Pelvic organ prolapse (POP) may be thought of as a silent disease. The silence is not due to lack of signs or symptoms but to the silence of women who suffer with urinary or rectal symptoms, pain, and discomfort. Women may be too embarrassed to talk to their doctor and other health care professionals who all too often fail to ask women about these symptoms.

A brief overview of the etiology, incidence, manifestations, and treatment options of POP will be provided. The rest of the article will focus on a detailed description of the newest available conservative management option, the Colpexin™ Sphere. When used in conjunction with pelvic floor muscle exercises, this intravaginal device can improve both pelvic floor muscle strength/function and urinary continence status in women with advanced genital prolapse.

Pelvic Organ Prolapse

Pelvic organ prolapse is a common condition that can occur anytime during the female lifespan. Described as a “protrusion of pelvic organ(s) into or out of the vaginal canal,” POP is caused by denervation of pelvic floor muscles and/or disruption of endopelvic fascia or a break or weakness anywhere in the pubocervical or rectovaginal fascia (American College of Obstetricians and Gynecologists [ACOG], 1995). The pelvic floor musculature has been compared to a trampoline connected to the framework of the pelvic bones. The musculature supports and holds the pelvic organs (bladder, intestine, uterus, and vagina) in place. When the musculature becomes weakened or breaks, the pelvic organs may “fall” or protrude through the musculature.

As shown in Table 1, there are five types of genital prolapse relating to the specific organ(s) involved (Marinkovic & Stanton, 2004). Herniation of the bladder, rectum, or peritoneal contents into the vaginal lumen may result in cystocele, rectocele, or enterocele, respectively. Eversion of the vagina may occur with either vaginal vault prolapse or uterine prolapse. It is common for women to present with more than one type of prolapse (Davila, 2006).

Signs and Symptoms

In its early stages, POP is often asymptomatic. Table 2 lists common signs and symptoms associated with POP (ACOG, 1995; Marinkovic & Stanton, 2004). Women, who may or may not be aware that they have some degree of prolapse, may only report a palpable bulge or the feeling of something “falling out” of their vagina. Most symptoms relate to the type and location of the prolapse although the anatomic location and extent of prolapse may not correlate well with symptom severity (Ellerkman et al., 2001). Additionally, POP may result in decreased sexual activity (Barber, Visco, Wyman, Fantl, & Bump, 2002; Digesu, Chaliha, Salvatore, Hutchings, & Khullar, 2005), social interaction, and exercise due to worries of loss of bladder/bowel control, urinary tract infections due to urinary retention, and bowel impaction due to chronic constipation.

Etiology, Incidence, and Risk Factors

While often overlooked, POP is common among parous women...
with an incidence of all stages and types of prolapse ranging as high as 50% (Marinkovic & Stanton, 2004). The Pelvic Organ Support Study noted that the prevalence distribution of POP by stage follows a bell-shaped curve with most subjects having early stage (Stage 1 or 2) disease (Swift et al., 2005). In that study of 1,004 women, the majority of patients were premenopausal (mean age 42.7 years) with a mean gravidity of 2 and mean parity of 2. While Hispanic race was reported as a risk factor, the authors indicated that this may have been due to the characteristics of the study population. They noted that studies that have cited a higher incidence of POP in Hispanic and black women may have been conducted in study populations that are not reflective of the U.S. population as a whole. A higher incidence of obesity in certain racial subgroups may more accurately reflect the true risk factor for prolapse (Swift et al., 2005).

### Table 1.
**Types of Pelvic Organ Prolapse**

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystocele</td>
<td>Central or midline defect in the pubocervical fascia which results in herniation of anterior vaginal wall and bladder into vaginal lumen</td>
</tr>
<tr>
<td>Rectocele</td>
<td>Break in the rectovaginal septum which results in herniation of rectum and posterior vaginal wall into vaginal lumen</td>
</tr>
<tr>
<td>Enterocele</td>
<td>Pubocervical fascia and retrovaginal fascia separate allowing herniation of superior anterior or posterior vaginal wall and underlying peritoneal contents into vaginal lumen</td>
</tr>
<tr>
<td>Vaginal Vault Prolapse</td>
<td>Herniation of vaginal apex (with or without the uterus) into the vaginal lumen; may result in eversion of the vagina</td>
</tr>
<tr>
<td>Uterine Prolapse</td>
<td>Failure of the uterosacral ligaments that allow the uterus to descend into the vagina; complete uterine prolapse results in the uterus falling outside the vaginal opening and eversion of the vagina</td>
</tr>
</tbody>
</table>

**Source:** Marinkovic & Stanton, 2004.

### Table 2.
**Common Signs and Symptoms of Pelvic Organ Prolapse**

- Palpable bulge
- Perception of something “falling out”
- Pelvic pressure and pain
- Lower-back pain
- Urinary frequency, urgency, retention, and/or incontinence
- Fecal or flatus incontinence
- Difficult evacuation of the rectum
- Sexual dysfunction
- Cervical mucosal irritation/ulceration

**Sources:** ACOG, 1995; Davila, 2006; Marinkovic & Stanton, 2004.

cystocele was the most common form of prolapse (prevalence rate 34.3% in women with a uterus) (Hendrix et al., 2002).

As is the case for many disease states, risk factors can be related to causation. There are three fundamental causes of POP (Davila, 1996; Marinkovic & Stanton, 2004).

1. **Neuromuscular damage** of the pelvic floor musculature due to childbirth (multiparity/vaginal delivery), hysterectomy, or pelvic fracture. There may be muscular and connective tissue damage during labor or inadequate ligament supports at the time of hysterectomy.

2. **Increased intra-abdominal pressure** due to pregnancy or obesity, chronic cough, constipation, or heavy lifting.

3. **Metabolic abnormality** due to estrogen deprivation in postmenopausal women or genetic predisposition to connective tissue weakness. With aging there is a decrease in collagen strength. Hypoestrogenism can contribute to pelvic devascularization and thinning of mucosal and support tissues. Genetics can play a role in POP. Women with genital prolapse may have weaker endogenous collagen type and composition.

Given these causes it is not surprising that obesity and gravidity are consistently identified as POP risk factors (Hendrix et al., 2002). A direct relationship exists between parity and risk of developing POP and urinary incontinence, with increased risk following a single vaginal birth and risk dramatically increasing with each subsequent vaginal delivery (DeLancey, 2005). As shown in Figure 1, the risk of developing POP increases dramatically with each pregnancy, from a relative risk that is 4 times that of nulliparous women following first pregnancy to risk that is 8 to 10+ times that of nulliparous women following 2 to
>4 pregnancies. These data imply that genital prolapse and urinary incontinence may be significant clinical issues among women in their childbearing years.

**Pelvic Floor Muscle Assessment**

While longitudinal studies documenting the natural course of POP have not been conducted, surgical data indicate that prolapse progresses over time (DeLancey, 2005). Therefore, it would appear intuitive that all patients, regardless of the type of prolapse, would benefit from screening and early diagnosis.

Pregnant and parous women of all ages should be screened for POP symptoms and urinary incontinence including assessment of pelvic floor musculature during every pelvic examination. A screening and diagnostic examination should consist of:

- Bi-valve speculum followed by disarticulated speculum (such as Sim’s speculum) to isolate defects and to grade prolapse.
- Assessment of the effect of maximum Valsalva effort on pelvic organ support.
  - Bulging and descent of each compartment (anterior, posterior, and apical).
  - Identify concomitant prolapse of adjacent compartments.
- Assessment of the effect of voluntary contraction of the pelvic floor muscles: lifting; no movement; reverse Kegel contraction (pushing down vs. lifting).
- Evaluation of the pelvic floor musculature should consist of assessment of:
  - Resting muscle tone, trigger points, and sensation or pain in all four quadrants.
  - Muscle contraction quality, looking for a lift and symmetry of the four quadrants as well as ability to relax.
  - Muscle strength and endurance evaluation using the examiner's finger used as a tool for biofeedback.
- Ability to hold a contraction in seconds and number of repetitions before fatigue occurs.

Currently there is no universally accepted pelvic floor grading scale to assess pelvic floor muscle strength, intensity, and levator muscular movement. Grading of pelvic muscle strength may be done using a standardized pelvic muscle assessment such as that developed by Brink (Brink, Sampsel, Wells, Dionko, & Gillis, 1989) (see Table 3) or any other scale with which you may be familiar, providing that there is consistency with each assessment and between clinicians within your practice setting.

**Figure 1. Relationship of Parity and Risk of Pelvic Organ Prolapse**

Relative risk is a measure of the extent to which a particular risk factor (in this case, parity) influences the risk of a specified outcome (in this case, urinary incontinence or prolapse). The figure shows that women with a parity of 1 have a risk of urinary incontinence that is 2 times higher and a risk of genital prolapse that is 4 times higher than nulliparous women; > 4 births confers a risk of urinary incontinence that is 2.8 times higher and a risk of genital prolapse that is 10.7 times higher than nulliparous women.

**Table 3**

<table>
<thead>
<tr>
<th>Parity</th>
<th>Relative Risk of Pelvic Organ Prolapse</th>
<th>Relative Risk of Urinary Incontinence</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>&gt; 4</td>
<td>2.8</td>
<td>10.7</td>
</tr>
</tbody>
</table>

**Source:** Adapted from DeLancey, 2005.

**Treatment Options**

Treatment options for POP include both surgical and nonsurgical (conservative) management options. The choice to undergo a particular surgical procedure depends upon a number of variables including symptom severity, bladder and bowel function, and degree of sexual activity (Davila, 2006). Women having mild-to-moderate genital prolapse often choose nonsurgical management, including:

- **Pelvic floor muscle exercises (PFME)** with or without adjuvant biofeedback; PFME have the greatest value when the leading edge of the genital prolapse is above the levator plate; when performed properly and routinely, PFME help regain proprioception and function post-partum, improve bladder/bowel function in women experiencing incontinence, and improve sexual sensation due to weak pelvic floor muscles.
- **Space-occupying devices** such as tampons or pessaries (passive treatment); pessaries are available in various shapes and sizes, and although hav-
ing such a wide variety of choices seems ideal, deciding on the optimal type and size for each patient can be challenging for the clinician (Davila, 2006).

- **Behavioral modification** such as avoidance or management of activities that contribute to chronic, repetitive, increased intra-abdominal pressure; such risk factors are heavy lifting, constipation, chronic coughing, and obesity. This includes weight loss, smoking cessation, and changes in recreational or occupational activities.

**The Colpexin™ Sphere**

In May 2006, the Colpexin Sphere (Adamed, Inc., Rutherford, NJ) was introduced in the United States. It is an intravaginal device (IVD) that provides support for the pelvic floor musculature. The IVD consists of a medical-grade polycarbonate sphere with an attached braided string (see Figures 2 & 3).

One of the unique characteristics of the Colpexin Sphere is that by elevating the prolapse defect, it facilitates the performance of proper PFME. Figure 4 provides instruction for use of the Colpexin Sphere during PFME. Many women will need counseling to understand which muscles should be exercised to obtain optimal benefit. All patients should be reminded that the quality of the exercise is more important than the number of contractions performed.

### Table 3.
**Pelvic Muscle Assessment Scale**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure</td>
<td>No response; cannot perceive on finger surface</td>
<td>Weak squeeze; felt as flick at various points along finger surface; not all the way around</td>
<td>Moderate squeeze; felt all the way around finger surface</td>
<td>Strong squeeze; full circumference of fingers compressed; override</td>
</tr>
<tr>
<td>Duration</td>
<td>None</td>
<td>&lt; 1 second</td>
<td>&gt; 1 to &lt; 3 seconds</td>
<td>&gt; 3 seconds</td>
</tr>
<tr>
<td>Displacement of Vertical Plane</td>
<td>None</td>
<td>Fingertips may move anteriorly (pushed up by muscle bulk)</td>
<td>Whole fingers move anteriorly</td>
<td>Whole fingers move anteriorly, are gripped and pulled in</td>
</tr>
</tbody>
</table>

**Source:** Adapted from Brink et al., 1989.

**Figure 2. Colpexin™ Sphere**

The Colpexin™ Sphere is an intravaginal device comprising a polycarbonate sphere with attached braided untreated nylon string. Indicated for the conservative management of pelvic organ prolapse and pelvic floor muscle weakness, it is available in 5 sizes: 44 mm, 42 mm, 39 mm, 36 mm, and 32 mm.

**Source:** Reprinted with permission from Adamed, Inc., Rutherford, NJ.

**Figure 3. Colpexin™ Sphere in Place**

The Colpexin™ Sphere is self-inserted with an applicator or by hand into the vaginal vault where it provides support for pelvic organ prolapse and facilitates the performance of pelvic floor muscle exercises.

**Source:** Reprinted with permission from Adamed, Inc., Rutherford, NJ.
Figure 4.
Patient Instructions for PFME with Colpexin™ Sphere in Place

The pelvic floor muscles (PFM) are a very important muscle group for women — they help support the pelvic organs (the bladder, uterus, and colon), assist in stopping and starting the flow of urine or the passage of gas or stool, and aid in sexual satisfaction. Attached to the pelvic bones, PFM are located at the bottom of your pelvis and form a funnel that spans the width and breadth of the pelvis. When contracted, a deep feeling of tension and firmness is sensed, the muscles move upward, and the openings of the vagina and anus close.

PFM Exercise Program
To begin, empty your bladder and lie on your back on a flat surface with your Colpexin™ Sphere in place. Keep your knees bent and apart and your head elevated and supported with several pillows. Remember, doing your exercises with the Colpexin™ Sphere in place will allow you to be sure you are using the right muscle group.

1. Contract or tighten the muscles around the vaginal opening and feel for a lifting of the Colpexin™ Sphere and closure of the vaginal opening. Locate the string on your Colpexin™ Sphere and gently pull on it so you can feel that the sphere is in the correct position, above the PFM. Now relax your muscles.

2. Perform the PFM contraction (feel for lifting of the Colpexin™ Sphere and closure of the vaginal opening).

3. Initially, you may only be able to hold each contraction for 1-2 seconds, gradually increasing the time to 3-5 seconds, relaxing for 3-5 seconds for up to 5 repetitions. As you get stronger, you can extend the time, holding the contraction for 5-8 seconds for 8 repetitions. Your goal is to reach 10 second contractions for 10 repetitions. Remember to always relax the PFM for an equal amount of time between contractions.

4. Do these exercises two times each day.

A few helpful hints ...
If you are unable to feel your PFM contract around the vaginal opening, try placing a folded hand towel between your knees squeezing them together for 1-2 seconds until you gradually build up your strength.

The quality of the exercises is more important than the number you perform or the seconds you are able to hold each contraction. As with all exercise, you will build strength over time as you follow your treatment regimen. Avoid straining, holding your breath, or using your buttock muscles while you exercise the PFM. Counting out loud can help prevent this from happening. If you still notice that you use your buttock muscles or hold your breath, you are probably contracting your muscles incorrectly. Review your exercise instructions and try again. If the problem continues, notify your healthcare provider for more instructions.

As your strength continues to improve, you may want to challenge your muscles further by gently tugging on the string while tightening your PFM. Be sure not to pull so hard as to cause the Colpexin™ Sphere to actually come out while exercising. If the sphere does come out when you add resistance, just reinsert it according to the directions and return to doing the exercises without adding resistance (pulling on the string).

Pelvic floor muscle exercises are a very important part of your treatment, so try to incorporate these exercises into your daily routine. For example, if you wear your sphere only during the day, try doing your exercises once in the morning after inserting the Colpexin™ Sphere and once in the evening before you remove your sphere. Make it a habit like brushing your teeth and you will be less likely to forget.

Learn more about the Colpexin™ Sphere by visiting www.colpexin.com

Special Instructions:

Source: Reprinted with permission from Adamed, Inc., Rutherford, NJ.
Review of Research Study

Lukban and colleagues evaluated the safety and effectiveness of the Colpexin Sphere in a 16-week, multicenter, single-armed, prospective clinical trial of women with advanced POP (Lukban, Aguirre, Davila, & Sand, 2006). I participated as a subinvestigator in this U.S. clinical trial.

Subjects. The study enrolled 39 women (mean age 59.2 years, mean weight 155.8 lbs) who had genital prolapse extending to or beyond the hymenal ring. These women were able to be fitted and retain the IVD, had a vaginal length ≥ 8 cm, and were willing and able to perform PFME. They were capable of completing voiding diaries and quality of life questionnaires. Subjects with a vaginal length <8 cm, irreducible uterine retroversion, pelvic neuropathy, urinary tract infection, severe vaginal atrophy, cervical or vaginal dysplasia, abnormal vaginal or uterine bleeding, or a pelvic mass, or who were unable to insert and remove the IVD or lay prone to perform PFME were excluded from the study.

Methods. Subjects were instructed to utilize the Colpexin Sphere throughout the day and night and to perform PFME with and without a PFME ball (Beyond Kegelball™) twice daily. Pelvic floor function (digital vaginal examination and the Colpexin Pull Test) and adverse events were assessed at the initial visit and after 5, 12, and 16 weeks of device use. In addition, study subjects were requested to complete a bladder diary on 3 consecutive days before each study visit as well as a patient satisfaction questionnaire at the end of the study.

The design of the Colpexin Sphere allowed for objective measure of pelvic floor muscle tone at rest and during maximal contraction with the device in place using a hand-held pressure gauge (Guerette, Neimark, Kopka, Jones, & Davila, 2004). A tensiometer was employed to measure the force (in pounds) required to remove a 36-mm sphere from above the levator plate. Averages of three consecutive measurements were taken at both rest and during contraction.

Findings. Among the 39 women who enrolled, the great majority were Caucasian (87%, 34/39), approximately half (49%; 19/39) had a history of prior hysterectomy, and more than one-third (36%; 14/39) were post-
menopausal and using hormonal therapy. Twenty-seven women (69%) completed the 16-week study; 7 subjects discontinued for device displacement, 3 were non-compliant, 1 chose to discontinue, and 1 was lost to follow-up. Among the 27 women who completed the study, 74% (20/27) reported urinary incontinence at the baseline visit.

Of those women who completed the 16-week trial, 81.5% (22/27) experienced improvement in at least one vaginal segment at 16 weeks with 63% (17/27) experiencing increased pelvic floor muscle function upon digital examination (see Figure 5). At 16 weeks, statistically significant improvement (p=0.029) was reported in mean pelvic floor muscle contraction strength compared to baseline as measured by the Colpexin Pull Test (2.14 ± 1.26 lbs vs. 1.84 ± 1.04 lbs, respectively) (see Figure 6). No significant improvement was observed in resting pelvic floor tone at 16 weeks compared to baseline.

Among the 20 women who reported urinary incontinence prior to entering the study, 75% (15/20) reported improvement in their incontinence status by the end of the study, including four women who stated they were “completely dry.”

The great majority of women completing this study reported that the Colpexin Sphere was comfortable (89%, 24/27), easy to insert (96%, 26/27), and easy to remove (100%, 27/27). In addition, 93% (25/27) noted that they would recommend the Colpexin Sphere for the treatment of genital prolapse.

A total of 107 adverse events were reported; none were considered serious and all were easily resolved; 23 adverse events were determined to be possibly or definitively related to the IVD. The most commonly reported adverse events were vaginal irritation or burning, discomfort or tenderness, discharge, or spotting (n=8); yeast infection (n=3); and urinary tract infection (n=3). Two women exhibited vaginal mucosal ulceration and two reported urethral discomfort. The device-related events were resolved with temporary cessation of IVD use and, in the case of the vaginal ulceration, treatment with local vaginal estrogen cream. No allergic reactions to the IVD were observed.

The authors suggested that the best candidate for the Colpexin Sphere is the woman who prefers a conservative approach for treating pelvic organ prolapse, can perform adequate PFME, and is motivated to enroll in a course of pelvic floor muscle rehabilitation (Lukban et al., 2006).

**Author’s Experience with the Colpexin™ Sphere**

In our small cohort of 11 subjects (who were among the 27 women who completed the study), 4 women have continued using the IVD for just over 2 years as part of an extension study. I am especially impressed with the perseverance and improvement in POP demonstrated in two of these subjects. Both individuals experienced a significant reduction of POP from baseline to 16 weeks; one woman sustained the improvement and the other regressed slightly. Case summaries are provided in Table 4.

Based on my experience with these two subjects, I believe that patients who are motivated to perform the daily PFME program while wearing the Colpexin Sphere can successfully manage their POP. No definitive conclusions can be drawn from these two cases but each provides insight into the need for sustained PFME.

Overall comments from the 11 subjects treated at our clinical study site indicated that these women generally liked the device. They reported that the Colpexin Sphere was easy to insert and remove, that they did not sense the IVD when it was in the vagina, and that they preferred the IVD over the use of a pessary. Long-term compliance to a PFME program appears to be the major challenge for these patients.

**Conclusion**

Pelvic organ prolapse is an extraordinarily common and overlooked problem among women of all ages. It can be a devastating condition, dramatically impacting important aspects of a woman’s life, ranging from her ability to perform daily activities to her self-image and sense of control. Given the outlook for progressive worsening of POP over time, early diagnosis should be a goal for all women. Early treatment offers the opportunity to positively impact a woman’s quality of life and potentially alleviate the need for future surgical intervention. It is important to proactively ask women about POP symptoms during routine examinations as many women are embarrassed to talk about their symptoms or may not be aware that the symptoms they are experiencing are related to POP.

The benefits of PFME as a management tool for women with POP or at risk of developing this condition are well recognized. Health education classes and adult fitness classes should incorporate PFME into their programs, and women involved in high-impact sports regardless of age should be counseled to perform these exercises to maintain their pelvic floor muscle health. The Colpexin™ Sphere is a new and welcome addition to the treatment armamentarium as it
Table 4. Case Summaries for Two Subjects Using the Colpexin™ Sphere for > 2 Years
(Data derived from subjects’ research study record)

<table>
<thead>
<tr>
<th>SUBJECT A: 80-year-old Caucasian, retired female with a long history of being physically active and is currently teaching dance to seniors.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolapse Defect</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Uterine Prolapse</td>
</tr>
<tr>
<td>Cystocele</td>
</tr>
<tr>
<td>Rectocele</td>
</tr>
</tbody>
</table>

Subject A recently returned to our clinical practice for her routine gynecologic examination and is still reportedly using the Colpexin™ Sphere daily (total time: 4.5 years). Her POP assessment revealed a 3rd degree uterine prolapse, 4th degree cystocele, 2nd degree rectocele, and a 2nd degree enterocèle. She was re-evaluated for appropriate IVD size and pelvic floor muscle strength. We found that the sphere was the correct size but her pelvic floor muscle strength was considerably weakened. Although she is a surgical candidate for repair of her POP, she chose to restart her PFME program since she has not had proven success with pelvic muscle rehabilitation in the past. She was re-instructed on PFME and encouraged to perform the exercises correctly and twice daily. She is scheduled for a follow-up assessment in 4 weeks.

<table>
<thead>
<tr>
<th>SUBJECT B: 56-year-old Caucasian female, educator and PhD candidate, who regularly exercised, mostly Pilates.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolapse Defect</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Uterine Prolapse</td>
</tr>
<tr>
<td>Cystocele</td>
</tr>
<tr>
<td>Rectocele</td>
</tr>
</tbody>
</table>

Subject B reportedly became very busy with her teaching position and completing her PhD program between week 16 and the termination of the extension study. She regressed by one degree with her cystocele. She admits to less attention to her exercise classes (Pilates) and performed PFME less frequently as compared to the initial study period. She recently returned to our office for specific treatment of her overactive bladder symptoms so the practitioner did not perform a pelvic examination at that time. She shares dual residences in Illinois and Iowa and it is unknown if she’ll follow-up with our center for her future gynecologic examinations. To date unsuccessful attempts have been made to determine if she is still using the Colpexin™ Sphere.


References

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