common space-filling pessary [54]. The RWS is often the first-line treatment choice as it can be effective regardless of the type of POP and can allow patients to independently manage their pessary (insertion, removal, cleaning, etc.) [6]. Whereas the Gellhorn is frequently used as a second-line option when a RWS cannot be retained by the patient [54].

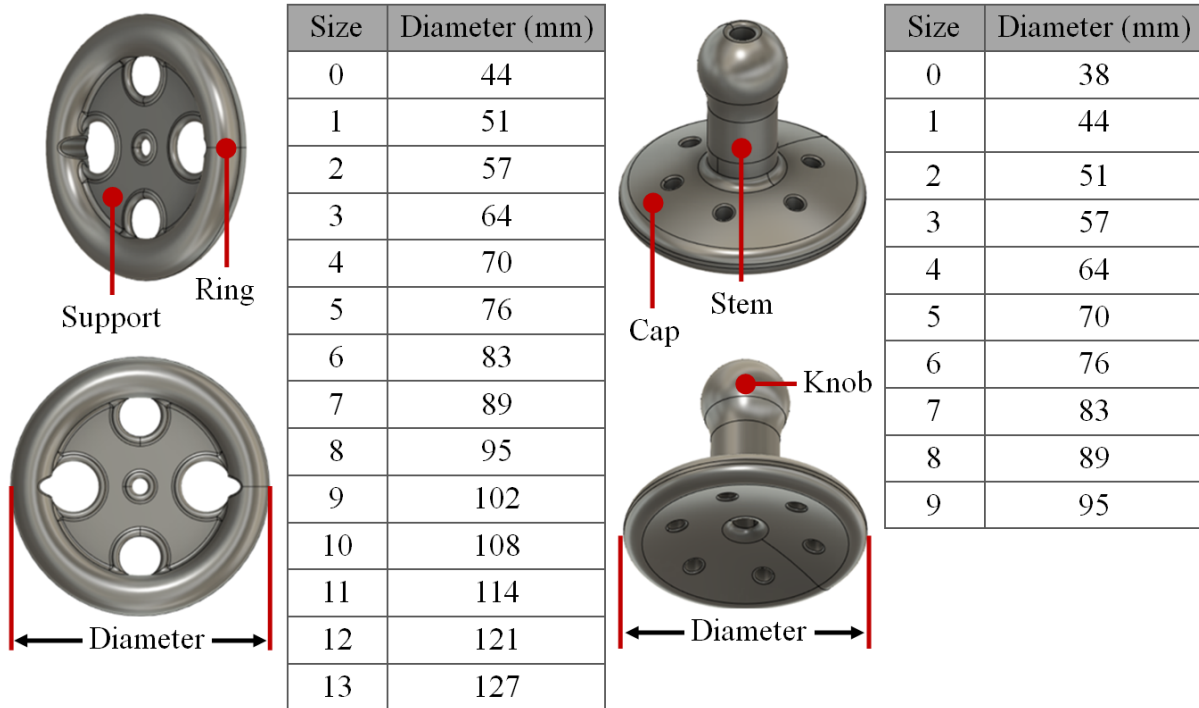


Figure 7: Standardized ring-with-support (left) and Gellhorn (right) pessary parts and sizing.

Due to an incomplete understanding of the mechanisms of pessary support, most physicians use trial-and-error methods to determine the optimal pessary size and shape from a wide selection of standard commercially available sizes. Unfortunately, unsuccessful fittings with recurrent incontinence problems are common [29], [55]. In fact, the current trial and error fitting method has reported success as low as 41% [1]. It is believed that the smallest pessary which will not fallout is optimal for patients as this avoids complications such as wear on the vaginal walls [6]. However, for a pessary to be maintained the vaginal chamber must be wider than the opening, such that the introitus and perineal body retain the pessary [6]. A larger introitus, such as 4 cm and wider, is less likely to comfortably retain a pessary, as a larger pessary is needed [6].

2.4.1 Pessary fitting

The trial-and-error method for pessary fitting begins with a clinician placing two fingers into the vagina and spreading them as widely as possible [6]. If while attempting to remove their fingers the clinician must close their fingers that patient is likely to be comfortable during pessary retention, as the vaginal chamber is larger than the opening [6]. However, if the fingers do not need to be closed for removal, any pessary attempted will likely dislodge when the patient stands or walks [6]. To choose a RWS,

Marland, or Gellhorn pessary the pessary diameter chosen by the clinician should be approximately the same width as the vaginal canal [6]. Once inserted the patient should not feel the pessary, if the patient experiences discomfort it will likely increase over time so it should be removed immediately [6].

After inserting a trial pessary, the patient is instructed to cough vigorously dislodging the pessary if it is too small, if the pessary remains in place the patient is instructed to cough again while the physician pulls at the edge of the pessary [6]. If the pessary dislodges with minimal force from the clinician, the pessary is too small [6]. If the pessary remains inserted throughout these tests with the patient in a supine position, they will then be repeated while standing [6]. If the pessary remains successful and comfortable it is likely the correct one, but a final test should consist of the patient straining while sitting on a toilet to assess whether the pessary would dislodge during a bowel movement [6]. If the pessary falls out during any of the tests, they are repeated with a larger or different shaped pessary [6]. Patients often experience vaginal irritation, especially if more than one pessary was placed and removed during a fitting, this is a normal result of the manipulation throughout the examination and testing [6].

Once a fitting pessary is found the patient is often sent home with the pessary in place and instructed to wear it for 1-2 weeks, on their next appointment the patient is questioned regarding quality-of-life improvement [6]. If the patient's symptoms have improved, they are given the opportunity to learn how to self-manage their pessary (in the case of the ring and RWS) [6]. If a patient masters self-management, they generally only require an annual visit if they are willing to remove their pessary frequently, as recommended nightly [6]. If a patient leaves their pessary out a minimum of 1-2 nights per week vaginal ulcers or abrasions are generally avoided [6]. If a patient cannot or will not manage their own pessary, they are scheduled every 2-3 months for pessary removal, cleaning, and replacement, as well as vaginal inspection and irrigation [6]. Satisfaction and continuation of a pessary use is often best when the treatment plan is simple and inexpensive [6]. Generally true complications result from non-compliance and lack of follow-up, leading to vaginal ulcerations, abrasion, or migration into adjacent viscera [6]. Common minor issues include finding occult stress UI, pessary-related vaginal discharge, minor vaginal spotting, spontaneous expulsion, and Pap test abnormalities from inflammation [6].

Unsuccessful pessary fitting has been associated with a vaginal length below 8 cm and a history of hysterectomy, while a genital hiatus to vaginal length ratio below 0.9 indicated success for patients with hysterectomy [55]. Large vaginal introitus width (6-7 cm) or a short vaginal length could be predictive of a failed fitting [56]. This may be due to a shorter vaginal length or narrowed vaginal apex causing difficulty retaining a pessary in the mid-region of the vagina above the levator plate. Posterior wall

prolapse has been predictive of unsuccessful fitting possibly due to rectocele complexity [57]. Pessaries are believed to typically use the levator plate for support and many studies have thought their main mechanism of support to be anterior, explaining why posterior wall prolapse is predictive of poor fitting, however, more evidence is needed [1]. Prior prolapse surgery has been studied as a potential predictor for successful fitting and some research suggests that prior prolapse repair or hysterectomy can narrow the upper vaginal cavity, altering the pelvic architecture, leading to failed fittings [58], [59]. Currently there is no association between stage of prolapse and successful fitting, except with complete inversion [56], [58], [60]–[62]. In a general practice setting (i.e., clinics) predictors of unsuccessful pessary fitting were age, BMI, and underactive PFM [1]. It is theorized that underactive PFM and BMI indicate the condition of the pelvic floor, where higher BMI increases pelvic pressure which may impede pessary fitting and lack of PFM strength may indicate poor support [1].

2.4.2 Pessary action

The pessaries available on the market differ in their positioning and orientation in the body, and as a result the mechanism of their support. The most common pessary types, the ring and Gellhorn are composed of a disc that prevents descent of the pelvic organs [29]. However, the Gellhorn and ring differ in how they are situated and provide support [29]. Ring pessaries, the most common shape composed of a silicone ring, are most effective for first or second-degree POP [63]. Benefits of the ring include allowing penetrative intercourse, due to its open structure, and that it can be retained in the vagina for long periods of time; however, it is possible for the cervix to protrude through its open structure (this is mitigated with the RWS) [63]. Ring pessaries have been thought to work by resting on the posterior fornix and against the posterior aspect of the PS, providing support by elevating the superior vagina [29], [64]–[66]. The Gellhorn pessary is another common shape but is typically used for higher stages of prolapse [29]. The Gellhorn is composed of a large flat cap and protruding stem and is thought to create suction between the vaginal wall and a disc diameter, which is larger than the genital hiatus [64], [65], [67]. When the patient is upright both the RWS and Gellhorn rest just inside the introitus, preventing POP symptoms which begin with vaginal bulging beyond the introitus [6].

The position and orientation of the ring and Gellhorn in the vaginal canal differ, indicating differences in their interaction with the pelvic floor [68]. Ring pessaries tend to be more posterior to the inferior point than Gellhorns, both pessaries are positioned distal to the cervix in the sagittal plane, with the Gellhorn somewhat further posterior [68]. Ring pessaries rest deeper in the vagina than Gellhorns [68]. There is also significant variation in the XY disc angle between the pessaries [68]. Ring

pessaries have a greater XY angle (sagittal plane) with more angle variation compared to Gellhorns [68]. The ring pessaries' angle variation could indicate rotational flexibility [68].

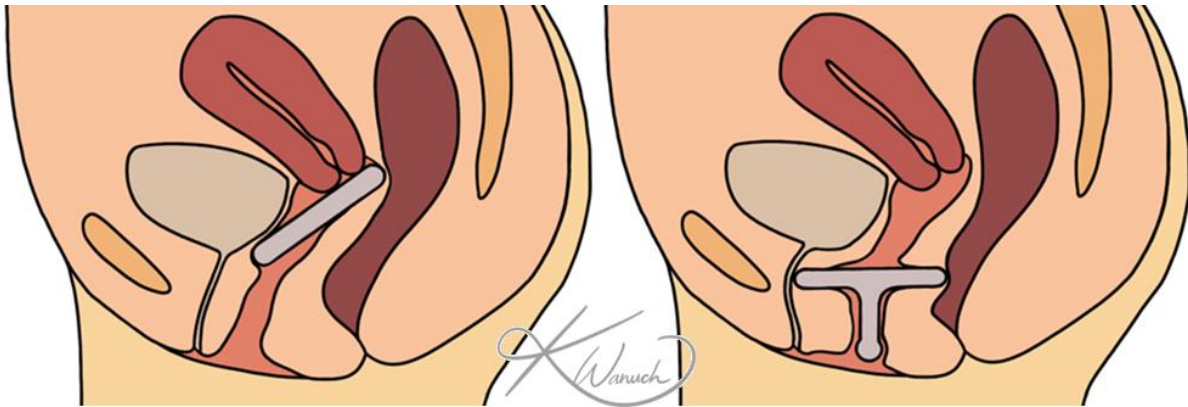


Figure 8: Pessary positioning in the vaginal canal, Ring-with-support (left) and Gellhorn (right)

The positional differences of the two pessaries could indicate that ring pessaries can function in various orientations while Gellhorns have less rotational flexibility due to their larger diameter and stem [68]. For ring or RWS pessaries the positive XY disc angle means that applied forces, such as IAP, would result in a posterior-inferior force vector which points away from the PS [68]. This supports the idea that the ring and RWS pessaries act through support against other pelvic floor structures [68]. The large diameter may lend Gellhorns more useful in treating higher stages of POP due to the suction effect that increases retention [68]. Gellhorn pessaries rest parallel to the pelvic floor with the stem facing downward allowing this pessary to exert a suction effect which makes them easier to retain [29]. The main mechanism of action for the Gellhorn is likely the large disc diameter which creates what was coined the “cork stopper” effect [68]. However, the larger diameter and suction effect of the Gellhorns make them difficult if not impossible for patients to self-manage [6], [66].

2.4.3 Pessary mechanical testing

Previous work has demonstrated the value of mechanical tests to evaluate the mechanical properties of ring pessaries when folded in half (Figure 9). This test was performed by compressing the RWS pessary with a uniaxial force to induce folding [29]. The resulting force-displacement curve exhibited clear buckling and folding regions as well as a final peak force when the ring came into self-contact [29]. This research observed that the RWS buckling and folding behaviour was dependent on pessary design [29]. In fact, the results demonstrated a squared inverse relationship between the force required to initiate folding and the pessary diameter [29]. The results of this mechanical test are important as they

evaluate the pessary design under mechanical forces required for pessary insertion and removal [29]. The forces required to fold the pessary for insertion and removal are critical to RWS pessary design as this pessary type allows for patient self-management [30]. Designing for optimal self-management is valuable as self-management can increase patient satisfaction during pessary use, improving quality of life [30].

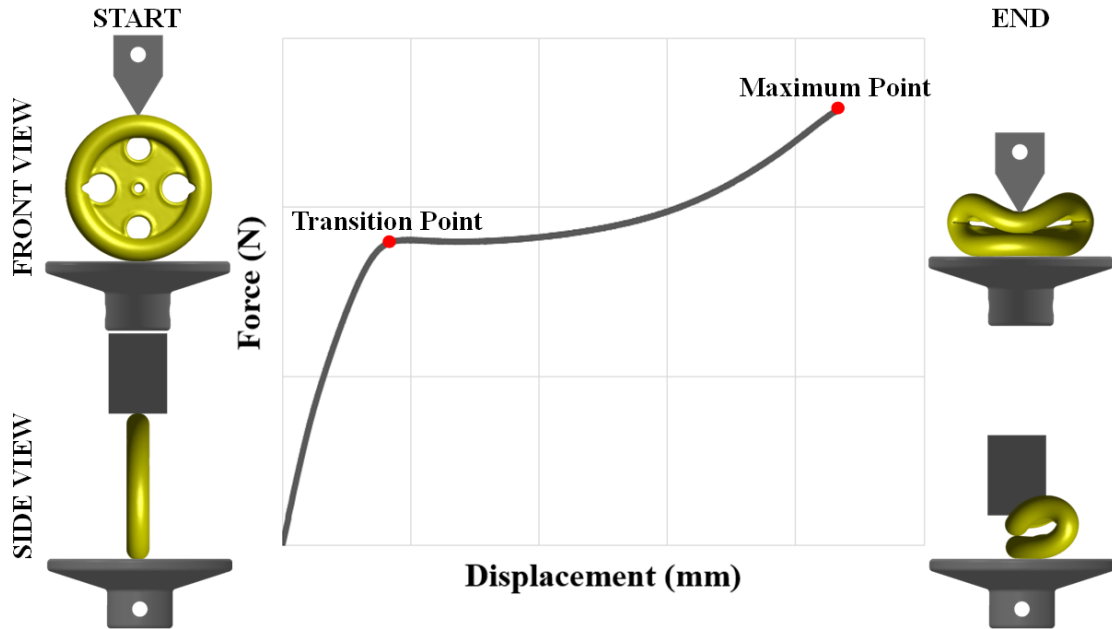


Figure 9: Ring folding mechanical test setup and results. This is an original figure generated for the thesis as an example for reference.

Another proposed test would evaluate the RWS under modified 3-point bending. By resting on the pelvic floor structures, pessaries acts against the downward sagging of the prolapse with gravity, inertial forces, or increased IAP during coughing, laughing, sneezing, or heavy lifting [25], [69]. Performing a mechanical test on RWS pessaries which simulates IAP-like loads on the center of the pessary, represents a secondary load application. This secondary bending scenario represents a variation on well established 3-point bending test while incorporating sliding between the pessary and test fixtures, evaluating this contact. This test would allow further design evaluation under center-applied loads and comparison throughout design iteration before patient trials.

2.5 Pessary finite element modeling

The design process performed by engineers and designers is comprised of modeling, simulation, visualization, analysis, design, prototyping, testing, and lastly, fabrication [32]. Before ever fabricating

the product, significant work must be done to ensure it fulfills its desired function, ensuring cost effectiveness in the process [32]. Modelling and simulation have become valuable techniques in the design process, with greater adaptation [32]. Finite element modelling approximates the solution of field variables in the problem by dividing it into smaller pieces called elements (with associated nodes) [32]. The approximation of continuous systems using discrete elements means that the solution within an element can be approximated using simple functions such as polynomials, allowing the variations of the solutions for all the elements to form the variation of the solution for the whole [32].

The behavior of a physical system depends upon the geometry or domain of the system, the property of the material, and the boundary, initial, and loading conditions [32]. As a result, the procedure for modelling a system in finite element methods has four steps: (1) modeling the geometry, (2) meshing (discretization), (3) applying material properties, and (4) specification of boundary, initial, and loading conditions (Figure 10) [32]. Modelling the problem geometry is often done using Computer Aided Design (CAD) software packages to generate appropriate files containing the geometry of the system [32]. This geometry must then be meshed into finite elements; this requires the approximation of curved lines and surfaces with straight edges elements, creating discretization error [32]. As a result, the accuracy in representing curved parts is controlled by the number of elements, where more elements provide smoother lines and greater accuracy but increases the computational time required [32]. Triangular or tetrahedral elements are most flexible and well established; however, these elements can provide reduced accuracy when compared to quadrilateral elements [32]. Next, the material properties must be applied to the overall geometry or sets of elements, while some materials have well defined properties other specialized materials require experiments to determine their properties [32]. Finally, boundary, initial and loading conditions can be defined for the geometries or meshes [32].

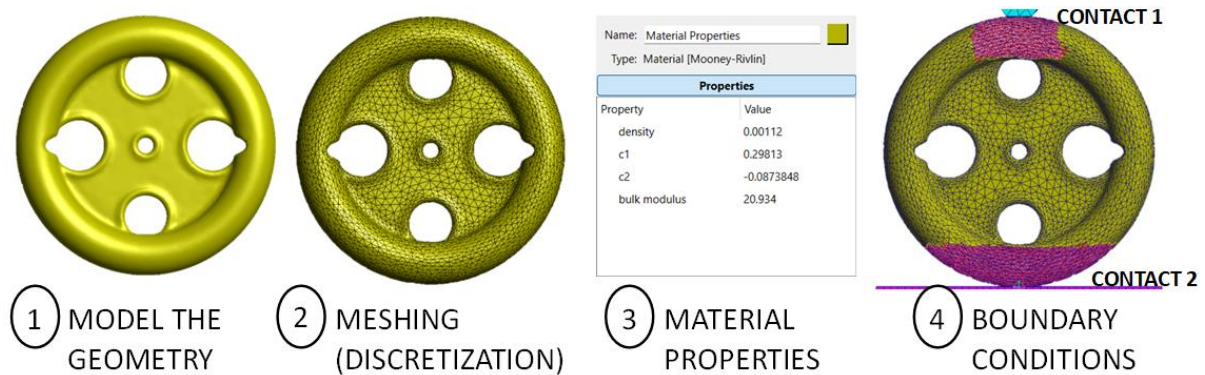


Figure 10: Finite element process demonstrated with a pessary. This is an original figure generated for the thesis as an example for reference.

Much like other engineering design problems the use of finite element modelling can aid in ensuring pessaries fulfill their desired functionality through cost-effective design iteration. In fact, generation of FE models to replicate the mechanical tests performed to evaluate pessaries would reduce the pessary manufacturing needed to perform the engineering design process. To create FE models, such as those to be used in pessary evaluation and iteration, the four modelling steps of geometry, mesh, materials, and boundary conditions (BCs) must be performed. The model geometry can be created using computer aided design (CAD) software then meshed appropriately using tetrahedral elements. A material model, however, provides a challenge as the silicones used for pessary manufacturing have not previously been characterized. Therefore, material samples must be mechanically tested and fitted with appropriate material models. Finally, the test setup and corresponding boundary conditions can be made to match the mechanical tests (folding and modified 3-point bending) performed in person, such that the results from the FE can be directly compared to the results of physical tests.

2.6 Pessary topology optimization

Topology optimization's purpose is to determine the optimal structure which fulfills all prescribed requirements (which can be multidisciplinary) while satisfying certain design restrictions (e.g., solid regions, manufacturing constraints) [36], [37]. Topology optimization contrasts structural analysis because rather than knowing the properties and aiming to evaluate the response, certain physical properties are unknown and the aim is to find the extreme (maximum or minimum) of the objective while fulfilling known constraints [36]. When applying this method, the prescribed requirements and design restrictions can be either geometrical or behavioural [36]. Geometrical stipulations could be the height, width, or overall material mass of the structure, whereas the behavioural stipulations are the stresses, displacements, or natural frequencies of the design [36], [37]. Common objective functions are the design weight or stiffness, material cost, capacity and more [36], [37].

The topology optimization described is achieved by representing the design domain as a set of distributed functions [37]. These functions are a parametrization of the domain's stiffness tensor, where the proper choice in parametrization achieves the topology optimized design [37]. The loads and boundary conditions of the optimization are applied to the reference domain, for which the variable stiffness tensor is defined [37]. The topology goal is determining the optimal placement of material and void, this is achieved by penalizing the continuous stiffness to achieve discrete values [37]. Discrete stiffness values of zero indicate locations of void while one indicates the placement of material [37]. Penalization is required to remove gradient locations, driving the solution to either remove or place

material in those locations, converging to a final optimized design solution (Figure 11) [37]. A common penalized proportional stiffness method is the Solid Isotropic Material with Penalization (SIMP) model [37]. This method achieves penalization by rejecting (setting to zero, in essence removing the material) any variable stiffness which is lower than a specified multiple of the prescribed material stiffness [37]. Generally rejecting all stiffnesses lower than three-times or more the material stiffness is required to drive the design to its optimal design (discrete stiffness values of zero and one) [37].

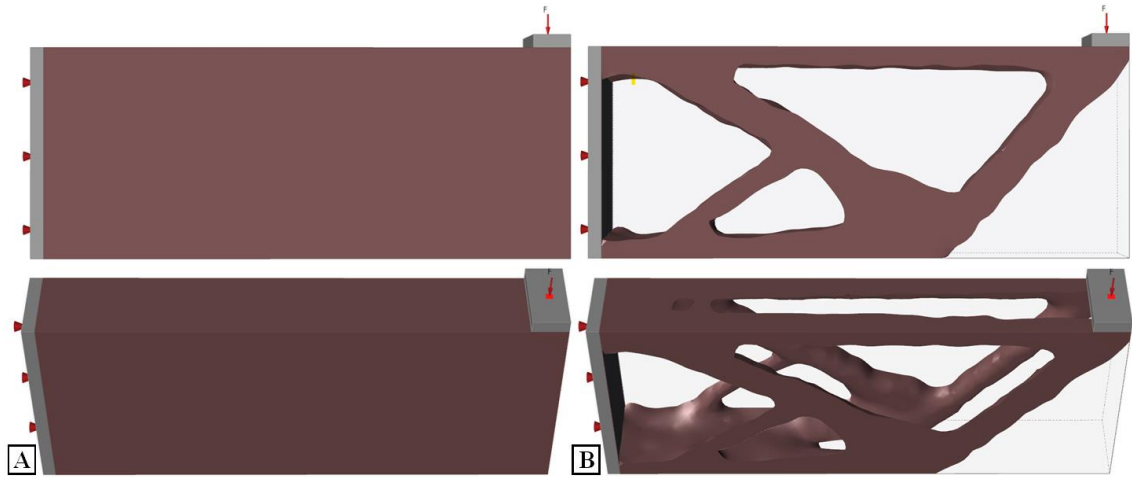


Figure 11: Altair Inspire example maximize stiffness topology optimization (A) setup and (B) results. This is an original figure generated for the thesis as an example for reference.

Chapter 3

Objectives & Hypotheses

Given the significant effect of PFDs on women, there is a need for further understanding of these conditions and their treatment. Therefore, this thesis work endeavoured to investigate two themes related to pelvic floor assessment and pessary treatment in an attempt to fill known knowledge gaps in these areas. The first theme related to developing a better understanding of pelvic floor impairment using image-based analysis. The goal was to assess dynamic ultrasound data, collected using the novel CDI system, to characterize vaginal contraction biomechanics. The second theme of this work was the characterization of pessaries, which was accomplished through two goals: (1) material characterization with FE modelling of RWS pessaries and (2) a pilot investigation of topology optimization driven Gellhorn pessary redesign.

3.1 Image-based analysis for pelvic floor assessment

3.1.1 Assessment of the distended vagina contraction using CDI

CDI has not yet been used to assess the dynamic changes of the pelvic floor during contraction while under distention. As a result, the objective of this original pilot image-based analysis is to develop a novel methodology to characterize the dynamic movement and shape change of the distended vagina during a contractile maneuver using CDI. Use of CDI provides both imaging and pressure measurements of the vaginal canal under distention. It is hypothesized that while providing anatomically relevant properties of the vaginal canal under distension, CDI will also improve vaginal canal visibility such that the motion and magnitude of a patient's contraction can be observed.

3.2 Pessary characteristics and modeling

3.2.1 Finite element analysis setup for pessary mechanical testing

Mechanical tests, like pessary folding and simplified intra-vaginal conditions, can be used to characterize pessary properties but are resource intensive. Simulating the mechanical tests through FE modeling can provide expedited results for pessary parameter and design analysis. The required stages for the completion of this goal include: (1) identify hyperelastic material models for two pessary silicone stiffnesses (Shore 60A and 40A), and (2) develop computational FE models of two pessary mechanical tests for RWS pessaries. It was hypothesized that hyperelastic material models could be

identified to sufficiently capture the force-deformation response of multiple RWS sizes with different boundary conditions and silicones.

3.2.2 Pilot investigation into pessary topology optimization

Topology optimization is a valuable tool through which designers can glean insight for design possibilities and decisions by optimizing for different properties (e.g., lightweighting, load conditions, etc.) [36], [37]. Gellhorn pessaries have not seen significant iteration, with the design reported in medical journals since 1944 [33]. Since the Gellhorn has remained relatively unchanged over time it presents a valuable candidate for investigating topology optimization-based redesign. Additionally, given known challenges of Gellhorn insertion and removal, improving the design with a focus on self-management serves as a clear goal for design iteration [6], [66]. It was hypothesized that this initial topology optimization of the Gellhorn will demonstrate the value of topology optimization in optimizing pessaries for loading conditions and functional objectives (e.g. insertion and removal).

Chapter 4

Assessment of Distended Vaginal Contraction Using CDI

4.1 CDI data collection methods

This study represents a secondary analysis of data collected during clinical investigations where CDI was being used for a pilot study [70]. Pelvic floor contraction maneuvers were performed and captured using CDI for 42 recruited patients in three approved studies, the inclusion criteria for which were as follows: below 18 years of age, pelvic radiation history or surgery for PFDs, inability to perform pelvic muscle contractions, restricted mobility that limits ambulation, neurologic-lesions, and/or history of pessary-related complications. The first two studies were reviewed and approved by the Mount Sinai Hospital Research Ethics Board (#20-0113-A and #20-0248-A). The third was reviewed and approved by the Western University Sciences Research Ethics Board (#113264). Each patient also provided written informed consent for the data collection. Each patient was successfully managing their POP using a pessary. Patients diagnosed with prolapse were selected as the sample population for this proof-of-concept study because women with prolapse on average have 40% lower maximum contractile force compared to those without [71]. This means the movements and pressures recorded were hypothesized to be less detectable than in a healthy volunteer population, therefore stress testing the system [72].

To perform CDI, a modified urodynamics system was used to fill an ultrathin oversized bag (thermoplastic polyurethane, 0.076 mm wall thickness, 850mL capacity) in the vaginal canal with water through a urodynamics catheter. The bag was retained using a novel device covering the introitus to prevent bag dislodgement during filling and providing a window to perform transintroital ultrasound imaging (Figure 12) [19]. Firstly, tissue preconditioning was performed to achieve steady and repeatable response from the vaginal tissues; this step is critical for biological tissue due to history-dependent tissue properties [73]–[77]. The effects of the tissues' history-dependent properties are mitigated through preconditioning by redistributing fluid and breaking transient hydrogen bonds which form while the tissue is not loaded [77]. The bag was then filled to maximum vaginal capacity, as indicated by the patient's sensation of vaginal fullness. Then, 25 mL of water was removed from the bag to facilitate pelvic floor maneuvers, which cannot be performed when filled to maximum vaginal capacity. The patient was then instructed to perform a pelvic floor contraction maneuver, which was

captured using 2D transintroital midsagittal ultrasound video. Pressure in the bag was continuously recorded throughout the rest, contraction, and release for analysis.

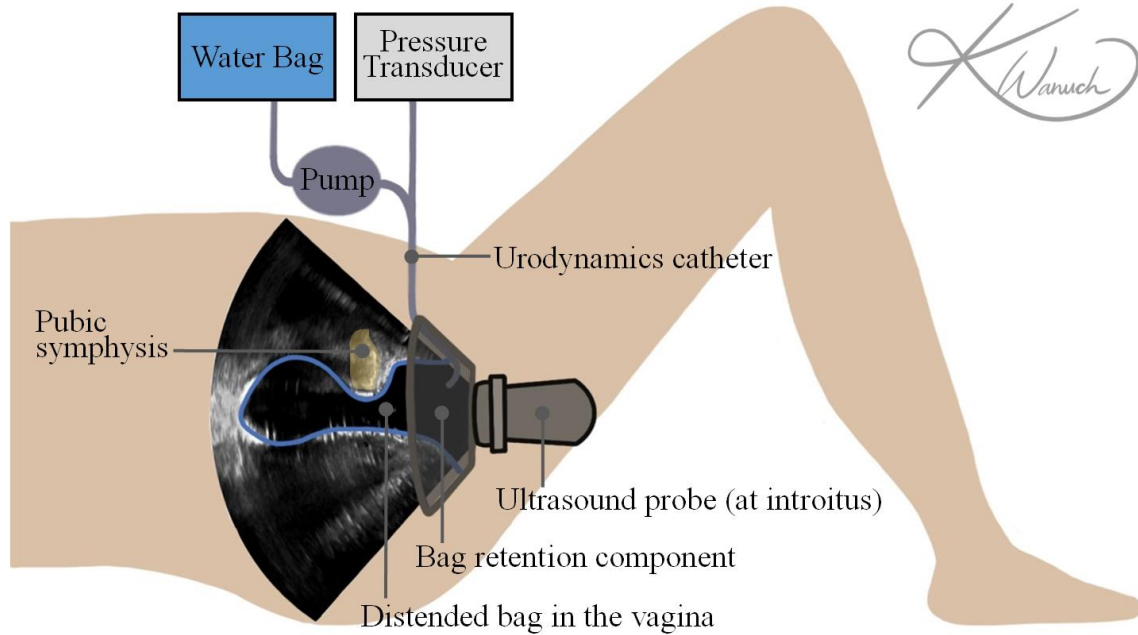


Figure 12: Colpodynamic imaging (CDI) schematic of the patient in a supine position.

The distended bag region in the ultrasound videos were manually segmented at varying intervals of 2D video images then interpolated between and visually assessed for accuracy (3D Slicer, v4.11). Videos ranged from 63 to 141 images in length across all patients examined. An automated script (Python, v3.7) was then used to place equally spaced, discrete point locations along the perimeter of the segmented bag. These points began horizontally aligned at the pubic symphysis (PS) and were spaced at intervals of 1 cm superiorly and inferiorly (Figure 13). The A-P location of these points were reported for each frame of the ultrasound video while the inferior-superior locations were kept consistent throughout. Several measures were derived from these segmentations and points, such as changes in 2D mid-sagittal bag area superior to the PS, minimum and maximum antero-posterior (AP) lengths, as well as mid-sagittal bag area and AP changes in the maximal change region (MCR), identified as the region which proportionally changes most during contraction (Figure 14). For each parameter, the contraction slope (proxy for pelvic floor muscle activation speed), holding slope (proxy for muscle control and endurance), and release slope (proxy for muscle control and relaxation speed) was measured, providing temporal evaluation of contraction dynamics. The average parameter curves of each CDI measure were found using ARCGen in MATLAB R2021a through time-based curve averaging technique [78].

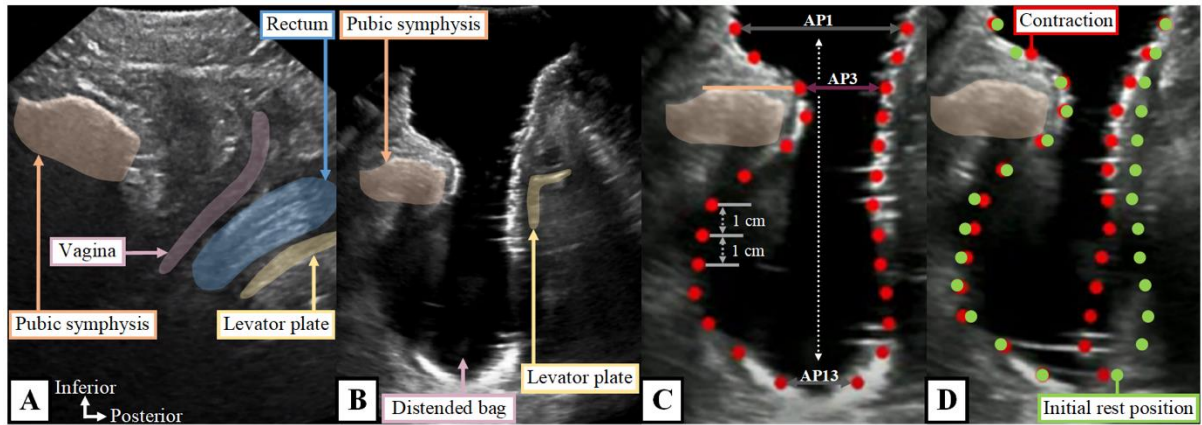


Figure 13: (A) Mid-sagittal transperineal ultrasound of the pelvic structures without distention, (B) mid-sagittal transperineal ultrasound of the bag-distended vaginal canal using CDI, (C) discrete points segmented on the CDI bag ultrasound at rest with anterior-posterior (AP) lengths annotated, (B) bag ultrasound at maximum contraction as compared to the initial rest position discrete points.

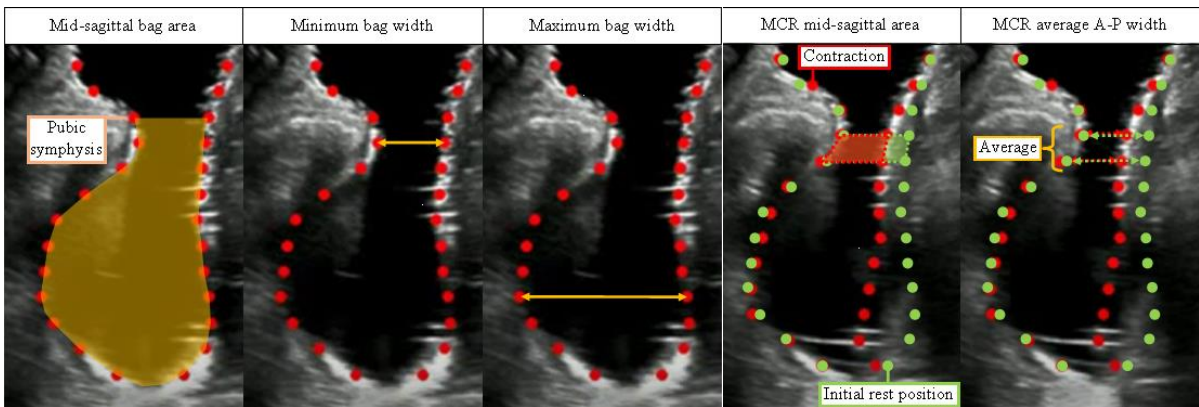


Figure 14: CDI ultrasound video parameter identification for the mid-sagittal bag area below the pubic symphysis, minimum bag width, maximum bag width, as well as the maximal change region (MCR) mid-sagittal area and average A-P width. The MCR represents the region which proportionally changes the most (percent change) during the pelvic floor contraction.

4.2 CDI data collection results

CDI ultrasound videos of the mid-sagittal plane were assessed from 19 patients, the patient metrics for which are summarized in Table 1. As a preliminary study for developing this CDI approach to characterize pelvic floor contraction, only ultrasound videos with adequate bag wall visibility, observed contraction, and the same imaging setup were included in the analysis, with 23 patient videos excluded. Dynamic ultrasound videos of the mid-sagittal plane using CDI during the contract maneuver were

successfully segmented, with an expert reviewer (over a year of experience analyzing 3D TPUS volumes) confirming segmentation accuracy. The parameter average slopes (contraction, holding, and release) as determined from individual patient curves (Figure 15A) and visualized through ARCGen time-based curve averaging (Figure 15B) are summarized in Table 2 and Figure 16. A single patient example of bag mid-sagittal area change overlayed with an inverted pressure change was included to demonstrate the time-based alignment observed between vaginal shape and pressure changes (Figure 17). Finally, the nineteen patients' data was averaged, using ARCGen, based on their clinician assigned MOS (MOS 1: n = 5, MOS 2: n = 7; MOS 3: n = 4; MOS 4: n = 3), an initial investigation of MOS trends in minimum bag width and mid-sagittal area (Figure 18).

Table 1: Demographic and clinical characteristics of study patients (N = 19)

Variables	Mean (SD)
Age (years)	63.3 (12.0)
BMI	24.2 (5.0)
Parity	2.1 (0.7)
POP-Q stage	2.3 (0.4)
POP-Q stage distribution	
Stage 2	14 (73.7%)
Stage 3	5 (26.3%)

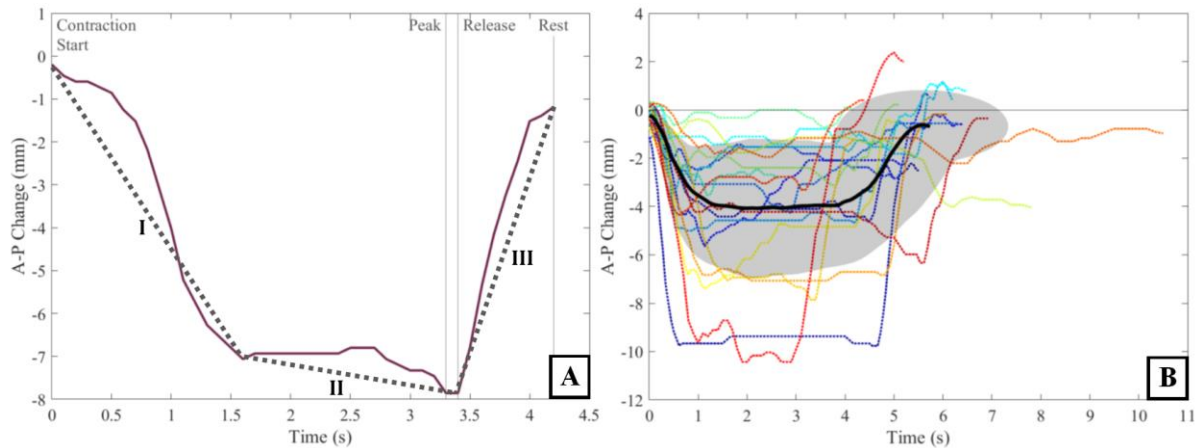


Figure 15: (A) Bag minimum width during contraction (I: contraction slope, II: holding slope, III: release slope), (B) ARCGen patient average (black solid line) of minimum width changes with response corridor (shaded) and individual patient data (coloured dotted lines).

Table 2: CDI measurements from pressure monitoring, 2D ultrasound video segmentation, and discrete point placement. The average and the standard deviation (SD) are shown for the 19 patients.

Measure	Description	Mean (SD)		
		Contraction Slope (I)	Holding Slope (II)	Release Slope (III)
Change in bag pressure (cmH ₂ O/s)	Pressure of the intra-vaginal bag was measured throughout rest and contraction. Slopes are the pressure change over time.	12.3 (6.3)	-0.2 (1.6)	-9.9 (6.2)
Changes in mid-sagittal bag area (cm ² /s)	Visible area of distended vagina superior to pubic symphysis, displaced water proxy.	-6.6 (4.7)	-0.2 (0.3)	5.8 (3.8)
Change in min A-P bag width (mm/s)	Changes in the smallest antero-posterior (A-P) length at any given time during the contraction, excluding the most superior AP.	-5.1 (2.5)	-0.1 (0.6)	4.7 (2.9)
Change in max A-P bag width (mm/s)	Changes in the largest antero-posterior (A-P) length superior to the pubic symphysis at any given time during the contraction.	-7.7 (4.9)	-0.2 (0.6)	8.7 (5.4)
Changes in MCR mid-sagittal area (cm ² /s)	Area changes in the maximal change region (MCR), positioned at the most reactive region, APs which change first and most.	-0.9 (0.8)	0.0 (0.1)	0.7 (0.7)
Average change in the MCR APs (mm/s)	Average AP changes in the maximal change region (MCR), at the most reactive region, APs that change first and most.	-7.1 (3.6)	-0.1 (0.8)	5.0 (3.0)

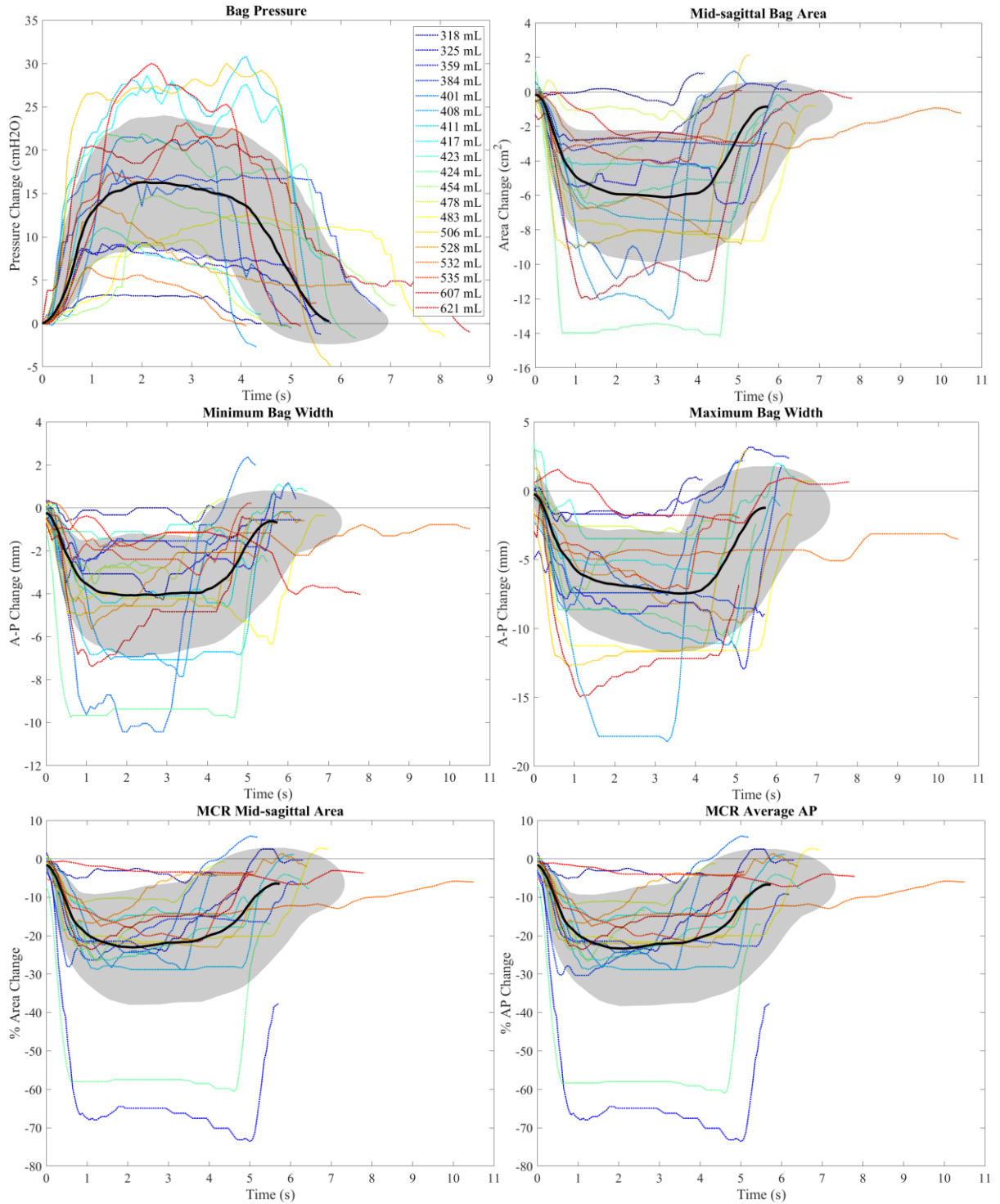


Figure 16: ARGen patient averages (black line) and response corridors (grey area) with individual patient data in a colour scale for ascending patient bag volume (smallest patient volume: darkest blue, largest patient volume: darkest red) for the six identified patient measures.

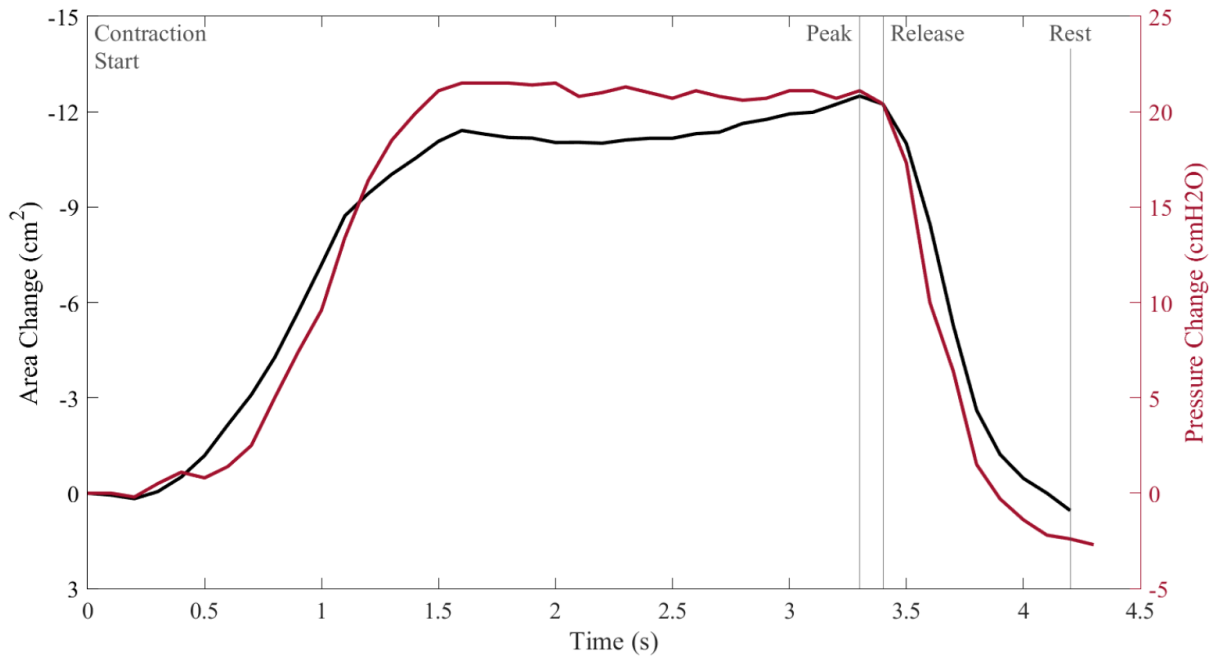


Figure 17: Changes in bag area superior to the pubic symphysis during contraction (black, left) and change in pressure of the distended bag during contraction (red, right).

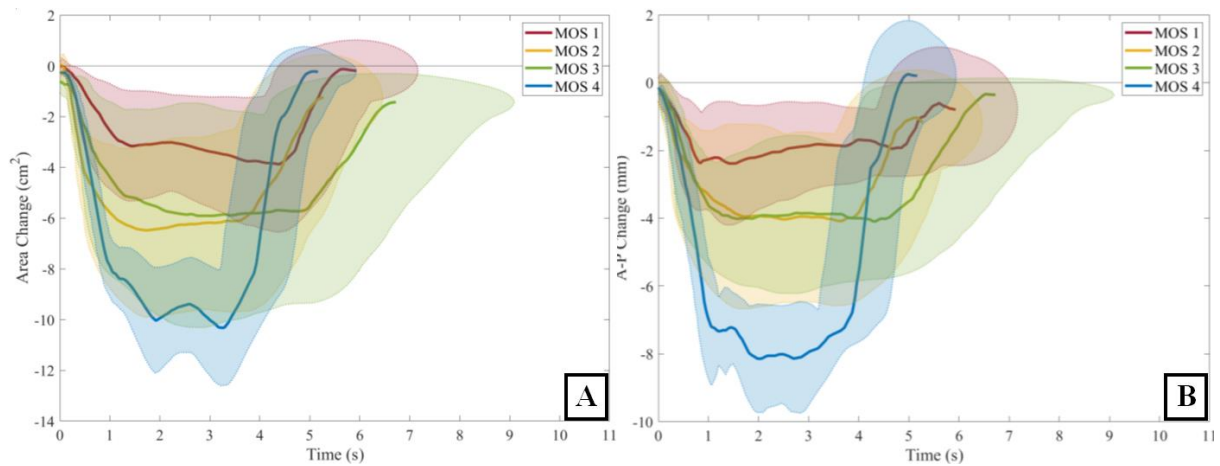


Figure 18: ARCGen plots of (A) Mid-sagittal bag area, and (B) minimum bag width patient averages with different clinically assigned Modified oxford scores (MOS). The number of patients in each groups was as follows - MOS 1: n = 5, MOS 2: n = 7, MOS 3: n = 4, MOS 4: n = 3.

4.3 CDI analysis discussion

This original study successfully demonstrated a novel method of analyzing real-time pressure, geometric shape changes, and motion of the distended vagina during a pelvic floor contractile

maneuver, proving the initial hypothesis. The results of this study from subjective observation seem to indicate that distention facilitates visualization of changes in the vaginal canal during the contract maneuver compared to difficult and inconsistent segmentation of the vaginal canal on non-distended ultrasound images (Figure 13A and B). The analysis method developed also allows dynamic novel measurements to be taken from the vaginal walls throughout the contract maneuver (Figure 13CD and 14). The measures extracted can be broken down into different components such as overall displacements and slopes (Figure 15A), the curves for which can be averaged across patient groups to understand the general trend (Figure 15B). A consistent trapezoidal trend is observed in Figure 16 for the bag area (both full and MCR), and AP length changes (minimum, maximum, and MCR). Dynamic pressure monitoring allows for an understanding of the pressures seen in the distended bag during maneuvers. The pressure displays, as expected, an inverted relationship compared to the bag dimensions (e.g. bag area, though all bag measures display this trapezoidal relationship) (Figure 17).

Graphically comparing the four MOS patient averages demonstrates visual differences between MOS groups captured using CDI measurements (Figure 18). Both the minimum bag width and mid-sagittal bag area demonstrate distinct differences between the MOS 1 and 4 groups, while little difference is visible between MOS 2 and 3. These findings are understandable given the subjective nature of digital palpation and ranking scales. As expected, identifying a weak pelvic floor (MOS 1) or strong pelvic floor (MOS 4) is likely more consistent than assigning an intermediary strength (MOS 2 or 3), especially across multiple practitioners. This initial investigation into a link between CDI measurements and MOS represents a compelling potential for the CDI system which is worth further investigation in future work.

Comparing the pressures measured using CDI (16.8 ± 4.8 cmH₂O) to perineometry and vaginal probe measurements proves difficult given the wide range of contractile pressures measured and reported using different instruments. In their work Barbosa et al. (2009) found an average contractile magnitude of 43.2, 86.7, and 45.6 cmH₂O for the Neurodyn™, SensuPower™, and Peritron™ respectively [79]. Bø et al. (2005) compared measurement from the Camtech™ and Peritron™ probes, finding average contractile pressures of 19.7 and 36.5 cmH₂O respectively [10]. These values for pelvic floor contraction strength were found for younger presumably healthy individuals, resulting in better contraction strength. Bø et al. (2005) also concluded that pressures measured using different sized vaginal probes should not be compared [10]. As a result, it is not surprising or concerning that the pressure measurements taken using CDI do not perfectly align with literature reported values found with other instruments. The research of Auchincloss et al. (2012) found that pelvic floor muscle

activation is not affected by the presence of different probes in the vaginal canal [9]. Therefore, while using CDI the distending bag in the vagina should not significantly impact the pelvic floor muscle activity even while the size of the bag may be impacting contraction magnitude.

Previous work done to assess pelvic floor contraction was performed through the collection of transperineal ultrasound by Nyhus et al. (2019) for assessing pelvic floor contraction strength. This work compared 2D and 3D transperineal ultrasound data to MOS from digital palpation for women suffering from stress urinary incontinence, POP, and primigravid [12]. Comparison between the ultrasound data and MOS demonstrated ultrasound can provide objective assessment of contraction [12]. In particular, 2D levator hiatus AP diameter had the highest intra-class correlation coefficient and a moderate correlation to digitally determined MOS [12]. These findings support the collection of 2D transintroital ultrasound video data in this study, by demonstrating the value of 2D ultrasound of vaginal AP dimensions as possible objective measures of contraction. Future work could endeavour to compare measures of contraction under distension using CDI to the undistended ultrasound scale developed by Nyhus et al. (2019) for contraction assessment in ultrasound [12].

Jung et al. (2007) previously assessed the vaginal pressure profile of the observed “high pressure zone” (HPZ) by performing 3D ultrasound on a fluid-filled bag in the vagina [52]. The HPZ was found to lie approximately 3.3 cm above the perineal body, with maximum forces at its center [52]. The HPZ location shows some similarity to the MCR observed in the CDI data. Jung et al. (2007) also found that during bag filling the AP dimension of the vaginal canal gradually increase while no lateral changes were observed [52]. Contraction produced a decrease in the AP bag dimension with no lateral change [52]. These findings were further supported by observations of greater pressure measurements in the AP direction when compared to the lateral [52]. The study concluded that the puborectalis muscle generates the HPZ based on the HPZ characteristics and bag shape observed [52]. Contraction of the puborectalis muscle is thought to shorten its two limbs anteriorly lifting the anal canal and compressing structures in the levator hiatus [52]. Jung captured contraction at different volumes within the vaginal canal, the largest of which was 70cc for which contraction resulted in an average pressure increase of 51 mmHg (approx. 69 cmH₂O) [52]. The average increase in intravaginal pressure observed in CDI was significantly lower (approx. 15 cmH₂O) which may be a result of the significantly greater distension of the vaginal canal (average of 453cc).

The method of point placement along the vaginal canal performed in this study is similar to the method utilized by Spahlinger et al. (2014) to assess vaginal changes during Valsalva (bearing down)

maneuvers [25]. However, while Spahlinger et al. (2014) evaluated non-distended vaginal movement during Valsalva with MRI, allowing for the clear identification of the anterior and posterior vaginal walls without the need for distention [25]. Use of MRI also allowed for determination of the point trajectories whereas the ultrasound data captured focuses on overall wall movement as the points are fixed in the inferior-superior direction. However, advantages of capturing vaginal wall movement using CDI are accessible, affordable, dynamic, and portable ultrasound as well as concurrent pressure monitoring [11]–[13]. CDI also captures the distended properties of the vaginal canal which are of clinical significance given the organ's function [14]–[18]. Spahlinger et al. (2014) demonstrated changes in the motion trajectory given the type of prolapse, which was not possible in this study due to limited impairment information and a small sample size [25]. In fact, they found a difference in the vaginal walls' compliance based on whether they exhibited cystocele (anterior POP), rectocele (posterior POP), or normal support [25]. Since vaginal wall movement during Valsalva was affected by the type of POP, this may also impact the movement during contraction [25].

One major limitation of this study is the midsagittal dynamic ultrasound video only captures a 2D view of the maneuver. Fortunately, the research of Jung et al. (2007) and Nyhus et al. (2019) indicate the AP dimensions demonstrate consistent changes during contraction which can be used for assessment of the vaginal canal, such as during contraction [12], [52]. Furthermore, Jung et al. (2007) commented that the lateral dimensions of the bag did not significantly change during bag inflation or contraction [52]. Therefore, while the midsagittal video collection is limited to 2D this proves to be an acceptable limitation given the findings of previous work. The current setup and cost of the prototype CDI device (i.e., connected to a modified UDS machine) in this research is a limitation for widespread adoption, as a result further cost and usability improvements to the system will be made through future work. Another limitation arises from the sample which is both small and composed of patients with mixed dysfunctions (e.g. different types of POP). Future work is needed to expand the sample size of CDI with dynamic 2D transintroital ultrasound and evaluate the differences in contraction across different impairments. Tracking impairment differences is crucial as Spahlinger et al. (2014) identified movement differences based on POP type [25]. Additionally, although patient with POP is a valuable population to proof of concept the system, the performance of the analysis should be expanded to include healthy volunteers and other populations with PFDs.

Characterization of pelvic floor muscle activation effects on a distended vagina during pelvic floor maneuvers may provide a more objective method of understanding pelvic floor-related impairments by assessing genital hiatus closure. This work provides new understanding of pelvic floor biomechanics

during contraction while under distension, which may help to better inform treatment options, such as pessary use or surgical intervention, for women with PFDs. Comparing the shape changes and pressures from different PFDs as well as patients without prolapse could provide more in-depth information about the effects of PFDs on this assessment maneuver biomechanics. This system offers a method to assess patients' ability to generate closure of the genital hiatus, which is difficult to assess without vaginal distention. This data may be helpful for improving the design of novel pessaries with features which consider the hiatal closure force.

4.4 CDI data conclusions

Improved vaginal visibility as well as consistent trends in pressure and shape change were observed for the POP patients assessed under distention using the novel CDI setup. Next steps for this assessment method includes increasing the sample size of the CDI data (with consideration for dysfunction type), evaluating the response of patients without prolapse, and iterating the CDI setup.

Chapter 5

Finite Element Modelling of Silicone RWS Pessary Deformation

5.1 Silicone material characterization

Two types of commercial silicones used in cocoon moulding manufacturing of pessary designs were investigated in this study: Shore 60A (LSR 4360, Elkem SILBIONE, East Brunswick, NJ) and Shore 40A (LSR 4340, Elkem SILBIONE, East Brunswick, NJ). The silicone material characteristics were first determined using uniaxial tension and compression mechanical test data. These tests were performed on standardized “dog-bone” shaped samples (Shore 40A: $n = 5$, Shore 60A: $n = 6$) for tension tests and cylinder samples (Shore 40A: $n = 5$, Shore 60A: $n = 5$) for compression tests. The approximate dimensions for the uniaxial samples were chosen from dimensions of the C (“dog-bone”) specimen in ASTM D412 and cylinder dimensions in ASTM D695 (Figure 19A and B) [80], [81].

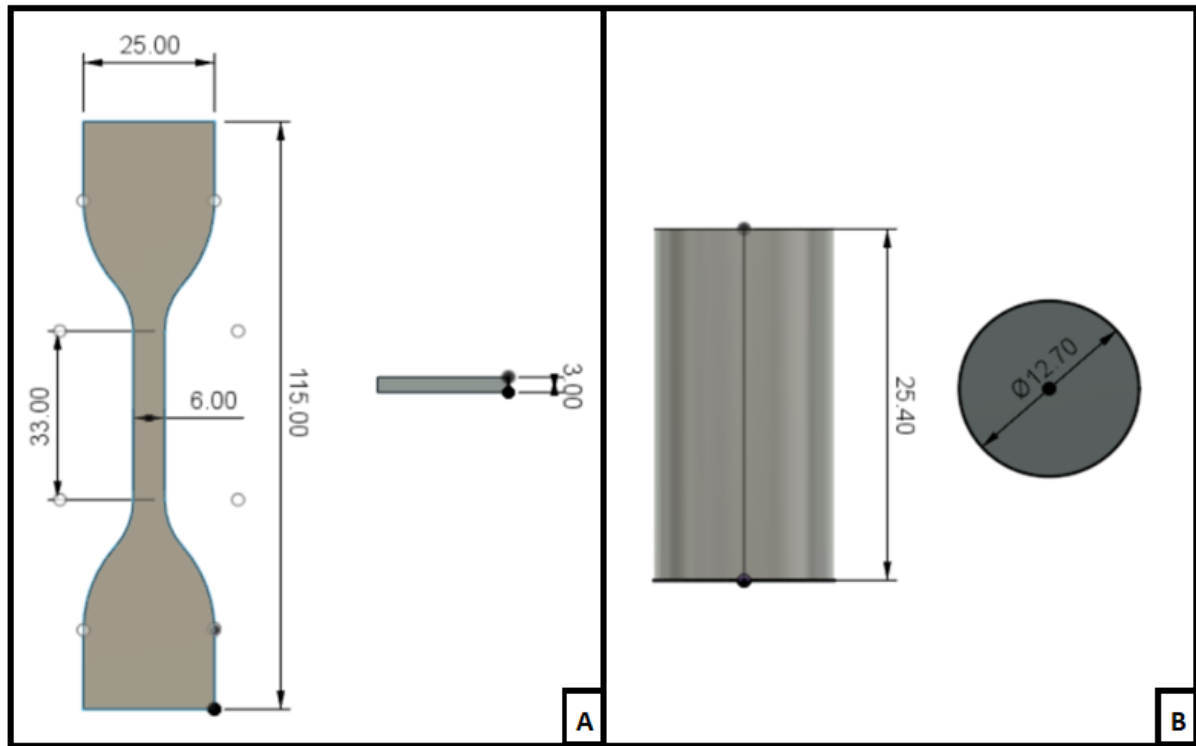


Figure 19: (A) Dogbone and (B) cylinder material samples (all dimensions in mm).

Cocoon moulding was performed to manufacture these samples. This involved 3D printing sacrificial moulds created in computer aided design software (Autodesk Fusion 360) using the Formlabs 3B printer, with the BioMed Clear material (material number: FLBMCL01) [70]. These moulds were then

injected with the medical-grade liquid silicone of interest (Shore 40A or 60A) [70]. Once the silicone was cured it was removed from the moulds and placed in a laboratory oven for postcuring at $200 \pm 10^\circ\text{C}$ for 4 hours [70]. During manufacturing the samples dimensions changed due to the moulding and postcuring processes, leaving the samples with slight dimensional differences to the initial designed moulds, this was tested for two “dog-bone” samples and one cylinder sample (Table 3).

Table 3: Dimensional differences observed on the tested “dog-bone” and cylinder samples.

Sample	Dimension	Design (mm)	Half cure (mm)	Full cure (mm)
“Dog-bone” 1	Overall length	115	113	113.1
	Overall width	25	24.2, 24.2	24.2, 24.2
	Gauge width	6	5.6	5.6
	Thickness	3	2.8	2.8
“Dog-bone” 2	Overall length	115	113.2	113.2
	Overall width	25	24.4, 24.2	24.3, 24.3
	Gauge width	6	5.6	5.6
	Thickness	3	2.8	2.8
Cylinder	Diameter	12.7	12.3	12.3
	Height	25.4	25	24.9

The “dog-bone” silicone samples were tested in tension through clamp-based sample fixation. The sample was initially stretched to a 1 N preload, after which a constant upward velocity of 200 mm/min was applied to the top clamp to stretch the sample until material rupture (Figure 20A). The cylinder sample was tested with flat plates for unconfined compression. The sample was compressed to a 1 N preload and then tested at a constant downward top plate velocity of 200 mm/min up to a maximum load of 390 N (Figure 20B). During the uniaxial tests, data was sampled at a rate of 100 Hz, recording the distance of the top fixture and the force on the load cell. Results of the two uniaxial tests for each material can be summarized through the average and standard deviation of the tests (Figure 21 and 22).

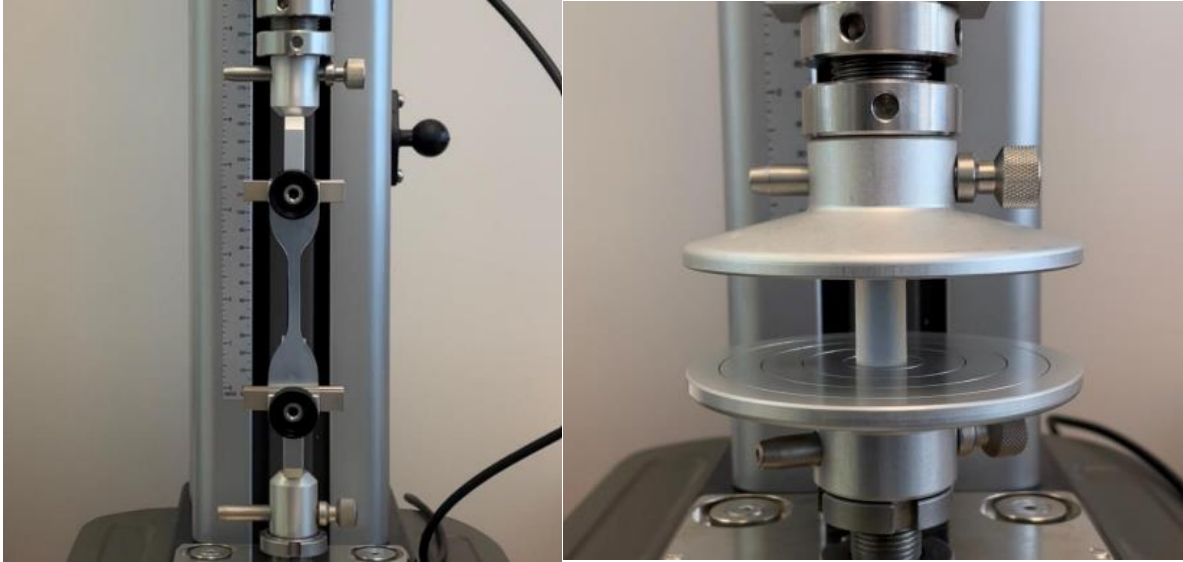


Figure 20: Starrett material testing setup for (A) uniaxial tension and (B) uniaxial compression

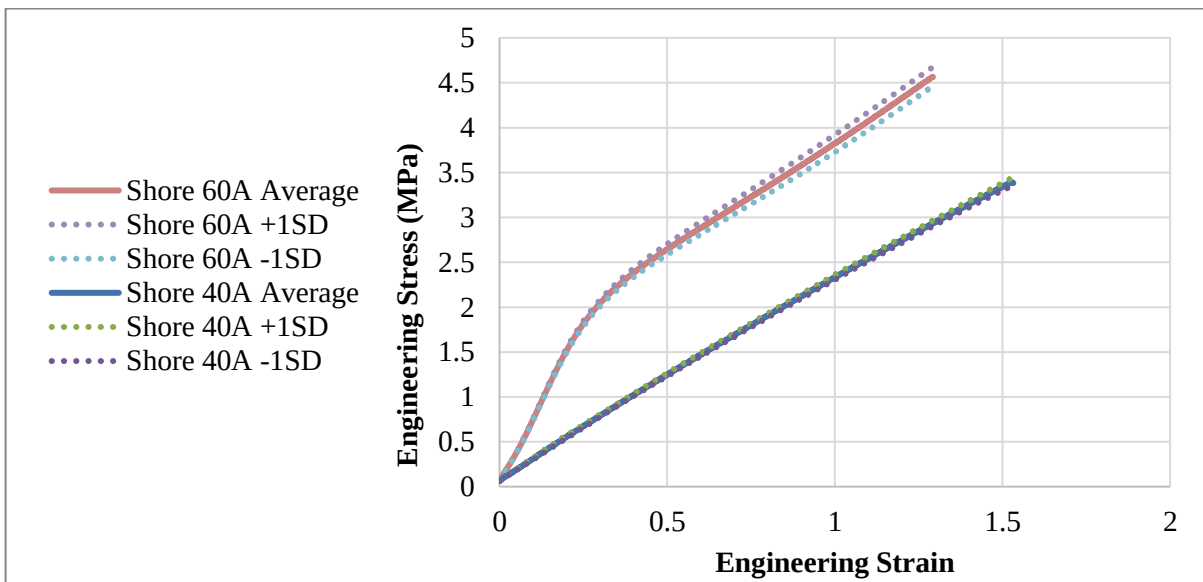


Figure 21: Uniaxial tension results for the two silicone materials of interest, with average and standard deviation (SD) of each repetition of the test repetitions.

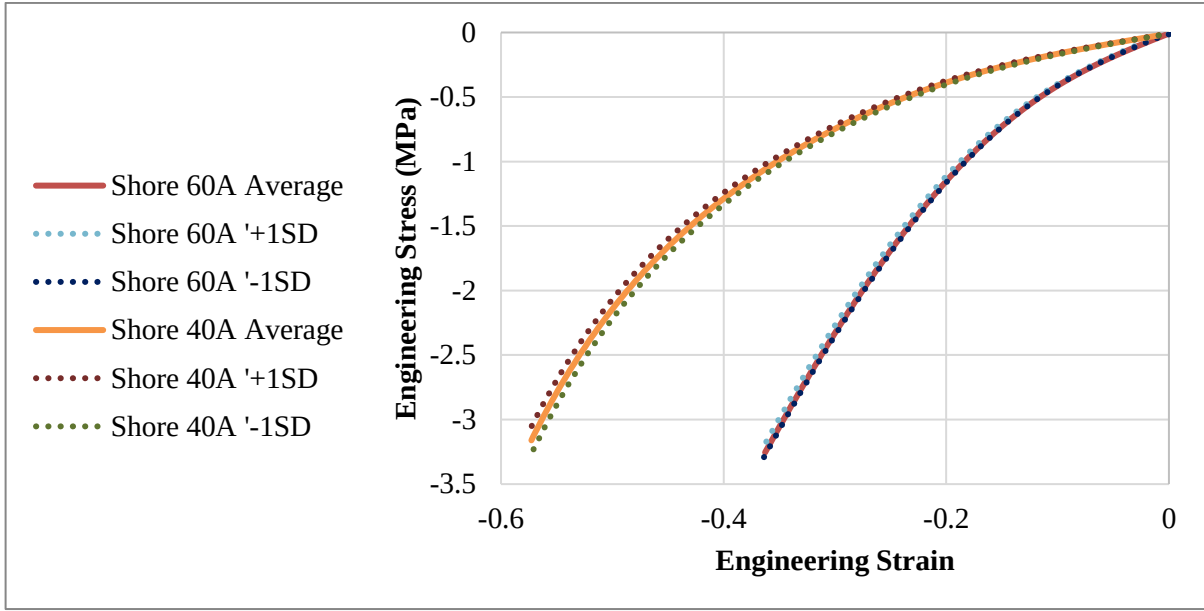


Figure 22: Uniaxial compression results for the two silicone materials of interest, with average and standard deviation (SD) of each repetition of the test repetitions

5.2 Material model fitting

The experimental tension-compression data collected for each silicone material was fitted with an independent hyperelastic Mooney-Rivlin (MR) material model, see Eqn. 1 [82], by minimizing the difference between the material model and corresponding physical test data. This was done by iteratively changing the MR coefficients (C_1 and C_2) to maximize the coefficient of determination (R^2), see Eqn. 2, between the MR material model's calculated engineering stress (Eqn. 3) and the average experimental engineering stress using Excel's (v2308, Microsoft Corporation, Redmond, WA) Solver functionality (GRG Nonlinear method).

Two fitting methods were attempted, the first being to fit the full tension-compression dataset. This initial method of fitting the full dataset was skewed for the Shore 60A material, likely because the material was able to withstand significantly more tension than compression (due to the force capacity limitations of the materials testing machine). For this material, the wealth of tension data skews the R^2 value in the fitting when performed on the full dataset. These differences can be assessed visually of the Shore 60A material (Figure 23) as well as through the comparison of the R^2 fit of different regions of the data (Table 4). It is clear through analysis that the end fit method (less than -0.2 and more than 1.0 engineering strain) significantly improves the fit for the Shore 60A material but does not significantly affect the fit for the Shore 40A material (Figure 24).

Table 4: Coefficient of determination (R^2) for different regions with different data fitting.

R^2 region	Shore 60A		Shore 40A	
	Full fit data	End fit data	Full fit data	End fit data
Full	0.9727	0.9584	0.9893	0.9885
Ends	-	0.9993	-	0.9908
Compression	0.7084	0.9626	0.8218	0.8135
Tension	0.9644	0.9290	0.9933	0.9922

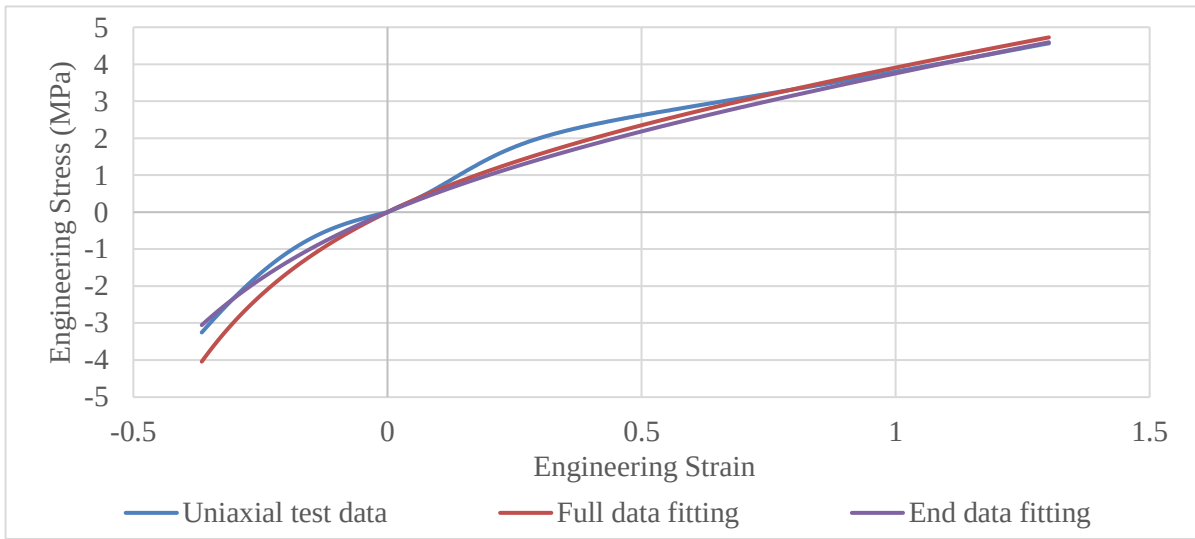


Figure 23: Shore 60A uniaxial test data fitting

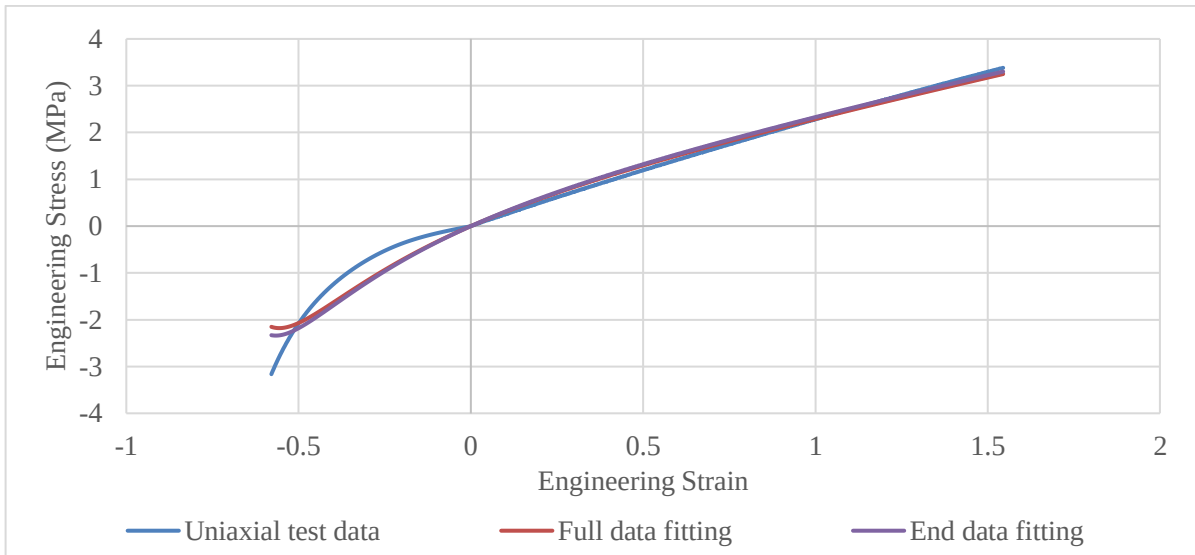


Figure 24: Shore 40A uniaxial test data fitting

Therefore, coefficient optimization was performed on the engineering strain ranges of less than -0.2 and more than 1.0 to ensure good fit of the material response for both the compression and tension ends of the data. A Poisson's ratio of 0.49 was assumed for near incompressibility and the shear modulus was calculated from the MR coefficients, see Eqn. 4. The bulk modulus like penalty parameter, K, required to model MR materials in FEBio was calculated from the Poisson's ratio and shear modulus, see Eqn. 5.

$$\psi = C_1(\tilde{I}_1 - 3) + C_2(\tilde{I}_1 - 3) + \frac{1}{2}K(\ln J)^2 \quad (1)$$

Equation 1: Strain-energy function of the Mooney Rivlin (MR) material model, where C_1 and C_2 are the MR coefficients, I_1 and I_2 are the invariants of the deviatoric right Cauchy-Green deformation tensor, K is a bulk modulus-like penalty parameter and J is the determinant of the deformation gradient tensor [82].

$$R^2 = 1 - \frac{\sum_{i=1}^N (y_{exp,i} - y_{model,i})^2}{\sum_{i=1}^N (y_{exp,i} - y_{exp,mean})^2} \quad (2)$$

Equation 2: Definition of the coefficient of determination (R^2)

$$\sigma = C_1(2\lambda - 2\lambda^{-2}) + C_2(\lambda - 2\lambda^{-3}) \quad (3)$$

Equation 3: The stress (σ) function of the Mooney-Rivlin material model. The coefficients C_1 and C_2 are the Mooney-Rivlin material constants, whereas λ represents the material elongation, and is calculated by adding one to the material strain.

$$G = 2(C_1 + C_2) \quad (4)$$

Equation 4: Equation for the shear modulus (G) of a Mooney Rivlin (MR) material as calculated from the MR material model coefficients (C_1 and C_2).

$$K = \frac{2G(1+\nu)}{3(1+2\nu)} \quad (5)$$

Equation 5: The bulk modulus (K) relationship with shear modulus (G) and Poisson's ration (ν) for homogeneous isotropic linear elastic materials, used to approximate K for the bulk modulus-like penalty parameter required for Mooney Rivlin material models in FEBio.

5.3 Pessary Mechanical Testing

Cocoon moulded RWS pessaries in commercially available diameter-based standard sizes (3, 5, 7, and 11) [83] of the two silicones (Shore 40A and 60A) were selected for mechanical tests (Table 5).

Table 5: Commercially available pessary size diameter and thicknesses dimensions. N in paratheses refers to the number of samples tested for each size.

Size	Diameter (mm)	Thickness (mm)	
		Shore 60A	Shore 40A
3	64	12 (n = 1)	12 (n = 2)
5	76	13 (n = 4)	12 (n = 2)
7	89	12.5 (n = 1)	20 (n = 2)
11	114	13 (n = 1)	-

Each pessary size was subjected to two mechanical testing protocols (Figure 25). A folding test, to replicate simplified pessary insertion mechanics, was performed [29]. This test involved loading each pessary vertically, in its designed folding orientation, between a uniaxial load applicator and fixed plate until the pessary folded to self-contact (Figure 25A). Secondly, a modified 3-point bending test was also performed. This bending test was performed by applying a load to the pessary while horizontally suspended between two curved platforms spaced based on the pessary diameter, see Eqn. 6, until the pessary slipped out from between the two platforms (Figure 25B).

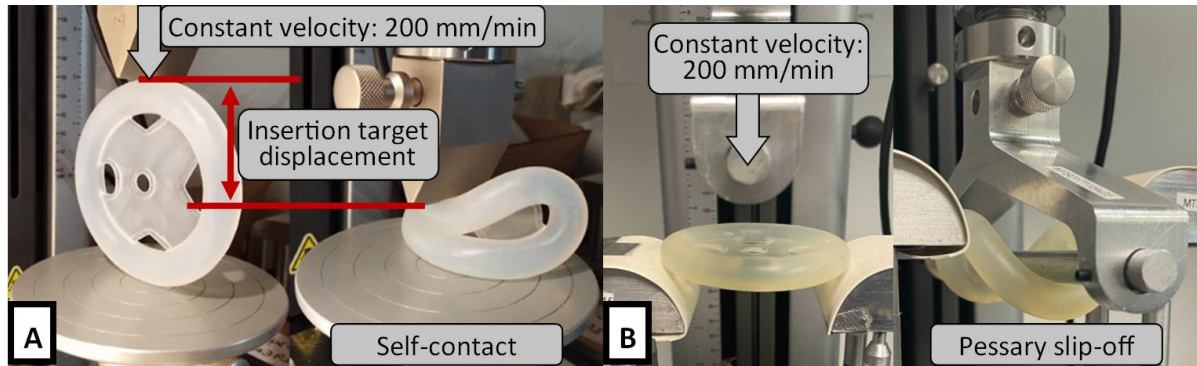


Figure 25: (A) Pessary folding test showing initial contact between the impactor and pessary as well as the complete fold at the impactor's target displacement, (B) pessary 3-point bending test showing initial suspension of the pessary between the platforms and the point right before pessary slip-off, the end of the test.

$$\text{Platform Spacing} = \text{Pessary Diameter} - 24\text{mm} \quad (6)$$

Equation 6: Distance between the platforms for the 3-point bending test was determined based on the pessary diameter minus twice the default ring thickness (12 mm), to maintain a 12 mm overlap between the pessary and platform on either side.

For both tests the pessaries were initially compressed to a 1 N preload, after which a constant downward velocity of 200 mm/min was applied to compress the pessary in the folding test or cause the pessary to slide along the curved platforms of the 3-point bending test. The folding test was completed when a target downward displacement was reached, see Eqn. 7. This displacement represents the point where the pessary has completely folded to self-contact (Figure 25A). The 3-point bending test was completed when a force decrease over 5 N was detected, corresponding to the pessary slipping off of the platforms (Figure 25B).

$$\text{Target Displacement} = \text{Pessary Diameter} - 2(\text{Pessary thickness}) \quad (7)$$

Equation 7: Target downward displacement for pessary folding test. This displacement brings the top and bottom edges of the pessary into contact. This final displaced position replicates the complete pessary fold required to insert the pessary into the vaginal canal.

5.4 Finite Element Modeling of Pessary Deformation

The pessary geometry was prepared for the FE analysis by importing stereolithography (STL) files from the pessary CAD models created for mould manufacturing. The pessary STLs were then meshed in FEBio using the TetGen, MMG Remesh, and mesh conversion tools. Firstly, the TetGen tool was used to create an initial editable volumetric tetrahedral mesh. The initial mesh was then iterated using MMG Remesh, targeting an element size of 4 mm and minimum element size of 2 mm (Table 6). The resulting meshes were then converted (using the mesh conversion tool) into tetrahedral elements with 10 nodes (Tet10). These elements were required to prevent mesh locking while using MR material models. The FEBio mesh inspector was used to evaluate the tetrahedral quality of the meshes (ratio of the circumscribed sphere radius to the shortest edge length; perfect value is approximately 0.62 but values below 1.5 are considered good), indicating good overall mesh quality (Table 6).

Table 6: FEBio pessary mesh details for the pessary models created to match the dimensions of the Shore 60A and 40A pessary samples dimensions. Namely the number and quality of the tetrahedral elements, where the quality represents the ratio of the radius of the circumscribed sphere to the shortest edge length. Below 1.5 is generally considered acceptable tetrahedral element quality.

Size	Number of elements		Average tetrahedral quality	
	Shore 60A	Shore 40A	Shore 60A	Shore 40A
3	23944	23944	0.695527	0.695527
5	32296	26712	0.870105	1.12862
7	33670	46262	1.29541	1.02878
11	90297	-	1.00735	-

The two pessary mechanical tests previously described in Section 5.3 were recreated in FE analysis software, FEBio v3.8 and FEBio Studio v1.9. The folding test was created using a blunted impactor and flat plate, which were defined as rigid bodies with the material properties of steel (Density: 7.85 g/cc, Young's modulus: 215 GPa, Poisson's ratio: 0.3) [84]. The flat plate was fixed in all directions, while the blunted impactor was prescribed a downward vertical velocity of 200 mm/min to compress the pessary while being fixed in all other directions. Sliding-elastic contacts were prescribed for the impactor-pessary, plate-pessary, and pessary-pessary (when folded to self-contact) contacts. The initial friction coefficient for these contacts was defined as 0.5, as it does not significantly impact the results of this folding test (there is little to no sliding). The MR material coefficients identified from uniaxial testing were then applied to the size 5 RWS model for each silicone. Initially, the FE model and experimental folding results did not match, indicating the need to iterate the MR material model coefficients. The MR coefficients were then linearly scaled until the folding test FE and the experimental results matched for the size 5 RWS pessary. These optimized material properties were then validated against FE models of the independent size 3 and 7 (and size 11 for Shore 60A) for the fold tests.

The modified 3-point bending test was created in FEBio through two rounded platforms and a cylinder-shaped impactor, matching the physical test setup, which were defined as rigid bodies with the material properties of steel used for the folding plate and impactor. The two platforms were fixed in all directions, while the cylindrical impactor was prescribed a downward vertical velocity of 200 mm/min

to displace the pessary while being fixed in all other directions. Sliding-elastic contacts were prescribed for the impactor-pessary (lateral impactor surface) and platform-pessary contacts. An approximate friction coefficient determined from manual testing was applied to the size 5 RWS FE bending test contacts with the scaled MR material coefficients (from the fold test) applied to the pessary. The friction coefficient was then iterated so the simulation result best matched the experimental bending test data for the size 5 RWS pessary. The optimized friction coefficient was then independently validated against FE simulations of the bending test on 3 and 7 (and size 11 for Shore 60A). Agreement between the FE models and experimental test data was further assessed using correlation and analysis software (CORApplus v4.0.5, Partnership for Dummy Technology and Biomechanics, Ingolstadt Germany) [85].

A mesh convergence investigation was also performed to evaluate the appropriate element size parameters to be used in MMG Remesh (element size and minimum element size) to optimize computational efficiency and accuracy. This investigation was performed on progressively more detailed meshes of the size 5 RWS, to evaluate the test results accuracy with increased mesh refinement.

5.5 Model results

The MR material coefficients for both pessary manufacturing silicones, as determined from the Excel Solver fitting, were initially applied to the size 5 RWS FE folding test (Figure 26B) then manually scaled to calibrate to the size 5 RWS data for the mechanical folding test (Figure 26A) results. The friction in the size 5 RWS FE 3-point bending test (Figure 26D) was set to initial manual test values of 0.5481 and 0.7107 for the Shore 60A and 40A silicones respectively. The friction coefficients were then scaled for the 3-point bending test (Figure 26C) results. Based on the material and friction calibrations performed on the size 5 RWS folding and modified 3-point bending, MR coefficients were identified for the Shore 60A and 40A silicone materials for RWS pessaries, the main study outcome (Table 7).

Table 7: Material model coefficients

Material Model Coefficients	Shore 60A	Shore 40A
C1	0.6410	0.2981
C2	-0.1238	-0.0874
Bulk modulus (K)	51.3765	20.9340
Friction Coefficient	0.5481	0.7920

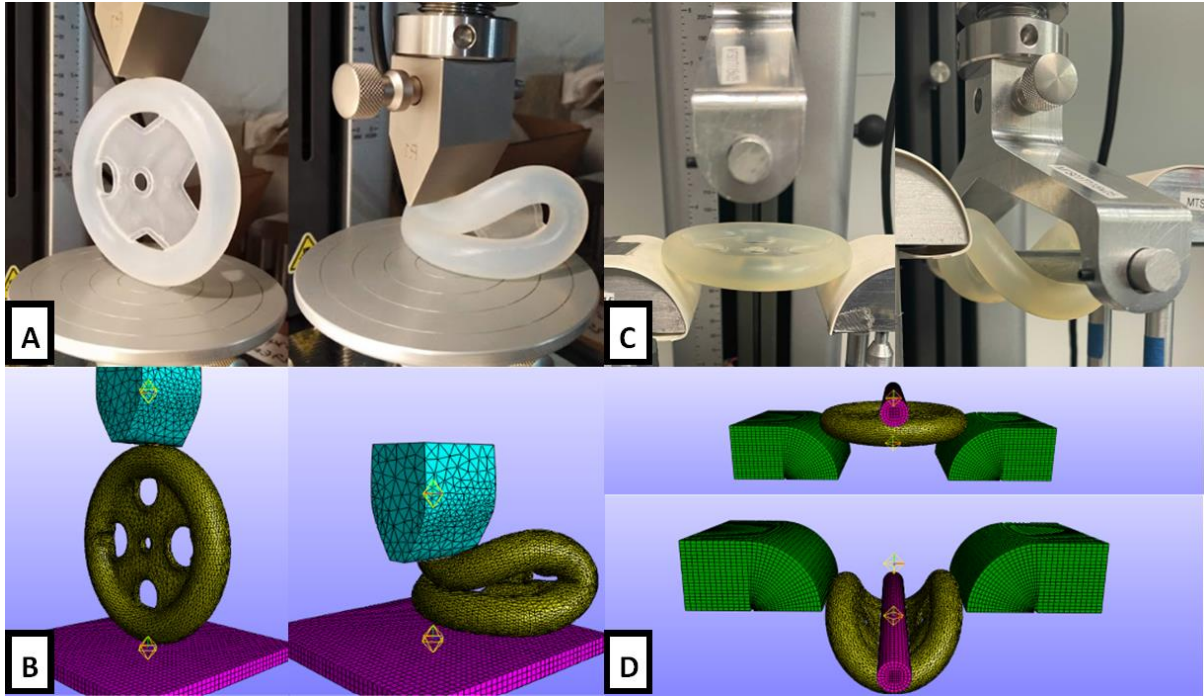


Figure 26: (A) Pessary folding test showing the initial contact between the impactor and pessary as well as the complete fold achieved at the target displacement of the impactor, (B) finite element (FE) recreation of the mechanical pessary folding test, (C) pessary 3-point bending test showing the initial suspension of the pessary between the curved platforms and the point right before pessary slip-off, the end of the test, (D) FE recreation of the mechanical pessary modified 3-point bending test.

Following the calibration of the material and friction coefficients, independent folding and 3-point bending test FE models with different pessary sizes were created for validation of the calibration results. Test data and FE results for the calibrated (size 5) and independent models (sizes 3, 7, 11) were plotted for comparison (Figure 27 and 28). Strong agreement between the FE and mechanical test data was also found through evaluation of the mechanical test and FE results using CORAplus (Table 8).

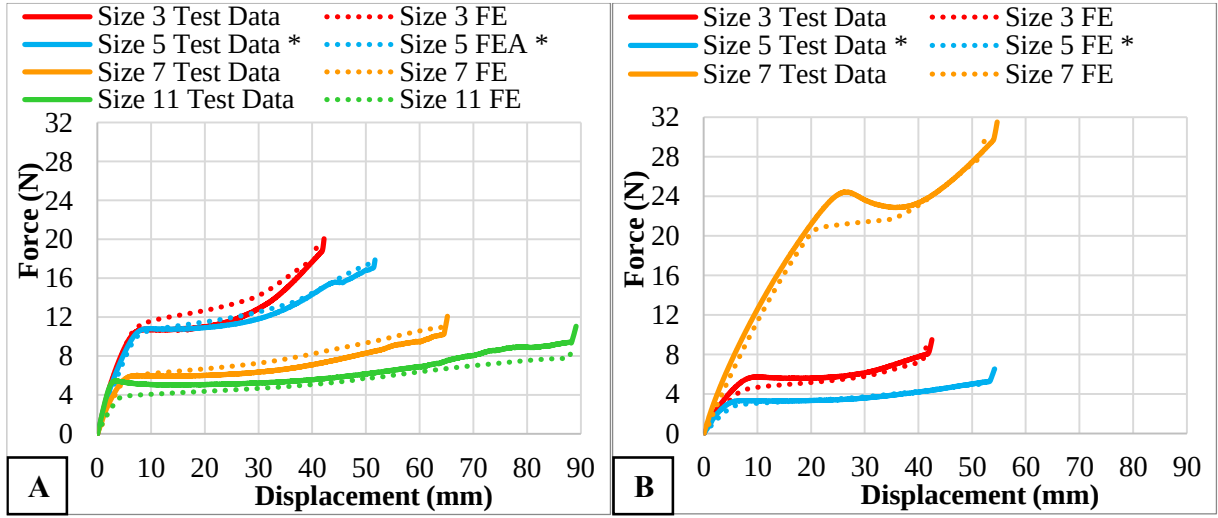


Figure 27: Results of the mechanical (solid lines) and FE (dotted lines) folding tests performed on (A) Shore 60A and (B) Shore 40A silicone pessaries. *indicates the material calibration data set.

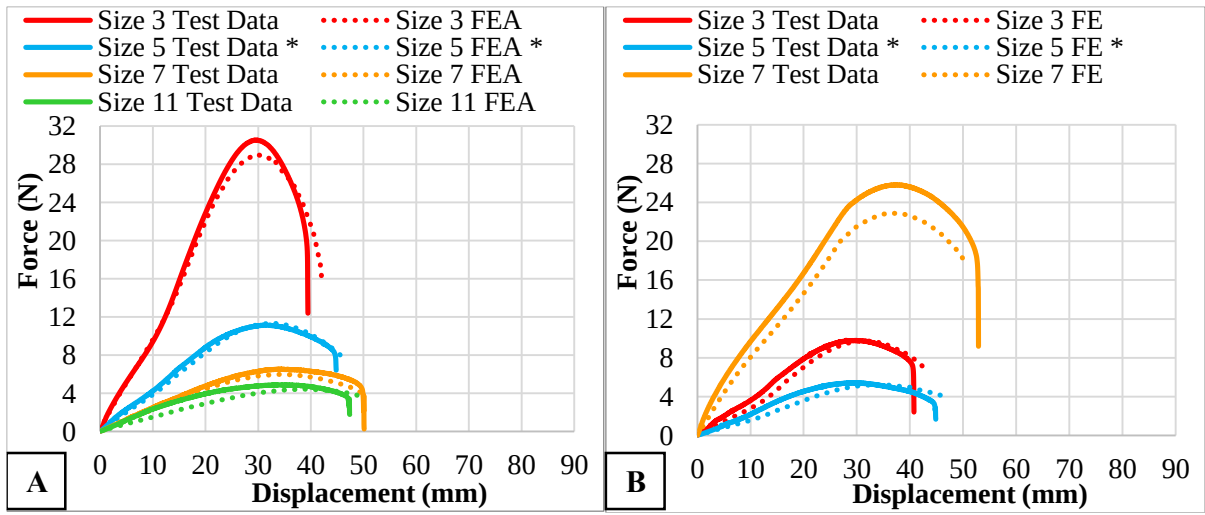


Figure 28: Results of the mechanical (solid lines) and FE (dotted lines) 3-point bending tests performed on (A) Shore 60A and (B) Shore 40A silicone pessaries. *indicates the friction calibration data set.

Table 8: Shore 60A and 40A CORAplus analysis results.

FE Test Pessary Size	CORA Scores			
	Shore 60A		Shore 40A	
	Folding	Modified 3-point Bending	Folding	Modified 3-point Bending
Size 3	0.921	0.975	0.920	0.891
Size 5	0.986*	0.994**	0.970*	0.716**
Size 7	0.881	0.929	0.954	0.857
Size 11	0.849	0.698	N/A	N/A
OVERALL	0.904		0.885	

*indicates the material calibration data set, ** indicates the friction calibration set

With respect to mesh convergence, increases in mesh complexity beyond a 4 mm element size and 2 mm minimum element size did not yield a significant difference in simulation results (Figure 29). However, comparison of the number of elements and computational time showed differences between meshes, namely the coarsest mesh had 32,296 elements and took 24:43 minutes to run, while the finest mesh was 111,809 elements and took 4:12:54 hours to run. Therefore, since there was little difference in the result accuracy, the coarse mesh (element size: 4 mm, minimum element: 2 mm) was chosen for computational efficiency.

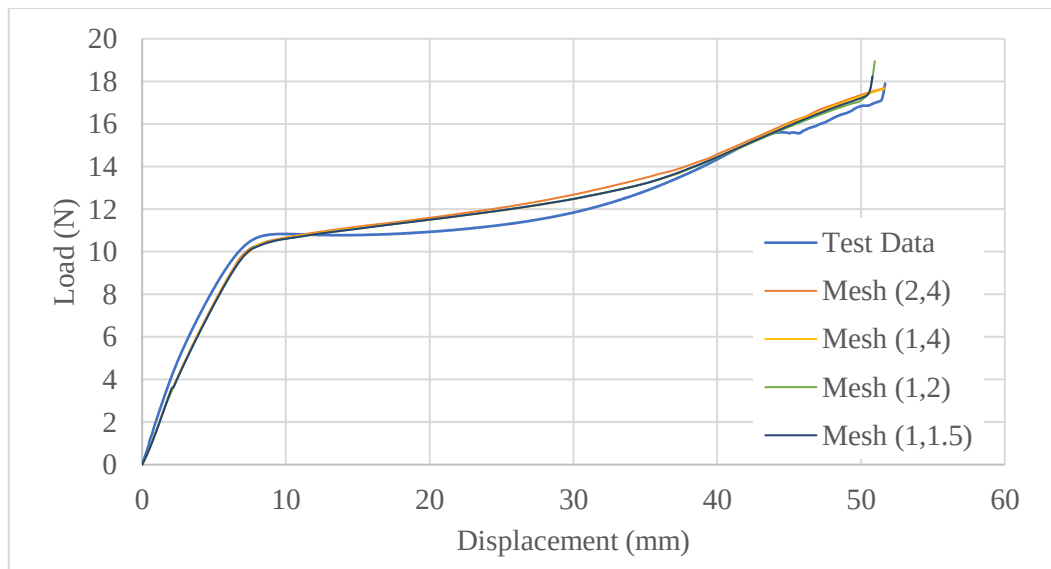


Figure 29: Mesh convergence results for Tet10 elements with minimum element sizes of 1 and 2 mm and element sizes of 4, 2, and 1.5 mm. The mesh names are “Mesh ([minimum element size in mm], [element size in mm])” and are compared to the folding mechanical test results labelled “Test Data”.

5.6 Model value and limitations

The mechanical testing and FE modelling performed resulted in MR material models for Shore 40A and 60A medical grade silicone for pessary manufacturing. Independent validation of the material models found good CORAplus agreement across a range of pessary sizes for both tests, indicating their validity at predicting the silicone material response. These models represent a valuable tool for pessary understanding and future modelling as they can be run in less than an hour while custom pessary manufacturing requires well over one business day to produce through cocoon moulding. Using FE modelling to simulate real-world RWS behaviour can save time and money by determining the mechanical properties of different sizes.

Comparison of the MR coefficients determined in this study to previous research indicates that the values determined are realistic for silicone rubbers with similar Shore hardness [86]–[88]. In particular the coefficients found are similar to those reported in other work, which reported Shore 50A silicone coefficients of 0.5076 and -0.1175 for the C_1 and C_2 MR coefficients respectively [88]. As expected, the magnitude of the Shore 60A MR coefficients are larger than those reported for Shore 50A, while the magnitude of the Shore 40A are smaller. The initial fitting of the uniaxial test data extremes (strains below -0.1 and above 1.0) ensured excellent fit of the data across the entire material response, whereas fitting the entire dataset resulted in poor fit of the compression region. In fact, the R^2 of the Shore 60A compression region increased from 0.71 to 0.96 with end-fitting. Poor fit of the compression region during fitting of the entire dataset is likely a result of the larger range of tension response data, causing overfit of the tension during R^2 maximization.

Mechanical test results from the RWS folding test demonstrate similar behaviour to those of Hong et al [29]. The similarity can be seen in the force-displacement curves obtained in both studies. The mechanical tests performed in both studies exhibit the in-plane dominant phase where the force rises significantly to the transition point, a local maximum, which is followed by a buckling phase where the force decreases before increasing to the global maximum when there is self contact [29]. Hong et al. identified a predictable pattern within the transition force of the pessaries, which they characterized as a $1/L^2$ relationship [29]. Among the pessaries with a 12 mm thickness (matching those tested by Hong et al.) the transition force matched the results from Hong et al. for the Shore 60A material (1.8% error) but did not match for the Shore 40A material (Table 9). This is expected as the Shore 60A material was intended to match the material currently used in commercial pessaries, whereas the Shore 40A material

is softer. The softer nature of the material is confirmed as it yields transition forces more than 60% lower than those reported by Hong et al. [29].

Table 9: Comparison between the transition forces observed and those reported by Hong et al. [29].

Diameter (mm)	Material	Transition Force (N)	Hong et al. Average Transition Force (N)	% Difference
64	Shore 40A	5.67	11.4 [29]	67.1
	Shore 60A	11.20		1.8
76	Shore 40A	3.31	6.8 [29]	69.0

The fold testing performed based on the protocol from Hong et al. was done for the calibration and verification of the RWS FE models. The reconstruction of this test in FEBio allowed for the material properties of the Shore 60A and 40A silicones, obtained from uniaxial sample testing, to be tailored without complex contact. Overall, by inspecting the fold test results obtained from FE analysis, one key observation is the difference in the transition points between the experimental test data and FE model. In fact, the FE model was not capable of capturing the force reduction observed in the test data after the transition point; this is most obvious when comparing the test data and FE model for the Shore 40A size 7 results. Due to the inability of the model to capture this force reduction, the transition force was underestimated by 3.8 N in comparison to the size 7 test data. An inability to effectively model this buckling represents a potential limitation of the fold test FE model in evaluating this response region, however it does not limit the application of these models for assessing regions of greater contact [29].

From the modified 3-point bending test it is evident that the peak force required to dislodge the pessary from between the two curved platforms varies significantly between the pessaries tested. The smallest peak force to dislodge the pessaries was observed for the size 11 Shore 60A pessary and the size 7 Shore 40A pessary, which exhibited peak forces around 4 N. The intravaginal pressure from IAP measured during a Valsalva maneuver has been found to achieve a maximum of 15 kPa [89]–[91]. Applying 15 kPa to the surface of the pessary, 8,413 mm² (0.008413 m²) for size 11 (largest pessary tested), would achieve approximately 126 N of force, significantly more force than is needed to dislodge the pessary based on the findings of the modified 3-point bending test. Therefore, this setup does not fully account for the IAP load magnitude which will be experienced by the pessaries *in-vivo*.

The modified 3-point bending test allows analysis of RWS pessaries response to force on the pessary center, lending possible insight for the pessaries' response to IAP; yet this simplified setup does not account for *in-vivo* conditions. The curved steel platforms cannot emulate the support of the pelvic floor structures, meaning the contact with the pessary silicone would be different than with compliant vaginal tissue. The vaginal canal has several tissue layers which also affect the interacting forces on the supporting RWS pessary [92]. Therefore, while this simplified bending test aids in better understanding the pessary silicone mechanics it does not represent true anatomical loading conditions, at best representing extreme IAP-like loading. Future work to model the vaginal-pessary interface with consideration for vaginal tissue properties could aid in assessing pessaries prior to *in-vivo* testing.

There are limitations to the material model generated, specifically the need for scaling of the MR material coefficients following the initial parameter determination. While the final MR coefficients were independently validated against various RWS pessary sizes, it is concerning that the uniaxial tension and compression data did not accurately represent the behaviour of the RWS silicone materials. One hypothesis is that the samples' oven curing alters the surface properties of the silicone, making the small and thin uniaxial test samples overly stiff. This may explain why the material coefficients from the uniaxial samples needed to be scaled down to match the observed properties of the RWS folding and 3-point bending tests. The identified MR coefficients for the hyperelastic silicone material models may not accurately represent the behaviour of significantly different pessary designs that have smaller features more affected by oven curing. The model is also limited to RWS behaviour and is untested for other pessary shapes, the material properties must be tested and optimized for application to new shapes. The nature of this study necessitated pessary manufacturing using cocoon moulding, for customized pessaries, however the industry standard injection moulding may yield different results.

5.7 Study conclusions

This study successfully identified hyperelastic materials and computational models to evaluate RWS pessary folding and modified 3-point bending for multiple RWS sizes and silicone material stiffnesses, as demonstrated by the strong agreement between the response of the FE models and mechanical tests. These results will allow computational testing and mechanical response evaluation to be performed on other RWS pessary sizes or possibly minor design changes expediting the labour-intensive iterative design process. The methods described for test setup and material identification could also be used in future to model other pessary types as well as assess novel pessary designs.

Chapter 6

Pilot Investigation into Pessary Topology Optimization

Current commercially available pessaries are manufactured in finite sizes, with limited patient customization options [34]. Additive manufacturing (AM) presents a valuable opportunity for addressing individual patient needs through customized pessary manufacturing [34], [35]. This method of manufacturing also widens the possibility of designs and dimensions which can be produced, allowing for the generation of novel pessary designs through topology optimization. Pessary insertion and removal prove to be challenging for patients utilizing Gellhorn pessaries resulting in the need for frequent appointments for pessary removal, cleaning, and reinsertion by a clinician [6]. This also serves as a valuable area for pessary design optimization as self-management can increase patient satisfaction and improve quality of life [30]. As a result, a pilot investigation was performed to iterate the Gellhorn design based on hypothetical loading conditions, as well as making the insertion and removal of Gellhorn pessaries manageable for patients who want or need to self-manage their pessary.

6.1 Gellhorn loading conditions

To improve Gellhorn self-management, it is first important to understand how Gellhorn pessaries are inserted and removed. Firstly, to insert the Gellhorn the stem is folded down against the edge of the cap, after which lubricant is applied to the opposite and leading edge of the pessary [66]. The ideal pessary folding force should withstand pressures in the vaginal canal but be minimized to allow folding for insertion and removal [29]. Once the pessary has been pushed past the patient's pubic symphysis the stem is released and the trailing edge is pushed upward, positioning the pessary cap to support the prolapse [66]. Gellhorns are hypothesized to create more friction and suction effects in the vagina; however, this makes insertion and removal difficult for patients [6], [66]. Therefore, patients with Gellhorns typically need to visit a gynecologist for pessary removal, cleaning, and insertion. For removal the stem-knob is grasped, generally with ring forceps, the cap is rotated to release suction and finally pulled downwards and folded for removal [66]. Otherwise, removal has been described as gripping the edge to release the suction, rotating it sideways, and pulling it out sideways [93]. To improve Gellhorn self-management these stages must be made more manageable for patients to perform independently.

From previous research the Gellhorn's position *in-vivo* remains relatively consistent with the stem facing inferiorly such that the Gellhorn cap is parallel to the floor [6], [68]. This pessary does not

experience significant rotation likely due to the shape or hypothesized suction mechanism [68]. This orientation as well as the large disc diameter creates the “cork stopper” effect of the Gellhorn, which allow it to treat more severe prolapse [68]. Finally, the pessary stem may interact with the patient’s perineal body aiding in its prolapse support, though this has yet to be confirmed [68]. The maximal loading condition of the Gellhorn *in-vivo* which could cause pessary fallout, is emulated by the Valsalva maneuver. During a Valsalva a patient bears down, as though performing a bowel movement, increasing their IAP causing improperly fitted pessaries to fall out [6]. Patients perform this test during pessary fitting to ensure the pessary will not fall out during everyday activities [6]. Pressures experienced during Valsalva are reported below 15 kPa with an approximate line of action following the vaginal wall movement at 50-60 degrees below horizontal [25], [89].

6.2 Current Gellhorn designs

Before beginning iteration of the Gellhorn design, a review of the Gellhorn pessaries currently commercially available was performed. Compiling images of the Gellhorn design across multiple commercial manufacturers allows for analysis of the design components which are consistent across the commercially available Gellhorns (Figure 30).



Figure 30: Pessary manufacturers and their associated Gellhorn designs

From visual comparison of commercially available Gellhorns, it became clear that their designs were similar, this is likely because commercial manufacturers tend to default to the legacy Gellhorn design,

reported in use since 1944 [33]. Each design has a slightly concave cap, a vertical stem (of which there are a few heights), and a spherical knob. As a result, there is significant room for design iteration within the space, especially when improving the pessary insertion, removal and loading optimization.

6.3 Design and manufacturing constraints

Several design and manufacturing constraints were identified and used to evaluate each design change (Table 10). These constraints were developed to direct the Gellhorn iterative design process, namely, to ensure the goals of the redesign remain the focus of each successive iteration. The Gellhorn redesign focused on ensuring iterations were made to meet the needs of the problem space, such as being manufacturable in custom sizes (requiring to AM), maintaining the pessary action, as well as improving pessary insertion and removal.

Table 10: Gellhorn Pessary Design and Manufacturing Constraints

Constraints	Summary	Description
Design constraints		
Constraint 1 (C1)	The design must be scalable to any required patient size.	Patients come in various shapes and sizes; the pessary design must be scalable to accommodate. E.g. commercial pessaries are 38-95 mm diameter.
Constraint 2 (C2)	The design should accommodate gripping for insertion and removal.	Changes should improve the ability of patients to grip and remove their own pessary, such as releasing suction [66], [93].
Constraint 3 (C3)	Improvement to pessary gripping should be able to be found <i>in-vivo</i> .	While different gripping methods may assist in pessary insertion, they must also be able to be found <i>in-vivo</i> to improve removal.
Constraint 4 (C4)	The pessary redesign should not significantly impact the pessary action.	The pessary must support the prolapse, in particular it is hypothesized that the cap acts through friction and suction, altering the cap may impact function [6].
Constraint 5 (C5)	The pessary should direct the pessary stem folding in one direction.	Directing the folding in one direction will allow easier folding but keep the pessary in position well for the other three directions.
Constraint 6 (C6)	Stem should withstand forces <i>in-vivo</i> but minimize folding force.	The pessary should not be folded and rotated by the forces of the POP; however, the stem should be able to be folded easily for insertion and removal [29].
Manufacturing constraints		
Constraint 7 (C7)	The design must be AM manufacturable.	This will allow for on-demand pessary manufacturing for custom sizes, this is to improve pessary fitting success through customization of pessary fitting.
Constraint 8 (C8)	Must be manufactured from a silicone material.	The pessary must be able to be folded for both insertion and removal, as well as flexing to not harm surrounding tissues [34].
Constraint 9 (C9)	The pessary must be manufactured in a medical grade silicone.	A pessary is a medical device which must be safe for vaginal insertion as well as requiring Health Canada approval.
Constraint 10 (C10)	The material should be able to be cleaned effectively and withstand cleaning many times.	Patients need to remove and clean their pessaries minimally every 2-3 months [6]. Therefore, the material must withstand this process many times throughout its lifecycle.

In summary, the design constraints of the Gellhorn can be grouped based on the goals of the redesign. Firstly, the design must be scalable allowing these pessaries to be customized so as to address populations which are not compatible with the standardized sizing. Secondly, the design must improve the Gellhorn design for self-management, this includes directing the pessary folding to minimize fold force while still supporting the prolapse as well as accommodate gripping for insertion and removal (consider ability to find folding features *in-vivo*). Finally, the design must maintain the pessary action (hypothesized friction and suction). Constraints for manufacturing the pessary include being manufacturable through AM for on-demand manufacturing of custom patient sizes, it should be manufactured using a medical grade silicone, and allowing thorough cleaning.

6.4 Functional/Performance requirements

To objectively evaluate the design using topology optimization, it was important to determine the performance requirements of the design. These requirements were based on the work of previous researchers who identified the support and position of the Gellhorn pessary *in-vivo*. The requirements as determined from literature are found in Table 11.

Table 11: Gellhorn pessary performance requirements

Requirements	Summary	Description
Requirement 1 (R1)	Minimal cap bending under a 15 kPa applied pressure.	The pessary cap should be able to support forces of Valsalva which have been measured with a max pressure below 15 kPa [89].
Requirement 2 (R2)	Minimal stem folding with 15 kPa applied pressure at the known angle of Valsalva (approx. 50-60 degrees below horizontal).	The pessary stem should not be fully folded with a concentrated pressure of 15 kPa at 50-60 degrees below horizontal [25], [89]. Reason being that this would allow for pessary rotation <i>in-vivo</i> and possible fallout.
Requirement 3 (R3)	Minimize stem folding force, above 15 kPa pressure on knob but below 144.2 N (weak grip of women 70-99 years) [94].	To improve patients' ability to fold the pessary for insertion and removal the force required to fold the stem should be minimal, ideally in one optimal direction [29].

The functional requirements were essential for the design optimization and analysis performed in Inspire (v. 2022.3, Altair Engineering Inc., Troy, Michigan, USA). To optimize the design, different

loading conditions representing the three functional requirements were created within Altair Inspire. Firstly, a 15 kPa pressure was applied to the cap with supports on the stem, to simulate the pressure during Valsalva. Secondly, a diagonal (50-60 degrees below horizontal) 15 kPa pressure was applied to the stem with support on the cap, to simulate *in-vivo* forces on the stem during Valsalva [25], [89]. Three loading conditions were created to maximize stiffness in three of the stem folding directions (to resist Valsalva), this allowed for the fourth folding direction to be minimized, resulting in directional folding for insertion. These were created by placing supports on the cap and applying the Valsalva pressure to the side of the knob. Finally, for the stem folding it was important the force to fold the stem was below the weak grip force of an elderly woman, the population most significantly impacted by POP. The gripping force threshold was determined for a weak grip in women 70-99 years of age is 14.7 kg or 144.2 N [94]. This was tested by supporting the Gellhorn cap and applying a 144.2 N force to the pessary knob, to fold the stem against the cap.

6.5 Gellhorn stem iteration setup

The first area of design iteration was to optimize the pessary design for the forces in the vaginal canal as well as for the folding performed for insertion and removal. The first step to optimizing the pessary design was to recreate an average pessary size in Solidworks (Premium 2019 SP4.0, Dassault Systèmes, Vélizy-Villacoublay, France). This was done for a 70 mm diameter (34.5 mm post height) recreation of a generic Gellhorn pessary, based on commercially available designs (Figure 31).

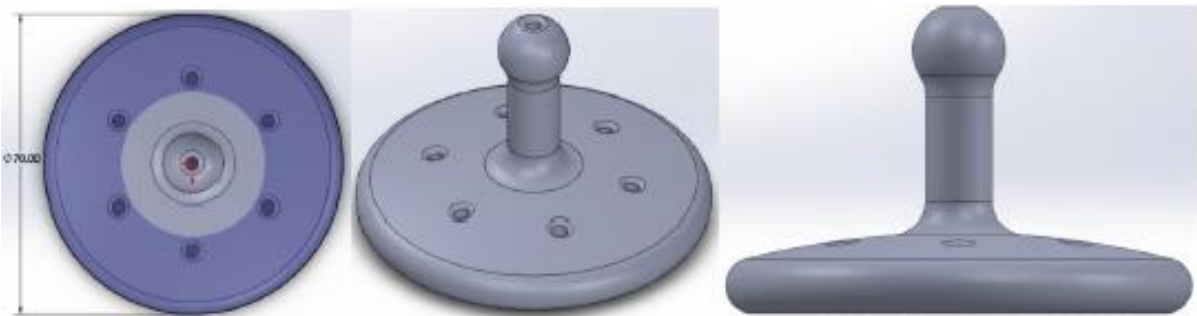


Figure 31: Commercial Gellhorn pessary recreated in Solidworks

For optimization, the Solidworks model was recreated in Altair Inspire and the loading conditions previously described for fulfilling the pessary performance requirements were applied. A material to represent pessary manufacturing silicone was defined using the properties of medical grade silicone rubber by Elkem (Table 12) [95]. The chosen material is used to manufacture medical parts, which includes long-term implants (30 days or more) [95]. The optimization was defined with a large

cylindrical design space within which the software could generate proposed designs, this design space was bisected by a mirror plane to generate a left-right symmetrical design. The cap and knob were maintained on the top and bottom with fixed contact to the design space, therefore maintaining these portions of the Gellhorn design to focus on stem iteration (Figure 32).

Table 12: Elkem Silbione BIO LSR M360 A material properties

E	Nu	Density	Yield Stress
2.300 MPa	0.499	1.130E-3 g/mm ³	8.800 MPa

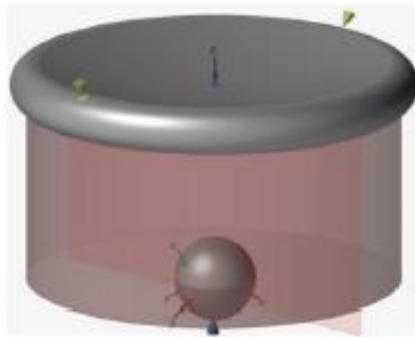


Figure 32: Pessary optimization setup with the loading condition arrows, design space in red, and a mirror plane down the plane which would correspond with patient's mid-sagittal.

6.6 Gellhorn stem iteration results

From the applied loading conditions and optimization setup described in section 6.5 the results for minimizing the mass and maximizing the stiffness were obtained (Figure 33).

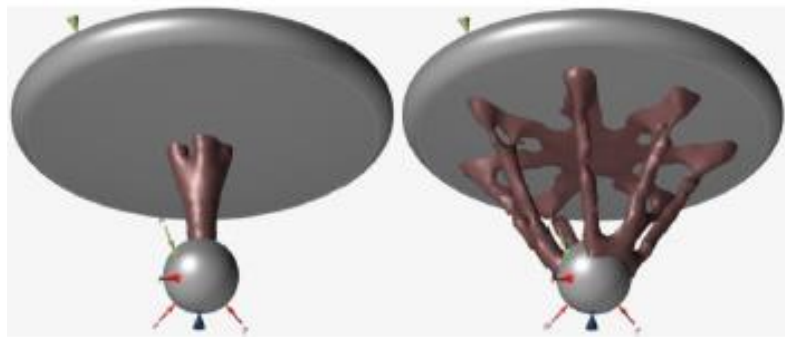


Figure 33: Minimum mass (left) and maximum stiffness optimization results (right).

The minimized mass and maximized stiffness optimization results obtained were compared. While the straight stem resulted in a minimized mass, the use of approximately 45-degree struts provided the

greatest design stiffness based on the applied loading conditions. As a result, a combined design was created from the results of both optimizations (Figure 34).

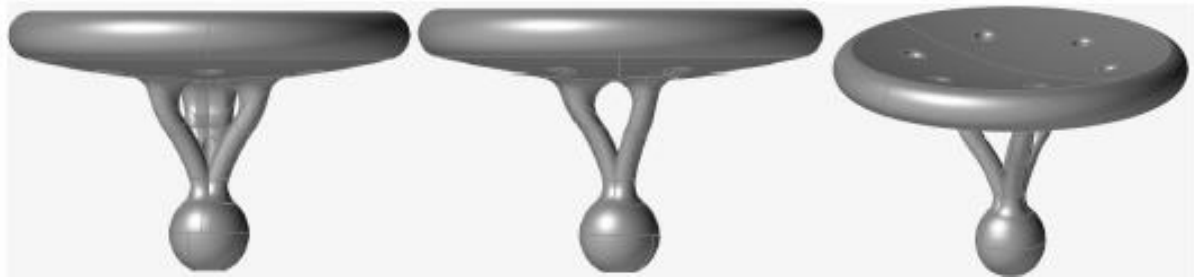


Figure 34: Optimization combination tripod design results

The new design utilized three struts which combine at the base of the knob. The strut spacing was determined from the tripod base of the straight stem seen in the minimum mass results, whereas increasing their angle was inspired by the maximum stiffness result. However, attaching the angled struts to the base of the knob (as opposed to around the outside of the knob as seen in the maximized stiffness) resulted in a more centralized stem, maintaining a shape closer to the original Gellhorn, which was hypothesized to preserve its function.

The next step was to perform a complete analysis of the new design. This was done by applying the previously reported *in-vivo* pressures to the pessary cap and stem (Figure 35). This analysis verified the new pessary design fulfilled the first and second design requirements (R1 and R2) which correspond to constraints C4, C5 and C6. Next, an analysis was performed for the stem folding force (R3) which corresponds to C5 and C6. This was done by applying an *in-vivo* force (to simulate IAP during a VM) and an elderly grip force (to fold the stem for insertion) to the stem (Figure 36).

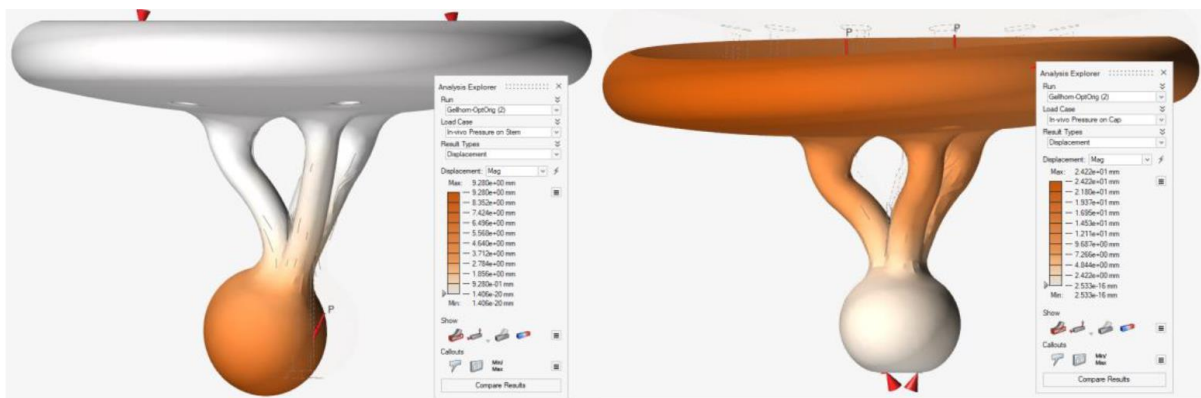


Figure 35: Optimization combination design *in-vivo* pressure analysis, (A) application of *in-vivo* pressure (P) to the stem knob (cap is fixed) in the intended fold direction and (B) application of *in-vivo* pressure (P) to the pessary cap (stem knob is fixed) in the direction of intraabdominal pressure action.

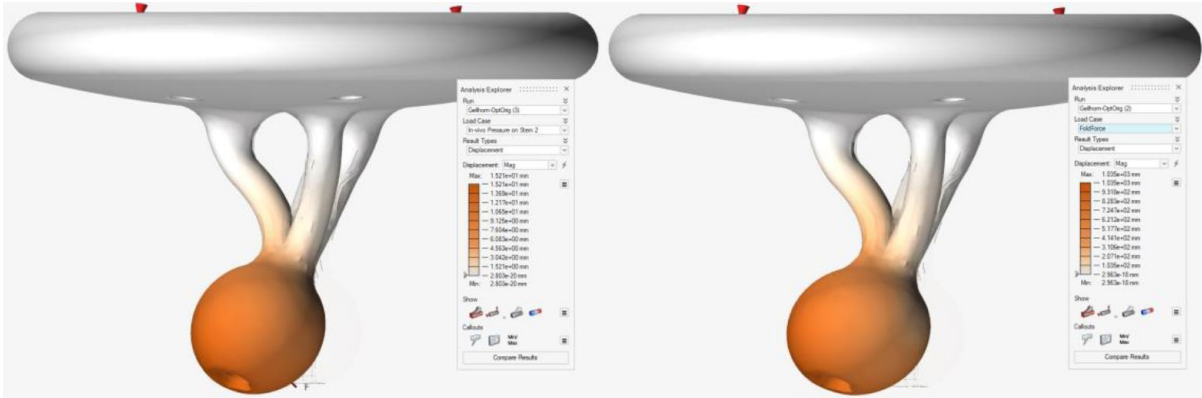


Figure 36: Optimization combination design stem fold analysis, (A) shows application of *in-vivo* pressures to the stem knob (cap is fixed) in the intended fold direction while (B) shows the application of elderly grip strength to the stem knob (cap is fixed) in the intended fold direction.

From the *in-vivo* pressure analysis on the cap and stem, it was evident that while the pessary deformed due to *in-vivo* pressures the deformation was not enough to facilitate fallout or impact pessary support and hypothesized action (friction and suction). When an *in-vivo* pressure was applied to the stem in the three non-fold directions the deformations were 8.9, 9.3, and 12.9 mm, indicating that while the Gellhorn deforms this would not result in folding or subsequent fallout, fulfilling R1 and R2. From the stem folding analysis, the application of *in-vivo* pressure in the optimal fold direction results in 15.2 mm of deformation while the weak gripping force of an elderly woman results in 1035 mm of deformation (277.1 mm vertically), a complete fold. Therefore, pessary folding fulfills R3 and subsequently fulfills C5 and C6.

Two minor improvements were made to reduce *in-vivo* load deformation: thickening the tripod struts and removing the hole through the stem and knob (Figure 37). This reduced *in-vivo* cap deformation to 22.2 mm (from 24.2 mm), *in-vivo* stem folding to 9.1 mm (from 15.2 mm) and folding under an elderly grip force to 875.3 mm with 291 mm vertically (from 1035 mm with 346.7 mm vertically). Therefore, undesired folding was reduced while maintaining the ability to completely fold the stem for insertion. The non-optimal fold directions also had reduced deformation of 421.2 mm, 433.3 mm, and 724.2 mm, indicating the desired directional folding. While these changes increased the material volume this was deemed allowable to improve functionality. Changes to the tripod leg curvature were attempted yielding only slight cap deformation improvement while increasing stem deformation from lateral forces.

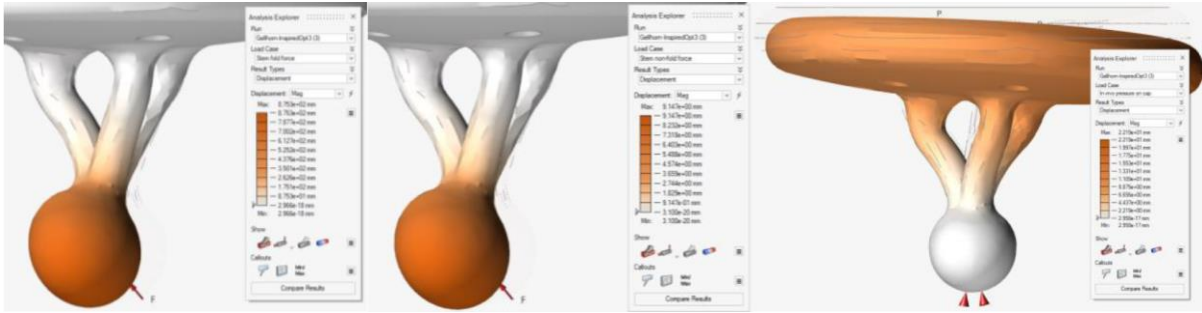


Figure 37: Thickened tripod design analysis

6.7 Gellhorn gripping iteration

The next area for design iteration was improving grip on the stem and cap of the Gellhorn for insertion and removal. The stages of pessary removal include gripping the pessary edge to release the cap suction, rotating the pessary sideways to fold it and finally pulling the pessary out [93]. Several possible methods for improving the method of pessary removal for patients to potentially self-manage their pessary were brainstormed and summarized (Table 13). These ideas were then recreated on the average commercial pessary size model initially utilized for optimization (Figure 38).

Table 13: Pessary Removal Redesign Ideas

Design Idea		Comments/Evaluation
A	Cut-out at the pessary edge for gripping and release.	Challenge to feel around the edge to grip the cut-out. Alternatively, this provides a clear indication of the direction in which to fold the Gellhorn stem.
B	Hole in pessary cap for putting finger through for gripping/suction release.	Challenge to ensure it will fit anyone's finger (e.g. 95th percentile women). Additionally, this significant hole in the cap will likely significantly reduce the suction of the pessary.
C	Handle on the pessary cap for gripping the edge to release suction.	Handle can be used to grip the cap. The stem can also be folded under the handle to hold for insertion, then pushed off. For removal the handle can again be placed over the post.
D	Hole in the pessary cap that the head of the post is pushed through.	The stem can be folded into the hole for insertion, then pulled out. For removal the stem can be pushed into the hole. This solution still requires a method for gripping the cap.
E	Add a ring to the end of the pessary post for easier gripping the end of the post.	This allows for better gripping the end of the post so the end does not slip from fingers, can indicate the direction to fold (push on the flat edge of the pessary to fold towards the cap).

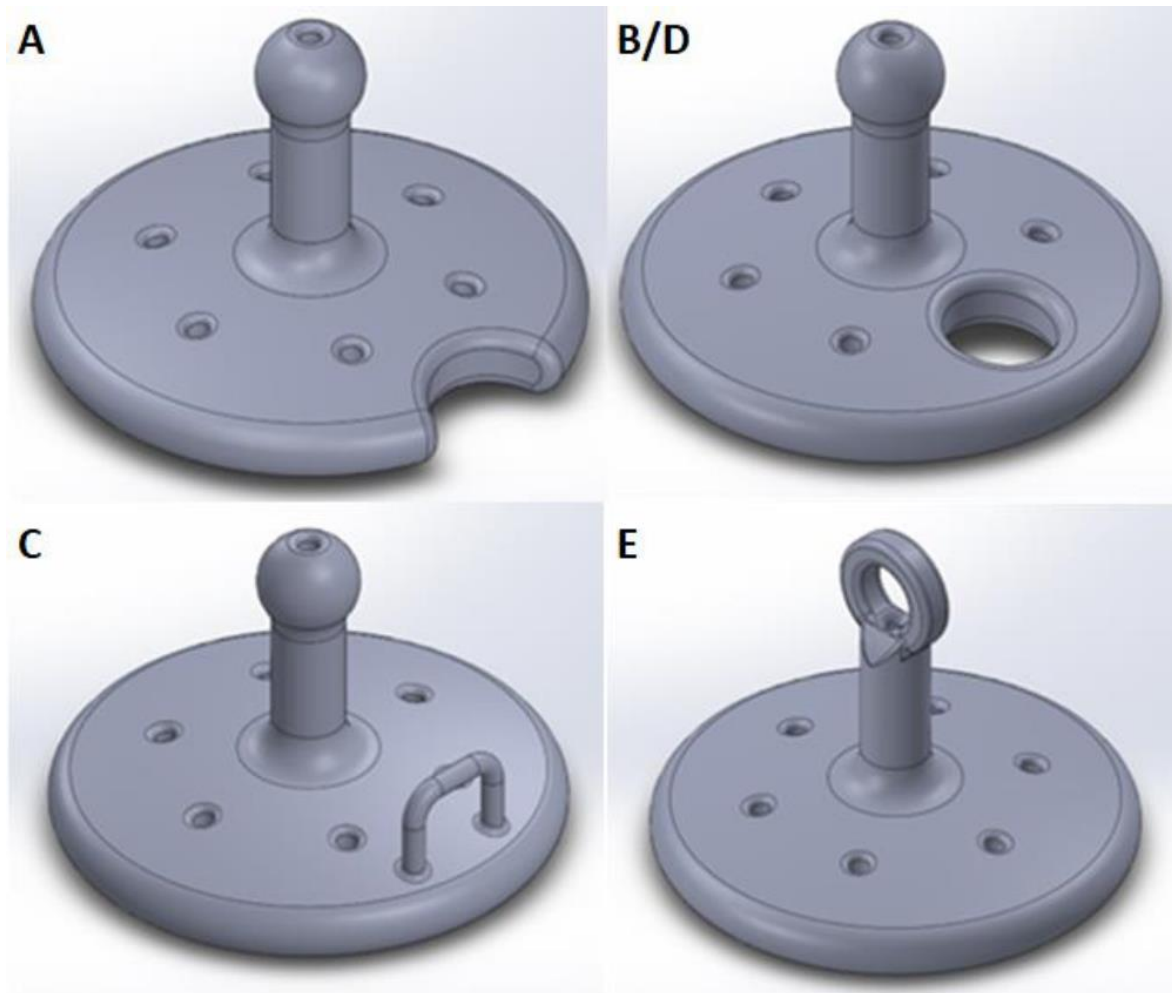


Figure 38: Pessary gripping redesign ideas A through E

The five brainstormed gripping methods were evaluated using a decision matrix to determine the optimal method for improving the insertion and removal of the Gellhorn pessary (Table 14). This decision matrix focused on the design constraints created to direct the pessary iteration. In particular, the matrix included the ability to scale the feature to different pessary sizes (C1), gripping the pessary externally (C2) and *in-vivo* (C3), assessing whether there was significant impact to the pessary action namely changes to the cap impacting the hypothesized suction effects (C4), being manufacturable using AM (C7), as well as being able to thoroughly clean the design (C10).

Table 14: Decision Matrix for Pessary Gripping Redesign Ideas

Pessary design:	A	B/D	C	E
(C1) Scale to patient sizes.	Scalable, but would impact smaller pessaries more with cut-out	Not scalable as the hole is very large for the cap of small pessaries	Very scalable, is not impacted by cap size besides area to connect to	Very scalable, is not impacted by cap size at all
	7	2	9	10
(C2) Grip	Can grip relatively well with some risk of slipping	Very good gripping as their finger can protrude through to securely grip	Very good grip by putting finger through handle	Not very good gripping for suction release only stem folding
	7	8	8	4
(C3) Grip <i>in-vivo</i>	May be challenging to feel for the cut-out along the vaginal walls	May be challenging to feel for the hole, but easier than the cut-out	Would be easy to find as only protrusion aside from the post	Would be easy to find as the post is easily findable on the cap
	6	7	8	9
(C4) Impact on pessary action	Cause some change to the pessary action by cutting the cap	Significant impact to the pessary action as the cap is not intact	Does not change pessary action	Does not change pessary action
	6	4	10	10
(C7) Ability to build with AM	Highly manufacturable	Highly manufacturable	Bit more challenging to build the small handle feature	Bit more challenging to build the small post loop
	9	9	7	7
(C10) Can be cleaned	Little to no change in cleaning from original pessary	Slight change to original pessary cleaning, hole to clean through	Slight change to original pessary cleaning, handle to clean through	Slight change to original pessary cleaning, handle hole to clean
	9	8	8	8
Total	44	38	50	48

** Table ratings are on a scale of 1 to 10, 1 being very poor and 10 being very good.

The decision matrix found that the handle on the pessary cap (design C) best improved the insertion and removal of the pessary without significantly altering the surface of the cap. Altering the cap was hypothesized to reduce the Gellhorn efficacy by impacting its hypothesized suctioning effect in the vaginal canal. Another design assessed for improving pessary gripping was the stem ring (design E) which could be combined with the cap handle to create a further improved design. Therefore, these designs were combined with the tripod design previously established (Figure 39).

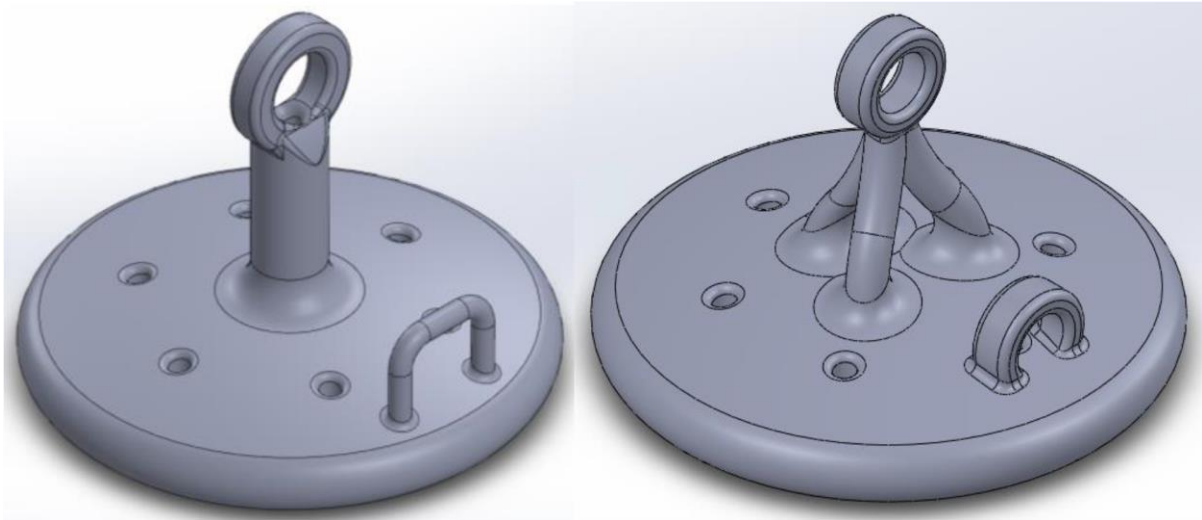


Figure 39: Combination of C and E designs (left) and combination with tripod stem (right)

To evaluate the ability of the stem ring and cap handle gripping methods to assist in insertion and removal, the force required to fold and hold the pessary stem must be quantified. This was done by applying a minimum force to fold the optimized pessary stem against the pessary cap. A minimum folding force of 36 N on the loop was identified to displace the tripod stem 34.79 mm vertically. This same minimum fold force was applied to the handle on the pessary cap, to determine whether it was strong enough to hold the folded stem. This handle analysis resulted in a 11.23 mm deformation. As a result, the handle required fortification to reduce deformation and was angled to better support the applied force. Changes to the handle reduced deformation from 11.11 mm to 3.622 mm (Figure 40).

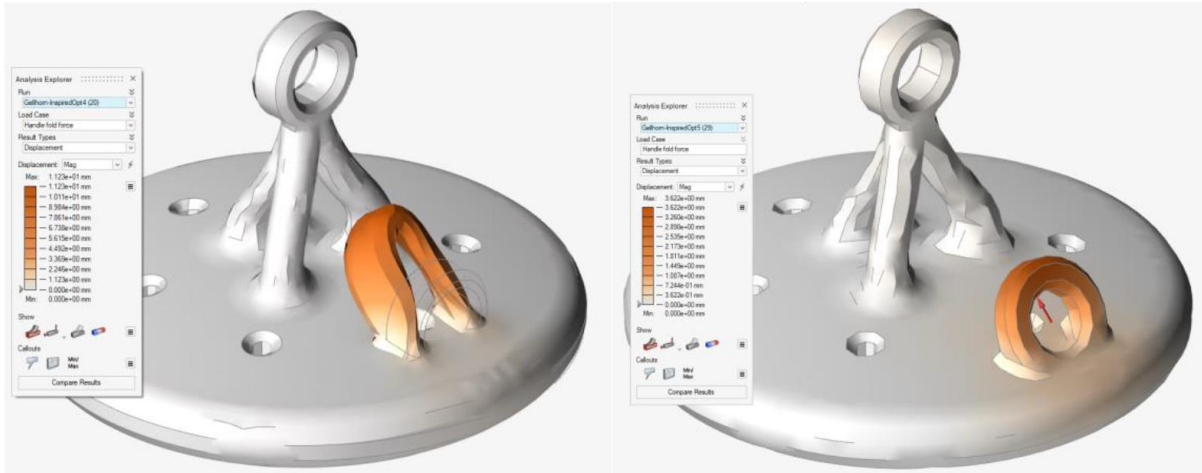


Figure 40: Initial handle analysis (left) and fortified handle analysis (right)

Finally, after these changes were applied to the pessary it became evident that adding the cap notch (design A) to the design would provide additional gripping methods. This design was not previously included due to challenges in finding this feature *in-vivo*; however, this is resolved by the presence of the cap handle. Therefore, a small notch was added near the cap handle to provide further options to release pessary suction. The cap handle may not be rigid enough for suction release given the deformation seen in previous analysis. However, it was not possible to evaluate whether the cap handle could release the suction in the vaginal canal as the suction effect has not been quantified. As a result, the design will benefit from a secondary gripping method to ensure proper functionality.

6.8 Detailed final design

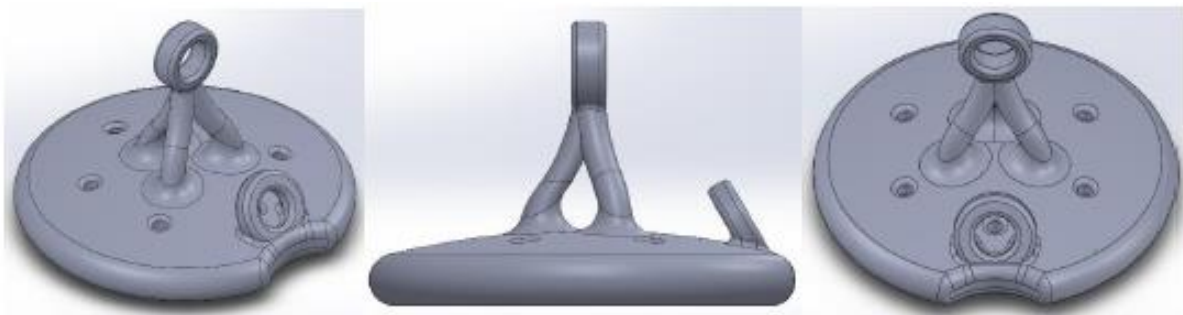


Figure 41: Final Gellhorn Pessary Design

From the described iterations the final Gellhorn design was obtained (Figure 41). The main changes to the design included the tripod stem, loop at the end of the stem, handle on the cap, as well as a cut-out

on the edge of the cap, all of which were assessed for AM (C7). The tripod stem created an optimal fold direction (C5) while facilitating folding with the application of a weak elderly grip strength to fold the pessary for insertion and removal (C6). The addition of the stem loop, cap handle, and edge cut-out also allow for easier pessary insertion and removal. Firstly, the loop on the end of the stem allows for easier gripping externally and *in-vivo* (C3). The handle on the pessary cap also assists in gripping while also serving as an option to hold the folded stem down during insertion (C2). The cut-out on the pessary cap provides a secondary method for gripping to release the pessary suction during removal (C2). Finally, these features can be scaled to various patient sizes while not significantly changing the pessary cap; this is hypothesized to not significantly affect the pessary's action *in-vivo* (C1 and C4).

6.9 Optimized Gellhorn reflection

The proposed design fulfilled the two main goals of pessary design iteration, namely optimizing for the pessary loads, as well as improving the Gellhorn pessary insertion and removal to increase the ability to self-manage. The optimal fold direction was created in hopes of making pessary stem folding easier while not affecting the pessary support and action. These goals were achieved through iteration of the pessary stem as well as the inclusion of several grip improvements. The improved gripping was achieved using a ring on the stem, handle on the cap, and a cut-out on the cap edge to improve the patient's ability to release the pessary suction and fold the pessary for removal. This gripping design has the added benefit of threading the post through the cap handle for insertion; however, this feature would not realistically be usable for removal as treading the stem through the cap handle would likely be too challenging to complete with the pessary in the vaginal canal. These features while assessed based on hypotheses and design constraints would significantly benefit from manufacturing and user testing to assess gripping.

Another goal of the design was the application of AM for manufacturing the pessary. While AM allows the manufacture of more complex designs such as the proposed Gellhorn redesign it also allows for pessaries to be customized. It was hypothesized in literature that the discrete commercial pessary sizes are not suitable for all patients, contributing to the low success rate of pessary fitting [34], [35]. Manufacturing the pessary using AM techniques allows for customization and on-demand manufacturing for optimal treatment. In particular, AM through the use of sacrificial moulds has been successfully applied to pessary manufacturing [70]. As a result, advances in AM have served to expand the customizability and efficacy of pessaries for the treatment of pelvic floor disorders, such as POP.

This manufacturing method allows for the casting and postcuring of medical grade pessary silicone (C8, C9) which is safe to use *in-vivo* for long periods of time and can be thoroughly cleaned (C10).

Disruption of the current pessary design requires verification that the changes to the pessary do not negatively impact its ability to support high stages of prolapse. While the loading conditions tested during the iteration process ensure the pessary can withstand the forces *in-vivo*, there remains uncertainty surrounding the design's function *in-vivo*. Given an incomplete current understanding of pessary function, with only hypotheses around their suction and support, it remains challenging to adequately iterate the design. As a result, this design iteration was limited to changes which did not significantly impact the pessary cap, lest they disrupt the pessary suction. It remains important that the pessary be tested *in-vivo* to ensure proper function. Furthermore, future significant advances in the understanding of pessary function could significantly impact the results of this optimization. Namely, better understanding the vaginal canal could improve the design optimization for ideal pessary support.

6.10 Gellhorn optimization conclusions

Gellhorn pessaries have not seen significant iteration, with the design reported in medical journals since 1944 [33]. Gellhorn pessaries are difficult or impossible to self-manage due to the pessary's friction and suction effects in the vagina, making them challenging to insert and remove [6], [66]. Pessary self-management may be desired or necessary for certain patient groups, as well as improving patient satisfaction with pessary use [30]. Therefore, the Gellhorn design was a valuable candidate for iteration; however, to perform this iteration the pessary loading conditions experienced *in-vivo* needed to be understood. Based on the *in-vivo* loading conditions found in previous work and a desired optimal fold direction the Gellhorn pessary stem design was iterated. Various methods of pessary gripping were also evaluated of which three were combined. The final design combined a tripod stem with a ring for gripping which could be folded down to a handle on the pessary cap, to support the stem for insertion. Finally, a cut-out was included on the pessary cap edge for easier insertion of a finger along the pessary edge for pressure release. While this design has been evaluated against what is known of the *in-vivo* vaginal environment, further research is needed to better understand this environment for future iteration. Additionally, further testing of this new design is needed *in-vivo* to ensure its functionality for support of the pelvic floor.

Chapter 7

Conclusions

7.1 Novelty

While investigating two themes related to pelvic floor assessment and pessary treatment, this thesis represents novel advancement in these areas of research. Firstly, the ultrasound analysis performed represents a new method for analyzing 2D dynamic CDI ultrasound videos which can be applied to CDI data collected in future research. The analysis of dynamic ultrasound, which has not been performed in previous research, allows for better understanding pelvic floor dynamics during contraction by assessing the slopes, which represent change over time of the vaginal shape and pressure. The use of distention in CDI also proves a valuable method of assessing the vagina by improving the vaginal wall visibility and capturing behaviour of the distended tissues. For pessary assessment, the FE analysis determined pessary silicone material models and computational mechanical tests represent novel applications of FE methods. Previous research has mechanically evaluated pessaries in folding; this new research significantly expands on that mechanical testing through the first characterization of pessary material and creation of FE mechanical test models. Finally, the pessary topology optimization is the first investigation into applying topology optimization to a pessary design. By applying topology optimization and design methods to the Gellhorn, a novel redesign of this pessary was produced.

7.2 Impact & Significance

The ultrasound analysis described represents a novel method which in future research will provide a better understanding of pelvic floor biomechanics during dynamic pelvic floor maneuvers. This method represents an application of CDI which aids in understanding the vaginal properties under distension, which is crucial as the vaginal canal distends to facilitate several of its anatomical functions. By better understanding the dynamic behaviour of the vaginal canal, treatments such as pessaries can be iterated to better meet the needs of patients. Additionally, these methods, in future, could be applied for quantitatively comparing the dynamic maneuvers of different pelvic floor impairments and stages to healthy volunteers. As a result, the conditions within the vaginal canal as well as areas for the application of different and novel pessary designs could be better understood. In particular, greater knowledge and understanding of pelvic floor biomechanics could improve pessary fitting, which requires iteration given that successful fitting rates are reported as low as 41% [1].

The work performed for pessary characteristic determination and modelling can also be used in future to improve pessary fitting and overall treatment success. Firstly, the FE material model and test setups for assessing RWS pessaries will serve as tools for future pessary property assessment and design. This is significant as RWS pessaries represent the first line treatment option for the majority of pessary applications, yet current rates of fitting failure point to the need for customized pessary sizing or pessary redesign. Understanding the current properties of RWS pessaries allows those properties to be tailored through custom pessary dimensions and well as highlighting possible areas for pessary improvement. Identifying the limitations of the current designs lays the foundation for pessary redesign. The pilot Gellhorn topology optimization represents a methodology by which pessaries can be iterated to better address the forces they experience *in-vivo* and allow for improved self-management, namely Gellhorn insertion and removal. Application of topology optimization and redesign methods to future pessary iteration would ensure that pessaries address true anatomical conditions (such as IAP changes) and desired properties (such as folding for insertion).

7.3 Future work

The ultrasound analysis methodology described represents an initial investigation into dynamic pelvic floor biomechanics analysis using CDI. Future work to refine the system and increase the ultrasound dataset will allow the biomechanics to be quantified and compared across different types and stages of impairment. Additionally, comparison to healthy pelvic floor biomechanics will aid in understanding how the distended dynamic behaviours of the pelvic floor change with impairment and across different patient groups. From the pessary design analysis further RWS and Gellhorn pessary iteration should be conducted using these piloted computational methods. The RWS FE analysis and topology optimization results can be further utilized for pessary development to improve patient outcomes through outright redesign as well as tailoring pessary dimensions for patients requiring custom sizing.

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