



**Physical Exam Procedure Manual**  
**Version 03/29/06 (A)**

**A. Anthropometric Measurements**

Measures of height and weight will be obtained at baseline and at the 12 and 24 month follow up visits.

Measures should be taken without shoes.

**A.1. Height in Inches:**

Record the patient's height to the nearest whole inch. If the patient's height falls exactly between two whole numbers, round up to the next higher inch.

Examples:     If the patient's height is  $>65$  inches but  $<65\frac{1}{2}$  inches, record as 65 inches.  
                  If the patient's height is exactly  $65\frac{1}{2}$  inches, record as 66 inches.  
                  If the patient's height is  $>65\frac{1}{2}$  inches but  $<66$  inches, record as 66 inches.

**A.2. Weight in Pounds:**

Record the patient's weight to the nearest whole pound. If the patient's weight falls exactly between two whole numbers, round up to the next higher pound.

Examples:     If the patient's weight is  $>140$  pounds but  $<140\frac{1}{2}$  pounds, record as 140 pounds.  
                  If the patient's weight is exactly  $140\frac{1}{2}$  pounds, record as 141 pounds.  
                  If the patient's weight is  $>140\frac{1}{2}$  pounds but  $<141$  pounds, record as 141 pounds.

## B. Directed Neurological Exam

A directed neurological exam is performed at the baseline visits to identify abnormalities of the sensory, motor, and reflex functions of deep tendon knee reflexes, perineal sensation, and anal sphincter voluntary contractions.

**B.1. Deep Tendon Reflex Knee:** Deep tendon reflexes will be evaluated for the lower extremities only. The knee jerk reflex is mediated by the L3 and L4 nerve roots, mainly L4. Insult to the cerebellum may lead to pendular reflexes. Pendular reflexes are best observed when the patient's lower legs are allowed to hang and swing freely off of the end of an examining table. Record whether reflexes were “normal” or “decreased.”

**B.2. Perineal Sensation:** With the patient in the dorsal lithotomy position, touch the S2-S4 segments softly with a broken Q-Tip on the left and right side of the perineum separately. Indicate whether sensation was “normal” or “decreased.”

**B.3. Anal Sphincter Voluntary Contractions:** Contraction of the external anal sphincter and puborectalis muscles is assessed by using a four point scale for pressure and duration while a single index finger is inserted 4-6 cm into the anal canal. Instruct the patient to contract the muscles she would use if she were trying to hold in gas. Indicate whether the contractions were found to be “normal” or “decreased.”

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### C. Exam for pain in the suprapubic and perineal areas and the lower extremities

The physical exam completed at baseline and at the 2 and 6 week post operative visits will include procedures to ascertain the presence of pain in the **suprapubic, obturator, and perineal areas and the lower extremities**.

**Procedure:** Examiners should complete a history and physical exam for the assessment of pain in the specified locations in accordance with their standard clinical practice and record presence or absence of evidence of palpable pain in each of the follow areas:

lower abdomen, right side: (Yes/No)

lower abdomen, left side: (Yes/No)

inner thigh, right side: (Yes/No)

inner thigh, left side: (Yes/No)

vagina (inside) right side: (Yes/No)

vagina (inside), left side: (Yes/No)

vulva, right side: (Yes/No)

vulva, left side: (Yes/No)

lower back, right side: (Yes/No)

lower back, left side: (Yes/No)

front leg, right side: (Yes/No)

front leg, left side: (Yes/No)

back leg or buttocks, right side: (Yes/No)

back leg or buttocks, left side: (Yes/No)

## D. Pubococcygeus Contraction Assessment (PC Assessment)

The PC assessment will be performed at the baseline visit to assess pelvic muscle strength. This procedure is an adaptation of a test described by Brink, Sampsel, Wells, Diokno, and Gillis (*Nurs Res* 1989 Jul-Aug;38(4):196-9). Examiners will use stop watch accurate to the tenth of a second to assess duration of the pubococcygeus muscle contraction. The PC assessment is completed at the baseline visit.

### Procedure

1. **Position** patient in the dorsal lithotomy position.
2. **Teaching:** Explain that you will be testing her pelvic muscles by inserting one or two fingers in the vagina. Also explain that you will place your other hand alternately on her abdomen, hips, and thighs during the evaluation.
3. **Practice the test:** Gently insert the lubricated finger(s) (index or index and middle) 4-6 cm into the vagina with the palm facing down. Instruct the patient that you will be counting to three, and then instructing her to

*“Squeeze your pelvic muscles, the ones that you use to stop your urine stream, as strong as you can. I want you to hold the contraction for as long as possible or until I tell you to stop. As you do this, I want you to try to avoid contracting your tummy, bottom, or thigh muscles.”*

Any degree of flicker on the examiner’s finger(s) is considered evidence of ability to contract the muscle. If the patient demonstrates she can isolate and contract her pelvic floor muscle, then move on to the actual testing. If she cannot contract her pelvic floor muscle, continue coaching her with 1 to 3 more practice contractions until she contracts her pelvic floor muscles with minimal use of the accessory muscles. She may not be able to completely eliminate the use of the accessory muscles, but you want to minimize it as much as possible.

4. **Complete the test:** Repeat patient instructions above. Evaluate three elements of the pubococcygeus muscle contraction; i.e. 1) pressure, 2) duration and 3) displacement of the vertical plane.

#### Pressure should be categorized as:

- No response; cannot perceive any pressure on finger surface;
- Weak squeeze; pressure felt as a flick at various points along finger surface; not all the way around;
- Moderate squeeze; pressure felt all the way around finger surface; OR
- Strong squeeze

**Duration** of the contraction should be assessed using the stop watch accurate to the tenth of a second.

#### Displacement of vertical plane should be categorized as:

- None (no displacement)
- Fingertips may have moved anteriorly (pushed up by muscle bulk)
- Whole length of fingers moved anteriorly
- Whole fingers moved anteriorly; are gripped and pulled in

## E. Pelvic Organ Prolapse Quantification Exam

A pelvic organ prolapse quantification (POP-Q) exam will be performed pre-operatively at baseline and at the 12 and 24 month post-op visits. The POP-Q exam will be performed according to International Continence Society Guidelines (*Am J Obstet Gynec* (1996) 175:10-17) and will be standardized as demonstrated in a videotape produced by Duke University Medical Center (“Pelvic Organ Prolapse Quantification Exam”).

### Instruments and Materials

- Gynecologic chair
- Small handheld mirror
- Bivalve speculum
- Sims speculum
- Clear plastic ruler
- Graduated ring forceps

### Procedure

1. Have the patient empty her bladder.
2. Perform a standing screening exam to observe the maximally prolapsed measurement with the patient standing. [If the symptoms can be reproduced with the patient supine, the POP-Q exam can be performed with the patient in the supine position. If the standing symptoms are not evident in the supine position, the POP-Q measurements should be performed with the patient standing.]
3. Position patient in a gynecologic chair in the 45 degree upright position.
4. If the patient has complaints of vaginal prolapse / protrusion, have her bear down and compare this protrusion/prolapse to your own observations made during the standing screening exam. Also, instruct the patient to use a small hand-held mirror to visualize the protrusion. and confirm if the protrusion while supine is as extensive as the most severe protrusion she has experienced in her daily activities. Complete the POP-Q in the supine position if the protrusion is assessed to be prolapse to the maximum extent.
5. If not, the examiner should maximize the prolapse either by having the patient stand and strain or by applying traction to the prolapse.
6. Performing the POP-Q exam:
  - **Measure and record the maximum anterior-posterior length with maximum straining of the genital hiatus and perineal body.** The genital hiatus is measured from the middle of the external urethral meatus to the posterior midline hymen with a clear plastic ruler. If the location of the hymen is distorted by a loose band of skin without underlying muscle or connective tissue, the firm palpable tissue of the perineal body should be substituted as the posterior margin for this measurement. The perineal body is measured from the posterior margin of the genital hiatus to the mid-anal opening. Measurements of the genital hiatus and perineal body are expressed in centimeters.
  - **Location of the Six Primary Measuring Points (Aa, Ba, C, D, Ap, Bp) in Centimeters.** Note: the definitions of these primary measuring points as outlined in section 2.2.1.(b) of the International Continence Society’s standardisation report appear in Appendix A of this document. The anatomic position of the six defined points for measurement should be centimeters above or proximal to the hymen (negative number) or centimeters below or distal to the hymen (positive number) with the plane of the hymen being defined as zero (0). For example, a cervix that protruded 3 cm distal to the hymen would be + 3 cm.

a) **If all points are >0:** Measure the locations of the points distal to the hymen directly with a ruler, graduated rings forceps, or other measuring device while the patient is straining and the protrusion is maximum. Then replace the vagina and measure the total vaginal length as noted below.

b) **If any points are ≤0 but some points are >0:** Measure and identify (if possible) the points >0 directly while the patient is straining and the protrusion is maximum. If point C is ≤0, insert a bivalve speculum to visualize the cervix or the cuff and withdraw it slowly while the patient is straining. Use the graduated ring forceps or other measuring device to measure the maximum descent of point C. Then use a Sims speculum to selectively retract the anterior and posterior vaginal walls to measure the maximum descent of any other points that are ≤0.

c) **If all points are ≤0:** Insert a bivalve speculum and measure the maximum descent of point C by having the patient maximally strain and withdrawing the speculum in conjunction with the descent of the cervix. Avoid tightening the bivalve speculum screws so as not to interfere with maximum descent. Then retract the posterior wall with a Sims speculum and measure the maximum descent of points Aa and Ba. Next, retract the anterior wall and measure the maximum descent of points Ap and Bp.

**Location of Point D.** Point D is omitted as a point for measurement in the absence of the cervix. When it is located at ≤0 cm, its location can be measured either during the bivalve speculum examination as described for the location of the cervix (point C) above or by palpation relative to the position of the cervix during the digital examination for the determination of total vaginal length. For example, if the cervix is visualized to descend -2 cm and the posterior fornix is palpated to be 2 cm proximal to the cervix, the position of point D would be -4 cm. When Point D is >0, its location is measured directly. In cases of total uterine prolapse with vaginal eversion with the cervix as the most distal (dependent) point, Point D will be assigned a value equal to the value for Points Ba, Bp, and C.

- **Determination of Total Vaginal Length.** Point C or D is digitally reduced with one or two fingers to its full extent without putting the wall on excessive tension. Eccentric elongation of a prolapsed anterior or posterior vaginal wall should not be included in the measurement of total vaginal length. In such a case, the total vaginal length is not the maximum depth of the vagina with the elongated vaginal wall maximally reduced, but rather the depth of the vagina at the cuff with Point C or D reduced to its full normal extent. With the prolapse maximally reduced, insert the measuring device and measure from the vaginal cuff to the hymenal ring.

### Record the POP-Q measurements

The following data points for the POP-Q will be recorded on every patient:

- Points Aa, Ba, C, D, Ap, Bp, GH, PB, TVL

## F. Q-Tip Test

A Q-Tip test will be performed at the baseline visit to quantify bladder neck hypermobility. It will be standardized as described below.

### Instruments and Materials

- Robinson Pocket goniometer (7.25", 180° with a 5° increment)
- Sterile cotton or dacron swab
- Lubricating anesthetic jelly

### Procedure

1. The patient's bladder should be empty and she should be in the dorsal lithotomy position.
2. Insert a lubricated cotton or dacron swab (Q-Tip) into the urethra until it lies just within the urethrovesical junction.
3. **Angle at rest:** Using the Robinson Pocket goniometer (7.25", 180° with a 5° increment), measure the resting angle circumscribed by the distal end of the swab relative to the horizontal at rest.
4. **Angle at maximum straining:** Instruct the patient to perform a maximum Valsalva effort. Using the goniometer, measure the angle of the distal end of the swab at maximum straining relative to the horizontal.

NOTE: Bladder neck hypermobility is defined as a resting angle >30 degrees OR a maximum straining angle >30 degrees.

### Data Points

The following Q-tip test data points will be captured:

- Angle at rest
- Angle at maximum straining

## Appendix A

### TOMUS Physical Exam Measures Schedule

Physical Exam Measures	Baseline	Op	Interim	2 weeks	6 weeks	6 month	12 month	24 month
Height	✓						✓	✓
Weight	✓						✓	✓
Directed neuro exam	✓							
Exam for Pain	✓			✓	✓			
PC assessment	✓							
POP-Q	✓						✓	✓
Q-tip test	✓							
Stress test	✓					✓	✓	✓
Voiding Trial / PVR	✓	✓ <sup>@</sup>	✓ <sup>*</sup>	✓	✓	✓	✓	✓
UDS	✓						✓	

<sup>@</sup> A retrograde fill is required for the post-op voiding trial.

<sup>\*</sup> At least one interim trials is required if subject 'fails' the post-op voiding trial.



## Appendix B: POP-Q

### The Standardisation of Terminology of Female Pelvic Organ Prolapse and Pelvic Floor Dysfunction

*Am J Obstet Gynec (1996) 175:10-17*

#### *Definition of Anatomic Landmarks*

**(b) Defined Points.** This site-specific system has been adapted from several classifications developed and modified by Baden and Walker. Six points (two on the anterior vaginal wall, two in the superior vagina, and two on the posterior vaginal wall) are located with reference to the plane of the hymen.

**Anterior Vaginal Wall.** Because the only structure directly visible to the examiner is the surface of the vagina, anterior prolapse should be discussed in terms of a segment of the vaginal wall rather than the organs which lie behind it. Thus, the term “anterior vaginal wall prolapse” is preferable to “cystocele” or “anterior enterocele” unless the organs involved are identified by ancillary tests. These two anterior sites are as follows:

**Point Aa.** A point located in the midline of the anterior vaginal wall three cm proximal to the external urethral meatus. This corresponds to the approximate location of the “urethro-vesical crease”, a visible landmark of variable prominence that is obliterated in many patients. By definition, the range of position of Point Aa relative to the hymen is -3 to +3 cm.

**Point Ba.** A point that represents the most distal (i.e., most dependent) position of any part of the upper anterior vaginal wall from the vaginal cuff or anterior vaginal fornix to Point Aa. By definition, Point Ba is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in women with total post-hysterectomy vaginal eversion.

**Superior Vagina.** These points represent the most proximal locations of the normally positioned lower reproductive tract. The two superior sites are as follows:

**Point C.** A point that represents either the most distal (i.e., most dependent) edge of the cervix or the leading edge of the vaginal cuff (hysterectomy scar) after total hysterectomy.

**Point D.** A point that represents the location of the posterior fornix (or pouch of Douglas) in a woman who still has a cervix. It represents the level of uterosacral ligament attachment to the proximal posterior cervix. It is included as a point of measurement to differentiate suspensory failure of the uterosacralcardinal ligament complex from cervical elongation. When the location of Point C is significantly more positive than the location of Point D, this is indicative of cervical elongation which may be symmetrical or eccentric. Point D is omitted in the absence of the cervix.

**Posterior Vaginal Wall.** Analogous to anterior prolapse, posterior prolapse should be discussed in terms of segments of the vaginal wall rather than the organs which lie behind it. Thus, the term “posterior vaginal wall prolapse” is preferable to “rectocele” or “enterocele” unless the organs involved are identified by ancillary tests. If the small bowel appears to be present in the rectovaginal space, the examiner should comment on this fact and should clearly describe the basis for this clinical impression (e.g., by observation of peristaltic activity in the distended posterior vagina, by palpation of loops of small bowel between an examining finger in the rectum and one in the vagina, etc.). In such cases, a “pulsion” addendum to the point Bp position maybe noted (e.g., Bp = +5 [pulsion]; see below for further discussion). The two posterior sites are as follows:

**Point Bp.** A point that represents the most distal (i.e., most dependent) position of any part of the upper posterior vaginal wall from the vaginal cuff or posterior vaginal fornix to Point Ap. By definition, Point Bp is at -3 cm in the absence of prolapse and would have a positive value equal to the position of the cuff in a women with total post-hysterectomy vaginal eversion.

**Point Ap.** A point located in the midline of the posterior vaginal wall three cm proximal to the hymen. By definition, the range of position of Point Ap relative to the hymen is -3 to +3 cm