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(54) Title: DEVICES AND METHODS FOR VAGINAL RECONSTRUCTION

(57) Abstract: The present invention concerns grafts and methods of vaginal reconstruction for treatment of pelvic organ prolapse. The method of the present invention is a minimally invasive procedure using a vaginal approach and fixed, (reproducible) anatomical landmarks in the pelvis as points of fixation for tension free graft attachment providing anatomical support for the vaginal apex, anterior and/or posterior vaginal walls.

DESCRIPTION

DEVICES AND METHODS FOR VAGINAL RECONSTRUCTION

CROSS-REFERENCE TO RELATED APPLICATION

The present application claims benefit of U.S. Provisional Application Serial No. 60/620,824, filed October 20, 2004, which is hereby incorporated by reference herein in its entirety, including any figures, tables, nucleic acid sequences, amino acid sequences, and drawings.

BACKGROUND OF THE INVENTION

Prolapse (from the Latin *prolapsus*, a slipping forth) refers to the falling or slipping out of place of a part or viscus. Pelvic organ prolapse is descent of the pelvic organs into the vagina, often accompanied by urinary, bowel, sexual, or local pelvic symptoms. Pelvic organ prolapse is a very common condition, particularly among older women; however, the incidence is difficult to determine, as many women do not seek medical advice. It is estimated that half of women who have children will lose pelvic floor support and experience some degree of prolapse in later life, and that of these women 10-20% seek medical care (Beck R.P., Pelvic Relaxation Prolapse, in Case N.G., Weingold, A.B., eds. *Principles and Practice of Clinical Gynecology*, New York: John Wiley, 1983:677-685).

Pelvic organ prolapse may also be referred to in the literature as vaginal prolapse, vaginal wall prolapse, genital prolapse, urogenital prolapse, uterovaginal prolapse, pelvic relaxation, pelvic floor dysfunction, or pelvic relaxation. Pelvic organ prolapse occurs when supportive structures in the pelvis become weak or damaged and can no longer support the pelvic organs resulting in a herniation of pelvic and/or abdominal contents into the vagina. Although prolapse is not considered a life threatening condition, it may cause a great deal of discomfort and distress. Additionally, it may cause or exacerbate defecatory and urinary dysfunction.

There are a number of different types of prolapse that can occur in the female pelvis. They are categorized according to the vaginal segment(s) involved: the front (anterior

segment) wall, back (posterior segment) wall, or top (apex/vault) of the vagina. It is not uncommon to have more than one type of prolapse.

Types of pelvic organ prolapse have traditionally been named for the adjacent organ. The pelvic viscera are supported by the pelvic floor, with the pubococcygeal portion of the levator ani decussating around the lower vagina and urethra before attaching anteriorly to the pubic bone. The vaginal wall consists of an inner epithelial lining surrounded by endopelvic fascia, which is composed of smooth muscle, elastin, and collagen and is attached to deeper pelvic supports. The cervix and upper third of the vagina are supported by the uterosacral and cardinal ligaments (the paracolpium). The middle third is attached by the pubocervical fascia to the arcus tendieus fasciae pelvis (the white line), which runs along the obturator internus muscle between the pubic symphysis and the ischial spine. The lower third is fused with the urogenital diaphragm, comprising the levator ani fascia, perineal membrane, and perineal body (DeLancey J.O., Anatomic Aspects of Vaginal Eversion After Hysterectomy, *Am. J. Obstet. Gynecol.*, 1992, 166:1817-1724).

A prolapse of the anterior vaginal wall is a cystocele (bladder prolapse). When the bladder prolapses, it descends into the vagina creating a large bulge in the anterior vaginal wall. It is common for both the bladder and the urethra to prolapse together. This is called a cystourethrocele. A prolapse of the urethra is an urethrocele. A prolapse of the posterior vaginal wall is a rectocele (prolapse of the rectum and sigmoid colon). A uterine prolapse occurs when the uterus drops down into the vagina.

Vaginal vault (apical) prolapse also commonly described as an enterocele typically occurs after a woman's uterus has been removed (hysterectomy). An enterocele is a herniation of small bowel into the vagina. Normally, the pelvic organs are held in place by the pelvic floor muscles and supporting ligaments, but when the pelvic floor becomes stretched or weakened, they may become too slack to hold the organs in place. The etiology of pelvic organ prolapse is largely unknown; however, chronic intra-abdominal pressure is believed to be an ensuing factor.

There are a variety of surgical techniques used to treat the various types of pelvic organ prolapse. However, the objective of most of the surgical treatments for prolapse is to lift the prolapsed organ(s) back into place. Hysterectomy (for uterine prolapse) is the common treatment that removes the prolapsed organ altogether. The choice of surgical

procedure depends on the type of prolapse, the patient's health and age, desire for fertility, and whether or not the patient is sexually active.

Anterior repair (colporrhaphy) is a surgical procedure used to treat prolapse of the bladder (cystocele), urethra (urethrocele), or both the bladder and urethra (cystourethrocele). The procedure is done through the vagina, usually under general anesthesia. It involves incising the anterior vaginal wall and dissecting it away from the bladder and/or urethra. The remaining "fascia" is reapproximated in the midline to add support for the bladder and/or urethra. The excess vaginal mucosa is excised and the vaginal wall is reapproximated with suture. This technique is believed to work through scarification of the reapproximated tissues. If the prolapse is recurrent, a graft (*e.g.*, synthetic and/or non-synthetic) may be used to help support the vaginal wall and reduce the reoccurrence rate. This may provide better long-term support, but may also cause additional complications such as infection and/or erosion into surrounding tissues.

Posterior repair (colporrhaphy/colpoperineorraphy) is a surgical procedure used to treat prolapse of the rectum and/or sigmoid colon (rectocele). The procedure is done through the vagina under general anesthesia. The procedure is similar to that previously described for the anterior repair; however, it is performed in the posterior vaginal wall and may or may not include a perineorraphy. A perineorraphy is similar to an episiotomy in which the perineal body is lengthened and the vaginal introitus is narrowed by re-approximation of the bulbocavernosis muscles in the midline. Again, if the prolapse is recurrent, grafts may be used to strengthen the vaginal wall and hold the prolapsed organ(s) in place.

Two surgical approaches for treating a uterine prolapse include removing the uterus (hysterectomy) or resuspending the uterus, the latter being recommended for women who want to keep their uterus or desire future fertility. In general, there are three uterine suspension procedures: sacrohysteropexy, sacrospinous fixation, and Manchester repair. The sacrohysteropexy procedure uses a strip of synthetic mesh to hold the uterus in place. The operation is done abdominally, either through a cut just above the pubic hairline or through keyhole surgery (laparoscopy). The physician attaches one end of the mesh to the cervix and top of the vagina and the other to the sacral promontory portion of the spine. Once in place, the mesh supports the uterus. There are complications associated with sacrohysteropexy, such as risk of infection and erosion into the surrounding tissues and, in some cases, the mesh must be removed.

Sacrospinous fixation supports the uterus by suturing it to one of the pelvic ligaments (the sacrospinous ligament). This procedure is done vaginally and is therefore less invasive than sacrohysteropexy, but also has lower success rates. There is a risk of vascular injury and damage to the pudendal and sciatic nerves that can lead to severe pain, weakness and/or paresis in the legs, buttocks, genitals, and pelvic area.

The Manchester repair (also called Fothergill operation) is no longer commonly performed, but used to be the only surgical alternative to hysterectomy for treating uterine prolapse. The procedure is done vaginally and involves removing part of the cervix and pushing the uterus back into place by shortening the ligaments that support it. The procedure has a high failure rate and many women require additional surgery (usually a hysterectomy). In addition, the entrance to the uterus may become either very narrow or very relaxed, which can cause problems during pregnancy and childbirth.

Vaginal vault prolapse is often treated through one of five surgical procedures: sacrocolpopexy, sacrospinous fixation, tight (anterior and posterior) repair, uterosacral vaginal vault suspension, or colpocleisis. Sacrocolpopexy uses synthetic mesh to support the top of the vagina. During the operation, the surgeon stitches one end of the mesh to the top (vaginal vault) of the vagina and the other end to the sacral promontory portion of the spine. The procedure is done abdominally, either laparoscopically or a through a larger cut above the bikini line. Complications are uncommon but there is a risk that the mesh may wear away (erode) into the surrounding tissues and/or become infected. In some instances, the mesh must be removed.

Sacrospinous fixation supports the vagina by attaching the vaginal vault to one of the ligaments in the pelvis (the sacrospinous ligament). The procedure is done through the vagina and uses only sutures (no mesh). Complications are rare, but can include vascular injury and damage to the pudendal and sciatic nerves, causing severe pain, weakness and/or paresis in the patient's legs, buttocks, genitals, and pelvic area.

Tight (anterior and posterior) repair is rarely done and involves removing a large amount of the vaginal tissue in order to tighten and support the vagina. The main complication of this procedure is severe pain and loss of sexual function.

Colpocleisis (colpectomy or Le Forts procedure), or vaginal closure involves closing off the vagina by stitching the front and back vaginal walls together to obliterate the vagina. The procedure is performed vaginally and can be carried out using a local, regional or general

anesthesia. Once the vagina is sewn up, penetrative intercourse is no longer possible. Vault prolapse may still recur, falling through what remains of the vagina.

It would be advantageous to have available a graft that utilizes fixed, reproducible fixation points in the pelvis for its attachment, which would provide support for the vaginal apex and the anterior and/or posterior vaginal walls, and which may be placed using a minimally invasive vaginal approach.

BRIEF SUMMARY OF THE INVENTION

The present invention concerns implantable devices (grafts) and methods involving surgical fixation of the grafts for treatment of pelvic organ prolapse. One aspect of the invention concerns an anterior vaginal wall graft that supports the anterior and anterior-apical vaginal walls. Another aspect of the invention concerns a posterior vaginal wall graft that supports the posterior, posterior-apical vaginal walls and the perineal body.

One embodiment of the graft of the invention provides support to the anterior and anterior-apical vaginal wall. This embodiment is referred to herein as the anterior graft or anterior vaginal wall graft. The anterior graft comprises four or more projections or appendages (referred to herein as "arms") extending from a major elongate portion (referred to herein as a graft "body" or "body portion"), having opposing ends (first and second ends) and opposing lateral edges (first and second lateral edges), and provides anterior apical support. At least two of the arms (proximal arms) extend bilaterally from the second end of the body portion, in a generally Y-shape or chevron configuration, and are to be affixed to the posterior surface of the pubic symphysis. At least two of the arms (apical arms) extend from the first end of the body portion, or preferably, from the first and second lateral edges of the body portion, in a generally Y-shape or chevron configuration, and are to be affixed to the respective ischial spines or the surrounding bone from which the ischial spines project. Preferably, the apical arms extend from the first and second lateral edges of the body portion, with the first end of the body portion extending centrally between them. The anterior graft can be used for correction and/or prevention of prolapse of the anterior vaginal wall (bladder prolapse; cystocele), the uterus, and the vaginal vault (apex). Preferably, each arm has an end or terminus that includes a device (fixation device) for fixing the arm to its appropriate fixation point (*e.g.*, the posterior surface of the pubic symphysis and ischial spine (or the surrounding bone from which the ischial spine projects)), such as a bone anchor.

In a preferred embodiment, the anterior graft has four arms and is generally H-shaped or cross-shaped, as shown in Figure 1, with two apical arms extending from the first and second lateral edges of the body portion, with the first end of the body portion extend from between the interfaces of the apical arms and the lateral edges of the body portion, and two proximal arms extending from the second end of the body portion. The two apical arms are to be attached to the ischial spines (or the surrounding bone from which the ischial spines project) and the two proximal arms are to be affixed to the posterior pubic bone.

Another embodiment of the graft of the invention provides support to the posterior and posterior-apical vaginal wall. This embodiment is referred to herein as the posterior graft or posterior vaginal wall graft. The posterior graft comprises two or more projections or appendages (also referred to herein as "arms") extending from a major elongate portion (also referred to herein as a graft "body" or "body portion"). At least two of the arms (also referred to herein as the apical arms) extend bilaterally first end of the body portion, or preferably from the first and second opposing lateral edges of the body portion, and are to be affixed to the ischial spines or to the surrounding bone from which the ischial spines project. During implantation of the posterior graft, the second end of the posterior graft (also referred to herein as the proximal end of the posterior graft) is sutured to the perineal body and/or surrounding tissues. The lateral edges are sutured to the underlying perirectal fascia. The posterior graft can be used for correction and/or prevention of prolapse of the posterior vaginal wall (rectocele), the uterus, and the vaginal vault (apex). Additionally, graft fixation reduces perineal body descent. In a preferred embodiment, the posterior graft has two arms and is generally Y-shaped, and resembles the anterior graft, with the first end of the body portion extending between the interface of the apical arms and the lateral sides of the body portion, but differs in having no proximal arms extending from the second end of the body portion, as shown in Figure 2. The two arms are affixed to each ischial spine, or to the surrounding bone from which the ischial spine projects, with a bone anchor.

In another aspect, the present invention concerns a method for correcting a prolapsed organ within a female patient's pelvic cavity. The method includes the steps of providing an anterior and/or posterior graft of the invention for supporting the prolapsed organ(s), positioning the graft(s) within the pelvic cavity of the patient's body to support the prolapsed organ(s), and fixing the graft(s) in place at the fixation points (*e.g.*, the ischial spines, or the surrounding bone from which the ischial spines project, posterior pubic bone, perineal body).

The method of the present invention is a minimally invasive procedure using a vaginal approach and fixed, reproducible fixation points in the pelvis for the attachment of a graft to provide support for the vaginal apex and the anterior, apical and/or posterior vaginal walls. Depending upon the needs of the patient, an anterior graft of the invention, providing support to the anterior, anterior-apical vaginal wall, may be utilized; or a posterior graft of the invention, providing support to the posterior, posterior-apical vaginal wall may be utilized; or both an anterior and posterior graft may be utilized.

The method of the invention may further include diagnosis of the female patient with pelvic organ prolapse, or risk thereof, prior to graft implantation. For example, a clinician, such as a gynecologist or nurse practitioner, may diagnose the patient with pelvic organ prolapse, or risk thereof, following a gynecological examination.

In another aspect, the present invention concerns a surgical kit for performing a surgical procedure on a female patient to restore a prolapsed organ within the patient's pelvic region. The surgical kit includes at least one graft of the present invention (*e.g.*, an anterior vaginal wall graft and/or a posterior vaginal wall graft), and a device (fixation device) for fixing the arms of the graft(s) to their respective fixation points.

The present invention is characterized by the following advantages: the grafts of the invention target readily accessible, fixed anatomic points for graft attachment, thus increasing the reproducibility of the method; preformed grafts may be utilized in carrying out the method; minimal dissection is required to carry out the method; readily accessible, fixed anatomic landmarks minimize variability in the method, thereby reducing operative time; the method employs a "tension free" technique for placement of vaginal wall graft(s); the method involves positioning the graft(s) such that they do not affect bladder neck mobility, thus reducing the risk of postoperative voiding dysfunction and enabling concominent suburethral sling placement for treatment of urinary incontinence; and the method of the invention is minimally invasive, utilizing a vaginal approach, thereby reducing postoperative patient discomfort and decreasing postoperative recovery time.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows an anterior graft **10** of the invention, which provides support to the anterior and anterior-apical vaginal walls.

Figure 2 shows a posterior graft **12** of the invention, which provides support to the posterior, posterior-apical vaginal walls and the perineal body.

Figure 3 is a drawing of the pelvic organs in cross-section, with an anterior graft **10** of the invention supporting the anterior-apical vaginal wall (thereby capable of correcting a cystocele and enterocele); and a posterior graft **12** of the invention supporting the posterior, posterior-apical walls and the perineal body (thereby capable of correcting a rectocele, enterocele, and perineal descent).

Figure 4 is a drawing of prolapsed pelvic organs in cross-section, showing a cystocele **160**, rectocele **150**, and enterocele **140**.

Figures 5 and 6 show an anterior graft **10** and posterior graft **12**, respectively, designed to reduce the effects of anatomical differences among patients, as described in Example 3.

Figures 7 and 8 show an anterior graft **10** and posterior graft **12**, respectively, designed to reduce the effects of anatomical differences among patients, as described in Example 4.

Figures 9 and 10 show an anterior graft **10** and posterior graft **12**, respectively, designed to reduce the effects of anatomical differences among patients, as described in Example 5.

DETAILED DESCRIPTION OF THE INVENTION

The present invention concerns implantable grafts **10** and **12** and methods of vaginal reconstruction for treatment and/or prevention of pelvic organ prolapse, such as prolapse of the anterior vaginal wall (bladder prolapse; cystocele **160**), posterior vaginal wall (rectocele), uterus, vaginal apex (enterocele **140**), and perineal body.

The anterior graft **10** and posterior graft **12** of the invention may be positioned in a therapeutically effective position (at a target site) to support a variety of structures at different anatomical locations within the female pelvis. The anterior graft **10**, for support of the anterior, anterior-apical vaginal wall, may be used for correction and/or prevention of one or more of the following conditions: cystocele **160**, enterocele **140** (vaginal vault prolapse) or uterine prolapse, (bladder prolapse; cystocele), prolapse of the uterus, and prolapse of the vaginal vault (apical). The posterior graft **12**, for support of the posterior, posterior-apical vaginal wall, may be used for correction and/or prevention of one or more of the following

conditions in a female patient: prolapse of the posterior vaginal wall (rectocele) **150**, enterocele (vaginal vault prolapse) **140**, prolapse of the uterus, and perineal body descent.

In preferred embodiments, both the anterior and posterior grafts **10** and **12** of the invention comprise a body portion **13**, which may be any elongated shape having a longitudinal axis and has greater length than width (such as a rectangle). Preferably, the body portion **13** is generally planar but may have various surface topographies and may have various curvatures. Preferably, the body portion **13** comprises a generally planar section, opposed first and second ends **15** and **17**, and opposed first and second lateral edges **14** and **16** that terminate at the first and second ends **15** and **17**; opposed first and second apical arms **18** and **19**, wherein the first apical arm **18** extends from the first lateral edge **14** at a first interface **26** closer to the first end **15** of the body portion **13** than the second end **17**, wherein the second apical arm **19** extends from the second lateral edge **16** at a second interface **27** closer to the first end **15** of the body portion **13** than the second end **17** of the body portion **13**. As used herein, the term "interface" is intended to mean a point of contact or overlap between an apical or proximal arm **18**, **19**, **20**, **21** and a lateral edge **14** and **16** of the body portion **13**. The anterior graft **10** further comprises opposed first and second proximal arms **21** and **20**, wherein the first proximal arm **21** extends from the first lateral edge **14** at a third interface **29** closer to the second end **17** of the body portion **13** than the first end **15**, wherein the second proximal arm **20** extends from the second lateral edge **16** at a fourth interface **28** closer to the second end **17** of the body portion **13** than the first end **15**.

In one embodiment of both the anterior and posterior grafts **10** and **12**, the first apical arm **18** extends from the first lateral edge **14** at a first acute angle (shown as 45 degrees in Figures 1 and 2 but may be any acute angle) relative to the longitudinal axis of the body portion **13** at the first end **15**, and the second apical arm **19** extends from the second lateral edge **16** at a second acute angle (shown as 45 degrees in Figures 1 and 2 but may be any acute angle) relative to the longitudinal axis of the body portion **13** at the first end **15**. In this embodiment of the anterior graft **10**, the first proximal arm **21** extends from the first lateral edge **14** at a third acute angle (shown as 45 degrees in Figure 1 but may be any acute angle) relative to the longitudinal axis of the body portion **13** at the second end **17**, and the second proximal arm **20** extends from the second lateral edge **16** at a fourth acute angle (shown as 45 degrees in Figure 1 but may be any acute angle) relative to the longitudinal axis of the body portion **13** at the second end **17**. In one embodiment, the acute angles defined by each apical

arm **18** and **19** (in the anterior graft **10** and posterior graft **12**) and each proximal arm **21** and **20** (in the anterior graft **10**) are between 20 degrees and 70 degrees. In another embodiment, the acute angles defined by each apical arm (in the anterior graft and posterior graft) and each proximal arm (in the anterior graft) are between 25 degrees and 65 degrees. In another embodiment, the acute angles defined by each apical arm **18** and **19** (in the anterior graft **10** and posterior graft **12**) and each proximal arm **20** and **21** (in the anterior graft **12**) are between 30 degrees and 60 degrees. In another embodiment, the acute angles defined by each apical arm **18** and **19** (in the anterior graft and posterior graft **10** and **12**) and each proximal arm **20** and **21** (in the anterior graft **10**) are between 35 degrees and 55 degrees. In another embodiment, the acute angles defined by each apical arm **18** and **19** (in the anterior graft **10** and posterior graft **12**) and each proximal arm **20** and **21** (in the anterior graft **10**) are between 40 degrees and 50 degrees. In another embodiment, the acute angles defined by each apical arm **18** and **19** (in the anterior graft **10** and posterior graft **12**) and each proximal arm **20** and **21** (in the anterior graft **10**) is approximately 45 degrees (as shown in Figures 1 and 2).

Optionally, the first and second apical arms **18** and **19** and the body portion **13** of the anterior graft **10** and posterior graft **12** can occupy the same spatial plane. Optionally, the first and second proximal arms **21** and **20** and the body portion **13** of the posterior graft **12** can occupy the same spatial plane.

Each apical arm **18** and **19** of the anterior and posterior grafts **10** and **12**, and each proximal arm **20** and **21** of the anterior grafts **10** has a free end (terminus) **22**, **23**, **24**, **25**, respectively, which may be attached to its intended anatomical attachment site. Optionally, the apical arms **18** and **19** of the anterior and posterior grafts **10** and **12**, and the proximal arms **20** and **21** of the anterior graft **10** further comprise a fixation device **60** capable of fixing the apical or proximal arm to bone. The fixation device **60** may be located anywhere along the apical and proximal arms **18, 19, 20**, and **21** but are preferably located at the terminus **22, 23, 24**, and **25** of each apical and proximal arm **18, 19, 20**, and **21**.

The fixation device **60** may be, for example, one or more bone anchors, such as a tack, screw, bone suture, stale, fastener, pin, nail, headless screw, or dart. Preferably, each apical arm **18** and **19** of the anterior and posterior grafts **10** and **12** include a fixation device **60** capable of fixing the apical arms **18** and **19** to the ischial spines **40** or surrounding bone from which the ischial spines project. Preferably, the proximal arms **20** and **21** of the anterior

graft **10** each include a fixation device **60** capable of fixing the proximal arms **20** and **21** to the posterior surface of the public symphysis.

Optionally, each apical and proximal arm **18**, **19**, **20**, and **21** includes one or more apertures that preferably traverse the thickness of the arm. Preferably, the aperture is of sufficient diameter to accommodate a fixation device **60** the use of which requires, or is facilitated by, such an aperture. The aperture(s) may be located anywhere along the length of the apical and proximal arms **18**, **19**, **20**, and **21** but are preferably at the free ends (terminus **22**, **23**, **24**, and **25)** of each apical and proximal arm **18**, **19**, **20**, and **21** distal to the graft body portion **13**.

Optionally, in the various embodiments of the invention (see, for example, the embodiments shown in Figures 1-2 and 5-10), the body portion **13** of the graft **10** and **12** includes markings and/or perforations (weakenings) **30** that provide a cutting pattern or template to customize the grafts of the invention **10** and **12** to a particular patient's pelvic anatomy. The markings and/or perforations **30** may be located anywhere on the graft body portion **13** and/or arms **18**, **19**, **20**, and **21**. The markings and/or perforations **30** can be oriented on the graft **10** and **12** such that options are provided for cutting the body portion **13** and/or arms **18**, **19**, **20**, and **21** during surgery to reduce the length and/or width of these components to easily fit a patient's anatomy. In this way, the perimeters (dimensions and/or shape) of the body portion **13** and arms **18**, **19**, **20**, and **21** can be easily modified before or during implantation of the grafts **10** and **12**. The markings and/or perforations **30** may form any regular or irregular shape or pattern but preferably form a generally arcuate shape. For example, the markings and/or perforations **30** on the body portion **13** may be generally U-shaped. In a preferred embodiment, the generally U-shaped markings and/or perforations **30** terminate at the interfaces **26**, **27**, **28**, and **29** of the arms **18**, **19**, **20**, and **21** and the body portion **13**. Preferably, the apex of the generally U-shaped markings and/or perforations **30** is located at the center of the first end **15** of the body portion **13** as shown in Figures 1 and 2. Likewise, the apex of generally U-shaped markings and/or perforations **30** can be located at the center of the second end **17** of the body portion **13** of either the anterior or poster graft **10** or **12**, as shown in Figure 2. In a preferred embodiment, the anterior graft **10** has generally U-shaped or arc-shaped markings and/or perforations **30** that terminate around the interfaces **28** and **29** of the proximal arms **10** and **21** and the body portion **13**, with the concave aspect of the arc or U-shape facing the second end **17** (proximal end) of the body portion **13**. This

facilitates cutting of the second end **17** to accommodate the bladder neck **120** if necessary. Furthermore, the body portion **13** of the graft **10** and **12** can have multiple markings and/or perforations **30** arranged concentrically to provide options in the way of length, width, shape, and taper of the body portion **13** (*e.g.*, multiple concentric U-shapes). In those embodiments of the graft in which the apical **18** and **19** and/or proximal arms **20** and **21** are of a sufficient width and material suitable for accommodating them, markings and/or perforations **30** can be provided on the arms **18**, **19**, **20**, and **21** for similar customization (forming a single pattern or multiple patterns). Optionally, in those embodiments with multiple markings and/or perforations **30**, arc-shaped or U-shaped markings and/or perforations **30** can overlap. Furthermore, the markings and/or perforations **30** can be oriented such that the concave aspects of the arc-shapes or U-shapes face opposite directions on the body portion **13** or arms **18**, **19**, **20**, and **21**.

Figures 5-10 show additional embodiments of the anterior and posterior grafts of the invention **10** and **12**. The embodiments of the anterior grafts **10** shown in Figures 5, 7, and 9 are inverted (oriented upside down) relative to the embodiment of the anterior graft **10** shown in Figure 1. The embodiments of the posterior grafts **12** shown in Figures 6, 8, and 10 are oriented upside down relative to the embodiment of the posterior graft **12** shown in Figure 2.

In the various embodiments of the invention, the apical arms **18** and **19** of the anterior and posterior grafts **10** and **12** and the proximal arms of the anterior graft **10** are integrally attached or non-integrally attached to the body portion **13** of the grafts. When one or more of the apical or proximal arms **18**, **19**, **20**, and **21** are integrally attached to the body portion **13** of the graft **10** and **12**, the arms and body portion **13** are constructed as a unitary article (*i.e.*, the arms **18**, **19**, **20**, and **21** and body portion **13** are not constructed as separate articles that are subsequently coupled together). In those embodiments in which the apical or proximal arms **18**, **19**, **20**, and **21** are non-integrally attached to the body portion **13** of the graft **10** and **12**, the arms **18**, **19**, **20**, and **21** can be attached to the body portion **13**, for example, by filament (such as suture), adhesive, or by other techniques of attachment that are compatible with implantation within a patient (as described in Example 4 and shown in Figures 7 and 8). For example, the apical or proximal arms **18**, **19**, **20**, and **21** can be threaded through a portion of the body portion **13**.

In some embodiments of the anterior and posterior grafts **10** and **12**, the first and second apical arms **18** and **19** are formed by a first flexible strap having a first free end and a

second free end, wherein the first free end functions as the first apical arm **18** and the second free end operates as the second apical arm **19**, and wherein the first flexible strap has a segment between the first free end and the second free end that is non-integrally attached **70** to the body portion **13** of the anterior or posterior graft **10** and **12** (as described in Example 3 and shown in Figures 5 and 6). The segment between the first and second free ends of the first flexible strap can be sutured to the body portion **13**. Likewise, the first and second proximal arms **20** and **21** of the anterior graft **10** can be formed by a second flexible strap having a first free end and a second free end, wherein the first free end of the second strap functions as the first proximal arm **21** and the second free end of the second strap operates as the second proximal arm **20**, and the second flexible strap has a segment between the first free end and the second free end that is non-integrally attached **70** to the body portion **13** (as described in Example 3 and shown in Figure 5). Like the first flexible strap forming the apical arms **18** and **19**, a segment of the second flexible strap can be attached to the body portion **13** by sutures or other methods.

In some embodiments of the anterior and posterior grafts **10** and **12**, the first and second apical arms **18** and **19** are formed by a first filament having a first free end and a second free end, wherein the first free end functions as the first apical arm **18** and the second free end operates as the second apical arm **19**, and the first filament has a segment between the first free end and the second free end that is attached **70** to the body portion **13**. Preferably, a segment between the first free end and second free end of the first filament is attached to the body portion **13** by being threaded (*e.g.*, woven) through the body portion **13**. Alternately, each apical arm and each proximal arm **18**, **19**, **20**, and **21** is a filament, *i.e.*, an individual suture (as described in Example 5 and shown in Figures 9 and 10). In embodiments utilizing a filament for the apical or proximal arms **18**, **19**, **20**, and **21**, suture is preferred, in which case the arms are referred to as "suture arms". In embodiments in which a filament is used for a single apical or proximal arm **18**, **19**, **20**, and **21**, one end of the filament is free for fixation to its designated anatomical point, while the other end is attached to the body portion **13** by any method, such as being threaded (*e.g.*, woven) into the body portion **13**.

The first and second proximal arms **21** and **20** can be formed by a second filament having a first free end and a second free end, wherein the first free end of the second filament functions as the first proximal arm **21** and the second free end of the second filament operates

as the proximal arm **20**, and the second filament has a segment between the first free end and the second free end that is attached **70** to the body portion **13**. Preferably, a segment between the first free end and second free end of the second filament is attached to the body portion **13** by being threaded (*e.g.*, woven) through the body portion **13**.

In another aspect, the present invention concerns a method for correcting a prolapsed organ within a female patient's pelvic cavity. The method includes the steps of providing a graft(s) of the invention **10** and **12** for supporting the prolapsed organ(s), positioning the graft(s) **10** and **12** within the pelvic cavity of the patient's body to support the prolapsed organ(s), and fixing the graft(s) **10** and **12** in place at the fixation points (*e.g.*, the ischial spines **40** or surrounding bone from which they project, posterior pubic bone, perineal body).

The method of the invention may further include diagnosis of the female patient with pelvic organ prolapse, or risk thereof, prior to graft implantation. For example, a clinician, such as a gynecologist or nurse practitioner, may diagnose the patient with pelvic organ prolapse, or risk thereof, following a gynecological examination. Symptoms include, but are not limited to, a bulge in the vaginal walls.

In one embodiment, the graft used in the method of the invention is an anterior-vaginal wall graft **10** which, when positioned, supports the anterior, anterior-apical vaginal wall. In a specific embodiment, the method includes (1) making a midline vertical incision in the anterior vaginal wall from the level of the bladder neck **120** to the vaginal apex; (2) dissecting the anterior vaginal mucosa bilaterally from the underlying bladder **75** wall; (3) dissecting to the level of the ischial spine **40** bilaterally; (4) applying a bone anchor **60** to each ischial spine **40** or to the surrounding bone from which each ischial spine **40** projects; (5) dissecting to the level of the posterior pubic bone bilaterally; (6) applying a bone anchor **60** approximately at the level where the arcus tendinous meets the posterior pubic bone; (7) performing an anterior repair, if necessary; (8) trimming the arms **18**, **19**, **20**, and **21** of the anterior graft **10** (length and/or width) as needed in order to tie the four arms **18**, **19**, **20**, and **21** down to the appropriate bone anchors **60** and create a tension-free hammock on which the bladder **75** and vaginal apex rest (preferably, the bone anchors **60** have a pre-attached piece of suture (such as permanent monofilament); (9) cutting the perimeter of the anterior graft **10**, if necessary, in order to fit the patient's pelvic anatomy (*e.g.*, tapering the length from the proximal end (second end **17**) of the anterior graft **10**, and tapering the posterior and/or lateral edges **14** and **16** of the anterior graft **10** as needed, the goal being to make the anterior graft

10 a tension-free support for the vaginal wall); (10) palpating a Foley balloon to identify the bladder neck **120**; (11) excising the U-shaped cut-out in the proximal end of the graft **10** as needed to avoid placement of the graft **10** under the bladder neck **120** or urethra (the goal is to maintain mobility at the bladder neck **120** and urethra **130**); (12) cutting the apex portion of the graft **10** as appropriate to fit the patient's pelvic anatomy; (13) optionally, attaching the apex of the graft **10** to the cervix or uterus (*e.g.*, via suture); (14) excising the excess anterior vaginal wall mucosa as needed; (15) re-approximating the anterior vaginal wall with a delayed absorbable suture; and (16) carry out cystoscopy as needed.

In another embodiment, the graft used in the method of the invention is a posterior vaginal wall graft **12** which, when positioned, supports the posterior, posterior-apical vaginal wall and perineal body. In a specific embodiment, the method includes (1) incising the perineal body; (2) incising the posterior vaginal wall in the midline from the perineal body towards the vaginal apex; (3) dissecting posterior-laterally, bilaterally to the ischial spines **40** bilaterally; (4) applying bone anchors **60** (preferably with preloaded suture, such as permanent monofilament suture) to each ischial spine **40**, or to the surrounding bone from which each ischial spine **40** projects; (5) performing posterior plication of tissue overlying the rectum as needed; (6) conducting a rectal exam to evaluate for rectal injury; (7) cutting the arms **18** and **19** of the graft **12** as needed; (8) tying the graft arms **18** and **19** down to the corresponding bone anchors **60** at the ischial spines **40** or at the surrounding bone from which the ischial spines **40** project; (9) cutting the perimeter of the graft **12**, if necessary, in order to fit the patient's pelvic anatomy (*e.g.*, tapering the length from the proximal end of the graft **12** to end at the perineal body, and tapering the posterior and/or lateral edges **14** and **16** of the graft **12** as needed, the goal being to make the graft **12** a tension-free support over the posterior-apical vaginal wall); (10) loosely suturing the lateral edges **14** and **16** of the graft **12** to the underlying tissue overlying the rectum **100** (these sutures will keep the graft **12** from shifting laterally); (11) incorporating the proximal end of the graft **12** into the perineoplasty; (12) excising the posterior vaginal wall mucosa, if necessary; (13) and reapproximating the vaginal mucosa in the midline.

In each of the various embodiments of the method of the invention, the method may optionally be initiated by a perioperative antibiotic treatment, placement of the female patient (woman) under regional or general anesthesia, and cleaning of the surgical area. Following positioning, the final location of the graft(s) **10** and **12** within the female patient will depend

upon a variety of factors including the particular surgical procedure(s) being performed, and any preconditions of the patient such as scar tissue or previous surgeries. During the process of reapproximating the vaginal mucosa in the midline, the underlying graft **10** and **12** may be incorporated in the closure to eliminate dead space.

It should be noted that the method of the present invention is particularly suitable for placing a graft **10** and **12** in a therapeutically effective position. The method may be utilized to support a variety of structures at different anatomical locations. Variations of these methods may occur due to the individual surgeon's techniques or a patient's particular anatomy. For example, the amount of dissection employed varies greatly between surgeons and procedures. As another example, the particular order in which the elements of the graft **10** and **12** are secured are also within the individual surgeon's discretion. Some surgeons may initially place a body portion **13** of the graft **10** and **12** and subsequently secure the arms **18**, **19**, **20**, and **21**. Others may initially place the arms **18**, **19**, **20**, and **21** and subsequently secure a body portion **13** of the graft **10** and **12**. Figures 5-10 show anterior grafts **10** and posterior grafts **12** of the invention designed to reduce the effects of anatomical differences among patients, as described in Examples 3-5.

Various options are available for the material used to make the anterior and posterior grafts of the invention **10** and **12**. The grafts **10** and **12** can comprise any tissue-compatible synthetic material, or any tissue-compatible natural (non-synthetic) material, including, but not limited to, autologous, allograft, xenograft, a tissue engineered matrix, or a combination thereof. For example, PROLENE polypropylene (ETHICON, New Jersey), which is approved by the U.S. Food and Drug Administration for implantation into the human body, is a tissue-compatible synthetic material. Suitable synthetic materials can include polymers and polymeric materials, metals (*e.g.*, silver filigree, tantalum gauze mesh, and stainless steel mesh), plastics, and any combination of such materials.

A variety of materials utilized for manufacture of surgical meshes may be used to construct the grafts of the invention. Commercial examples of non-absorbable materials that may be used for construction of the grafts of the invention include MARLEX (polypropylene) (Bard, Covington, R .I.), Prolene Soft Polypropylene Mesh or GYNEMESH (a nonabsorbable synthetic surgical mesh composed of monofilament PROLENE) (ETHICON, New Jersey), and MERSILENE (polyethylene terphthalate) Hernia Mesh also available from ETHICON, GORE-TEX (expanded polytetrafluoroethylene) (W. L. Gore and

Associates, Phoenix, Ariz.). Commercial examples of absorbable materials include DEXON (polyglycolic acid) (Davis and Geck, Danbury, Conn.), and VICRYL (ETHICON). Other examples of suitable materials include those disclosed in published U.S. patent application Ser. No. 2002/0072694. More specific examples of synthetic graft materials include, but are not limited to polypropylene, cellulose, polyvinyl, silicone, polytetrafluoroethylene, polygalactin, SILASTIC, carbon-fiber, polyethylene, nylon, polyester (*e.g.*, DACRON) polyanhydrides, polycaprolactone, polyglycolic acid, poly-L-lactic acid, poly-D-L-lactic acid and polyphosphate esters (See Cervigni *et al.*, "The Use of Synthetics in the Treatment of Pelvic Organ Prolapse", *Current Opinion in Urology* (2001), 11: 429-435).

If the grafts **10** and **12** are constructed of non-synthetic materials, the grafts **10** and **12** can be made from cadaveric or autologous fascia, from the abdominal wall or fascia lata, or from dermal components (*e.g.*, PELVICOL, CR BARD, Inc., porcine collagen), for example. Thus, suitable non-synthetic materials (*e.g.*, non-synthetic grafts or synthetic/non-synthetic composites) include allografts, homografts, heterografts, autologous tissues, cadaveric fascia, autodermal grafts, dermal collagen grafts, autofascial heterografts, whole skin grafts, porcine dermal collagen, lyophilized aortic homografts, preserved dural homografts, bovine pericardium and fascia lata. The anterior graft **10** and posterior graft **12** need not be constructed of the same material or types of materials (*e.g.*, synthetic, non-synthetic). Thus, the anterior graft **10** may be constructed of one material and the posterior graft **12** may be constructed of another material, for example.

In another embodiment, the graft **10** or **12** is a combination of a synthetic material and a natural material. For example, the natural material can be centered or sandwiched between the synthetic material, or be placed over or incorporated into a generally central portion of the synthetic material (*e.g.*, at the body portion of the graft). Natural material can be connected to the synthetic material by modes such as sewing, use of a biocompatible glue, cell culturing techniques (*e.g.*, cell seeding), or other known methods.

The grafts of the invention **10** and **12** may be single or multi-ply (*e.g.*, double-ply) to provide additional supporting strength. The grafts **10** and **12** may comprise different types of material, such as bioabsorbable and/or non-bioabsorbable material. The grafts **10** and **12** may also be coated with, or incorporate a drug, such as an antimicrobial or antibiotic additive to prevent or minimize infection. The grafts **10** and **12** may be coated with, or incorporate, a lubricous coating, such as a bioabsorbable hydrogel. The grafts **10** and **12** may include an

imageable material (such as radio-opaque material) or be of a contrasting color to the body tissue, to facilitate subsequent diagnostic visualization. The grafts **10** and **12** can be porous and have a pore size sufficient for tissue in growth. In one embodiment, the grafts are a non-absorbable knitted polypropylene mesh, such as PROLENE or SOFT PROLENE, manufactured by ETHICON, Inc. (Somerville, N.J.). In another embodiment, the grafts **10** and **12** are constructed of a partially absorbable polypropylene and polyglactin mesh such as VYPRO, which is also manufactured by ETHICON, Inc., or may be any combination non-absorbable and absorbable biocompatible material. The porosity, shape, elastic property, potential for tissue in-growth, and the biocompatibility of the materials used to construct the anterior and posterior grafts of the invention **10** and **12** may be optimized for the particular application.

A hole may be provided in the body portion **13** (A_1 and/or A_2) and/or the arms **18**, **19**, **20**, and **21** (B and/or C) of the anterior and/or posterior vaginal wall grafts **10** and **12** to afford convenient conformation of the graft to irregular anatomical structures.

As indicated above, the anterior and/or posterior grafts **10** and **12** may also include markings and/or perforations **30** in the body portion **13** (A) and/or the arms **18**, **19**, **20**, and **21** (B and/or C) to provide a cutting template, in order to facilitate tailoring the graft **10** and **12** to a particular patient's pelvic anatomy (such as the perineal body shape), as shown by the dashed line in Figures 2, 6, 8, and 10, for example.

Depending upon the particular device used for graft fixation, pre-drilling of the bone to insert the fixation device into the bone may or may not be necessary. Similarly, the fixation device may or may not require cement or other fixative to remain in place.

The fixation device **60** can be bone anchors, such as tacks, screws, bone sutures, staples, fasteners, pins, nails, headless screws, darts, or any suitable device (*e.g.*, article) for bone anchoring. More preferably, the bone anchors comprise self-tapping bone screws. More preferably, each bone screw has a suture attached thereto (*e.g.*, a polypropylene monofilament). The bone anchors may be of various dimensions, *e.g.*, having various lengths and diameters. For example, the bone anchors may comprise those disclosed in any of U.S. Patent Nos. 5,520,700, 5,674,247; 5,807,403; 5,873,891; 5,972,000; 6,334,446; and/or U.S. Patent Publication 2004/0106847 (the entire contents of which are herein incorporated by reference). As an example, not intended to be limiting, the fixation device may comprise medical grade titanium bone anchors with associated sutures. The sutures may comprise

monofilament polypropylene or braided polyester or braided polyester coated with polytetrafluoroethylene (TEFLON, PTFE), such as those generally available from GENZYME/DEKNATEL of Fall River, Mass.

Bone anchors should be used in a sterile state. Various types of bone screws can be used as fixation device in accordance with the present invention. A bone screw having a conical tip and a screw body may be used, for example. The diameter of each of the screw threads (the grooves, recesses or indentations in the material of the screw) may be constant or vary along the screw body. For example, the diameter of the screw threads may increase from a smaller diameter near the apex of the conical tip to a greater diameter near the screw body. The screw threads can be located on all or a portion of the screw body as well, if desired. Typically, the suture is attached through a hole along the length of the bone screw (*e.g.*, in the middle or at the end of the bone screw). Bone screws may be of various dimensions.

The bone screw is typically made of a medical grade alloy such as Stainless Steel 316 or titanium. The bone anchors may also be partially or completely absorbable. Preferably, the anchor features sufficiently wide threads and a sufficiently small core to optimize bone purchase. Its sharp tip and small diameter allows for its penetration through the periosteum, without pre-drilling a hole. For example, the IN-FAST bone screw system and/or the IN-TAC bone anchor system (INFLUENCE, San Francisco, Calif.) may be utilized. As the screw is rotated by a bone anchor applicator, it enters further into the bone until it reaches a prescribed depth within the bone. The screw can then be disconnected (*e.g.*, manually or automatically) from the bone anchor applicator.

As described herein, sutures may be utilized to ligate (attach) or suture tissues (*e.g.*, pubic bone, ischeal spine **40** or the surrounding bone from which the ischeal spine **40** projects) to the graft body **13** (A; A_1 and/or A_2), and/or to ligate (attach) or suture apical arms (B) and/or proximal arms (C) **18**, **19**, **20**, and **21** to the graft body **13** (A; A_1 and/or A_2), where desirable. Sutures that are utilized in the grafts **10** and **12**, methods, and kits of the subject invention may be constructed of a variety of materials, and may be multifilament or monofilament. Suitable suture materials may be classified into natural, synthetic, absorbable, and non-absorbable categories. Suture materials include, for example, VICRYL (synthetic; absorbable - 60 to 90 days), DEXON (synthetic; absorbable – 60 to 90 days), PDS (polydiaxone; synthetic; absorbable - 6 months), MAXON (absorbable; 6 months), chromic

gut (absorbable; but there is risk of being tissue reactive, *e.g.*, immunogenic); PROLENE (polypropylene; non-absorbable; inert), nylon (*e.g.*, ETHILON; non-absorbable; inert), NOVAFIL (polybuester; synthetic, non-absorbable), and silk (natural, non-absorbable; but there is risk of being tissue reactive, *e.g.*, immunogenic). The choice of suture material(s) may depend upon the site, where it will be used, and the practitioner or surgeon's preference.

The suture can be uncoated or coated. For example, the suture can be coated with wax, such as beeswax, petroleum wax, polyethylene, or others, coated with silicone (*e.g.*, DOW CORNING silicone fluid 202A or others), silicone rubbers (NUSIL MED 2245, NUSIL MED 2174 with a bonding catalyst, or others), PTFE (TEFLON, HOSTAFLON, or others), PBA (polybutylate acid), ethyl cellulose (*e.g.*, FILODEL), or other coatings. Such coatings may improve lubricity of the braid, knot security, or abrasion resistance, for example.

Needles utilized for suturing may have various tips, eyelets, point types (*e.g.*, triangular cutting point, round point, tocar point, oval point, knife point), bodies, and swages. Needles may be straight or curved (*e.g.*, half curved, 3/8 circle, ½ circle), and may have any of a variety of point shapes, such as cutting, reverse cutting, and round-bodied. Needles may be of a size and curvature appropriate for the particular procedure. Further examples of suitable sutures and needles can be found in Szarmach R.R. *et al.* ("An Innovative Surgical Suture and Needle Evaluation and Selection Program", *J. Long-Term Effects of Medical Implants*, 2002, 12(4):211-229) and Szarmach R.R. *et al.* ("An Expanded Surgical Suture and Needle Evaluation and Selection Program by a Healthcare Resource Management Group Purchasing Organization", *J. Long-Term Effects of Medical Implants*, 2003, 13(3):155-170).

Suture knots may be utilized with the grafts **10** and **12**, methods, and kits of the invention. Sutures knots may be utilized to ligate graft **10** and **12** (*e.g.*, body portion **13**, apical arms **18** and **19**, and/or proximal arms **20** and **21**) to tissue (*e.g.*, pubic bone, ischeal spine **40** or surrounding bone from which the ischial spine **40** projects), tissue to tissue, graft **10** and **12** to graft **10** and **12**, suture to graft **10** and **12**, apical and/or proximal arms **18**, **19**, **20**, and **21** to graft **10** and **12**, *etc.* Examples of suture knots that may be utilized in the invention include but are not limited to an instrument tie, hand tie, and reef knot (square knot). Other suitable suture knots may be found in Trimbos J.B. ("Security of various knots commonly used in surgical practice", *Obstetrics and Gynecology*, 64(2):274-280).

In another aspect, the present invention concerns a surgical kit for performing a surgical procedure on a female patient to correct a prolapsed pelvic organ. The surgical kit includes at least one graft of the present invention (*e.g.*, an anterior vaginal wall graft **10** and/or posterior vaginal wall graft **12;** and, optionally, a fixation device(s) **60** for fixing the arms **18**, **19**, **20**, and **21** of the graft(s) **10** and **12** to their respective fixation points (such as bone screws). The surgical kit of the invention may optionally include one or more additional accessories, such as a device for deploying the fixation device **60**, *e.g.*, a bone anchor applicator, which may optionally include measuring (guide) markings along at least a portion of the applicator's shaft to determine the depth of the distal end of the applicator (enabling one to tailor the graft **10** and **12** to a patient's pelvic anatomy); a vaginal retractor (*e.g.*, the LONESTAR retractor system, LONESTAR Medical Products, Inc., Stafford, TX); one or more surgical needles; a surgical drape specifically designed for gynecological procedures; handles; dilators; and other elements for surgical convenience, for avoidance of contamination from one portion of the body to another, for ease of manufacturing or sterilization, or for surgical requirements. In some embodiments, the kits will include one or more anterior grafts **10**, and/or one or more posterior grafts **12**. Optionally, the kits can further include a fixation device(s) **60** of one or more types, such as bone anchors and/or sutures. Optionally, the fixation device may be provided in the kit attached to the graft body **13** (A_1 and/or A_2) and/or one or more arms **18**, **19**, **20**, and **21** as described herein, including Examples 1-5 and Figures 1-2 and 5-10.

The individual elements of the kits of the invention may be packaged together, separately, or in sub-assemblies depending on a variety of factors such as shelf life and sterilization requirements. The kits may include a cover and/or tray, for example. The kits may be manufactured at the manufacturing location or at the healthcare location. Any suitable sterilization procedure may be utilized to sterilize the contents of a kit, including the grafts of the invention **10** and **12**. Suitable sterilization techniques include, but are not limited to, steam sterilization (moist heat, *e.g.*, autoclave), ethylene oxide, ionizing radiation (*e.g.*, electron beam, gamma radiation), vapor (*e.g.*, hydrogen peroxide such as STERAD or peracetic acid), chlorine (*e.g.*, chlorine dioxide, such as CLIDOX, ALCIDE), aldehydes (*e.g.*, formaldehyde (6% sol.), glutaraldehyde), or plasma procedures.

Following are examples that illustrate materials, methods, and procedures for practicing the invention. The examples are illustrative and should not be construed as limiting.

Example 1—Anterior Graft and Method for Anterior Graft Placement Procedure

The anterior vaginal wall mucosa is incised in the midline. The dissection is carried back to the ischial spine bilaterally. Dissection is carried proximally to the posterior pubic bone approximating the point where the arcus joins the posterior pubic bone. The paravaginal space does not need to be entered. Next, with digital palpation, a bone anchor **60** with a pre-threaded prolene suture is placed in the ischial spines **40** bilaterally (or to the surrounding bone from which the ischial spines project). The anchoring device (bone anchor applicator) preferably has measuring (guide) markings to determine the distance from each ischial spine **40** or surrounding bone to the vaginal apex. Next, a single bone anchor or other fixation device **60** (under digital palpation) is placed on the posterior pubic bone—bilaterally at the point where the arcus meets the posterior pubic bone. The bone anchor device also acts as a measuring guide to help estimate the distance from the posterior pubic bone to the edge of the graft **10** to be placed. Anterior repair is performed, if necessary. The bladder neck **120** is identified. A preformed "H-shaped" graft 4.5 cm wide in the middle with 4 exaggeratedly long arms **18**, **19**, **20**, and **21** shall be used to provide anterior apical support (as shown in Figure 1). The apical arms **18** and **19** to be attached to the ischial spines **40** (or surrounding bone from which they project) are cut to the length determined by the previously obtained measurements during bone anchor application. The proximal arms **20** and **21** of the graft **10**, to be tied to the posterior pubic bone anchors, are, likewise, trimmed to the appropriate length. The graft **10** is then tied down to their corresponding bone anchors **60** in a tension free manner. The positioning of the graft **10** is such that it does not lie under the bladder neck **120** and therefore does not change bladder neck mobility. To achieve this, the proximal portion (second end **17**) of the graft **10** can be trimmed (tapered or shaped) so as not to lie under the bladder neck **120** and, therefore, does not hinder bladder neck mobility. The graft body **13** at the apex of the first end **15** can be trimmed in an appropriate fashion for the patient's anatomy. The excess anterior vaginal wall is trimmed and closed in the midline with suture.

As indicated above, Figure 1 shows an anterior graft **10** of the subject invention, which provides support to the anterior, anterior-apical vaginal wall. Table 1 shows exemplified and preferred dimensions for the anterior graft **10**. In Figure 1 and Table 1, "C" refers to the apical arms **18** and **19**. "D" refers to the proximal arms **20** and **21**. These dimensions are intended to be non-limiting.

Table 1. Anterior Graft

Body Portion	**Exemplified Dimension**	**Preferred Dimension**
A and B (length) A and B (width)	2 to 6 cm long 4 to 5 cm wide	4 cm long 4.5 cm wide
Arms		
C (length, using bone anchor fixation) C (width, using bone anchor fixation)	7 to 10 cm long 1 to 2 cm wide	8 cm long 1.5 cm wide
D (length, using bone anchor fixation) D (width, using bone anchor fixation)	2 to 6 cm long 1 to 2 cm wide	3 cm long 1.5 cm
C (length, using IVS type fixation) C (width, using IVS type fixation)	10 to 30 cm long 1 to 2 cm wide	20 cm long 1.5 cm wide
D (length, using transobturator fixation) D (width, using transobturator fixation)	5 to 10 cm long 1 to 2 cm wide	8 cm long 1.5 cm wide

In an exemplified embodiment, the angle from the arms **18**, **19**, **20**, and **21** of the anterior graft **10** to the nearest lateral edge **14** or **16** of the body portion **13** (or to the longitudinal axis of the body portion **13**) of the anterior graft **10** is within the range of about 25 degrees to about 65 degrees. Preferably, the angle from the arms **18**, **19**, **20**, and **21** of the graft **10** to the nearest lateral edge **14** or **16** of the body portion **13** (or to the longitudinal axis of the body portion **13**) is about 45 degrees, as shown in Figure 1.

Alternative Fixation Techniques for Anterior Graft Placement Procedure. In place of ischial spine bone anchors **60**, an IVS TUNNELER* device (U.S. SURGICAL, Inc. of

TYCO Healthcare Group, Norwalk, Conn.) may be used to place the apical arms **18** and **19** of the graft **10** at the level of the ischial spine **40** bilaterally. The IVS TUNNELER* comprises a fixed delta wing handle, a hollow metal tube and stylet that is placeable within the tube. The stylet has a rounded plastic tip on one end and an eyelet at the other end. The device is typically used to implant polypropylene tape for infracoccygeal sacropexy and other surgical procedures (See Farnsworth, "Posterior Intravaginal Slingplasty (Infracoccygeal Sacropexy) For Severe Posthysterectomy Vaginal Vault Prolapse--A Preliminary Report on Safety and Efficacy", *Int. Urogynecol. J.* (2002) 13:4-8; Petros, "Vault Prolapse II. Restoration of Dynamic Vaginal Supports by Infracoccygeal Sacropexy, an Axial Day-Case Vaginal Procedure", *Int. Urogynecol J.* (2001) 12:296-303; and Petros, "The Intravaginal Slingplasty Operation, a Minimally Invasive Technique for Cure of Urinary Incontinence in the Female", *Aust. N. Z. J. Obstet. Gynaecol.* (1996) 36: 4:453). Two perianal incisions are made, lateral and inferior to the external anal sphincter. The IVS tunneler type needle device is inserted through the incision, tunneled through the perirectal space, brought up through the ipsilateral levator muscles and arcus tendentious at the anterior base of the ischial spine **40**. The needle is then brought up through the incision in the anterior vaginal wall through which the initial dissection was made to gain access to the perivaginal space. This is then repeated on the opposite side. The apical arms **18** and **19** of the anterior vaginal wall graft **10** are then pulled into position to lie at the anterior base of the ischial spines **40**.

Alternatively, the CAPIO suturing device (BOSTON SCIENTIFIC) may be used to suture the apical arms **18** and **19** to the arcus tendineus at the level of the ischial spine **40**. For proximal fixation of the graft arms **20** and **21**, the transobturator technique may be used to pull the graft arms **20** and **21** into place via use of a transobturator needle (using a device such as OBTAPE (MENTOR, Santa Barbara, Calif.) The transobturator device is inserted through the paravaginal space 1 cm below the level of the bladder neck **120** so as not to place the graft **10** under the bladder neck **120** or urethra **130**. Alternatively, the CAPIO suturing device may be used to attach the proximal arms **20** and **21** of the graft **10** to where the arcus tendineus meets the posterior pubic bone.

Example 2—Posterior Graft and Method for Posterior Graft Placement

The posterior vaginal wall is insized in the midline. The dissection is carried to the ischial spines **40** bilaterally and to the perineal body proximally. A single bone anchor **60** is

applied to each ischial spine **40** (or to the surrounding bone from which the ischial spines **40** project) under digital direction. The markings on the bone anchor device are used to measure the distance between the ischial spine **40** (or surrounding bone) and vaginal apex. This measurement is used to appropriately trim the arms of the preformed graft **12** (as shown in Figure 2). The apical arms **18** and **19** are then tied to the suture extending from the bone anchors **60**. A posterior repair may be performed, if necessary. The proximal end (second end **17**) of the graft **12** is trimmed to end at the perineal body and then sutured into the perineal body. Bilaterally, the lateral edges **14** and **16** of the graft can be loosely sewn into the underlying perirectal tissues. Excess vaginal wall mucosa can be excised and closed with a suture in the midline. A perineoplasty may be performed as needed. The proximal end (second end **17**) of the graft **12** may further be incorporated into the perineoplasty.

As indicated above, Figure 2 shows a posterior graft **12** of the subject invention, which provides support to the posterior vaginal wall and posterior-apical vaginal wall. Table 2 shows exemplified and preferred dimensions for the posterior graft **12**. In Figure 2 and Table 2, "C" refers to the apical arms **18** and **19**. These dimensions are intended to be non-limiting.

Table 2. Posterior Graft

Body Portion	**Exemplified Dimension**	**Preferred Dimension**
A (length) A (width) B (length) B (width)	6 to 12 cm long 4 to 5 cm wide 2 to 6 cm long 4 to 5 cm wide	10 cm long 4.5 cm wide 4 cm long 4.5 cm wide
Arms		
C (length, using bone anchor fixation) C (width, using bone anchor fixation)	7 to 10 cm long 1 to 2 cm wide	8 cm long 1.5 cm wide
C (length, using IVS type fixation) C (width, using IVS type fixation)	10 to 30 cm long 1 to 2 cm wide	20 cm long 1.5 cm wide

In an exemplified embodiment, the angle from the apical arms **18** and **19** of the posterior graft **12** to the lateral edges **14** and **16** of the body portion **13** of the posterior graft **12** (or to

the longitudinal axis of the body portion **13**) is within the range of about 25 degrees to about 65 degrees. Preferably, the angle from the arms **18** and **19** of the graft **12** to the lateral edges **14** and **16** of the body portion (or to the longitudinal axis of the body portion **13**) is about 45 degrees, as shown in Figure 2.

Alternative Fixation Technique for Posterior Apical Procedure. The IVS device can be used to pull the apical graft arms **18** and **19** into place at the level of the bilateral ischial spines **40**. Alternatively, the CAPIO suturing device (BOSTON SCIENTIFIC) may be used to suture the apical arms **18** and **19** to the arcus tendineus at the level of the ischial spine **40**.

Example 3—Versatile Graft and Method for Graft Placement to Address Anatomical Variation

An alternative graft design and method of graft fixation may be utilized during pelvic floor surgery. In order to reduce any negative effects that anatomical variation among patients may have on fixing the graft **10** and **12** at a desired anatomical location, the preferred fixation devices **60** are reabsorbable or non-reabsorbable bone anchors. More preferably, reabsorbable bone anchors are utilized.

Anterior Graft. The anterior graft **10** has at least two apical arms **18** and **19** and at least two proximal arms **20** and **21**. Each pair of apical arms **18** and **19** and each pair of proximals arms **20** and **21** are formed by a flexible "strap" having at least two free ends prior to fixation. The anterior graft's **10** apical arms **18** and **19** are each fixed to an ischial spine (IS) **40** or the surrounding bone from which the IS **40** projects by suture and bone anchor **60**, as shown in Figure 5. The anterior graft's **10** proximal arms **20** and **21** are fixed to the back of the pubic bone bilaterally by suture and bone anchor **60**, as shown in Figure 5. The straps forming the anterior arms **18** and **19** and proximal arms **20** and **21** are preferably adjusted to a "tension free" fit. A standard graft body portion **13** (A) (composed of synthetic or dermal material, for example), can be cut to size along markings and/or perforations **30** and sutured or otherwise attached to the straps, as shown in Figure 5.

Table 3 shows exemplified and preferred dimensions for this embodiment of the anterior graft **10**. In Figure 5 and Table 3, "B" refers to the apical arms **18** and **19**. "C" refers to the proximal arms **20** and **21**. A_1 refers to the section of the body portion **13** between the second end **17** and the interface **26** and **27** with the apical arms **18** and **19**. A_2 refers to the

section of the body portion **13** between the first end **15** and the interface **26** and **27** with the apical arms **18** and **19**. These dimensions are intended to be non-limiting.

Table 3. Anterior Graft

Body Portion ($A=A_1+A_2$)	**Exemplified Dimension**	**Preferred Dimension**
Length Width	6 to 12 cm long 3.5 to 5 cm wide	8 cm long 4 cm wide
Arms		
Apical Arm (B) Length (entire strap) Apical Arm (B) Width	15 to 22 cm long 1 to 2 cm wide	20 cm long 1.5 cm wide
Proximal Arm (C) Length (entire strap) Proximal Arm (C) Width	8 to 12 cm long 1 to 2 cm wide	10 cm long 1.5 cm wide

Posterior Graft. The posterior graft **12** has at least two apical arms **18** and **19**, with the pair of apical arms **18** and **19** each formed by a flexible "strap" having at least two free ends prior to fixation. The posterior graft's **12** apical arms **18** and **19** are each fixed to an ischial spine (IS) **40**, or to the surrounding bone from which the IS **40** projects, by suture and bone anchor **60**, similar to the anterior graft **10**. The graft body portion **13** (A), which is preferably composed of synthetic material, is sutured or otherwise attached to the strap, as shown in Figure 6. The proximal portion (second end **17**) of the graft body portion **13** (A) can be cut along markings and/or perforations **30** such that it is tailored to the perineal body, as shown in Figure 6.

Table 4 shows exemplified and preferred dimensions for this embodiment of the posterior graft **12**. In Figure 6 and Table 4, "B" refers to the apical arms **18** and **19**. A_1 refers to the section of the body portion **13** between the second end **17** and the interface **26** and **27** with the apical arms **18** and **19**. A_2 refers to the section of the body portion **13** between the first end **15** and the interface **26** and **27** with the apical arms **18** and **19**. These dimensions are intended to be non-limiting.

Table 4. Posterior Graft		
Body Portion ($A=A_1+A_2$)	**Exemplified Dimension**	**Preferred Dimension**
Length Width	6 to 12 cm long 3.5 to 5 cm wide	8 cm long 4 cm wide
Arms		
Apical Arm (B) Length Apical Arm (B) Width	15 to 22 cm long 1 to 2 cm wide	20 cm long 1.5 cm wide

Example 4—Versatile Graft and Method for Graft Placement to Address Anatomical Variation

Anterior Graft. As an alternative to the embodiment in Example 3 (the "strap" embodiment), the apical arms **18** and **19** and proximal arms **20** and **21** are free at one end, after being anchored to the pubic bone and ischial spines (IS) **40**, as shown in Figure 7, or to the pubic bone and the surrounding bone from which the IS **40** project. This maximizes the anterior graft's **10** versatility for fitting a particular patient's anatomy. The free ends of the apical **18** and **19** and proximal arms **20** and **21** are then sutured or otherwise attached to the graft body portion **13** (A).

Table 5 shows exemplified and preferred dimensions for this embodiment of the anterior graft **10**. In Figure 7 and Table 5, "B" refers to the apical arms **18** and **19**. In Figure 7 and Table 5, "C" refers to the proximal arms **20** and **21**. A_1 refers to the section of the body portion **13** between the second end **17** and the interface **26** and **27** with the apical arms **18** and **19**. A_2 refers to the section of the body portion **13** between the first end **15** and the interface **26** and **27** with the apical arms **18** and **19**. These dimensions are intended to be non-limiting.

Table 5. Anterior Graft		
Body Portion ($A=A_1+A_2$)	**Exemplified Dimension**	**Preferred Dimension**
Length Width	6 to 12 cm long 3.5 to 5 cm wide	8 cm long 4 cm wide
Arms		
Apical Arm (B) Length Apical Arm (B) Width	8 to 20 cm long (each arm) 1 to 2 cm wide (each arm)	15 cm long (each arm) 1.5 cm wide (each arm)
Proximal Arm (C) Length Proximal Arm (C) Width	4 to 10 cm long (each arm) 1 to 2 cm wide	6 cm long (each arm) 1.5 cm wide

Posterior Graft. As with the anterior graft **10**, the apical arms **18** and **19** are free at one end, after being anchored to the ischial spines (IS) **40**, as shown in Figure 8, or to the surrounding bone from which the IS project. This maximizes posterior graft's **12** versatility for fitting a particular patient's anatomy. The free ends of the apical arms **18** and **19** are then sutured or otherwise attached to the graft body **13** (A).

Table 6 shows exemplified and preferred dimensions for this embodiment of the posterior graft **12**. In Figure 8 and Table 6, "B" refers to the apical arms **18** and **19**. "A" refers to the body portion **13**. A_1 refers to the section of the body portion **13** between the second end **17** and the interface **26** and **27** with the apical arms **18** and **19**. A_2 refers to the section of the body portion **13** between the first end **15** and the interface **26** and **27** with the apical arms **18** and **19**. These dimensions are intended to be non-limiting.

Table 6. Posterior Graft		
Body Portion ($A=A_1+A_2$)	**Exemplified Dimension**	**Preferred Dimension**
Length Width	6 to 12 cm long 3.5 to 5 cm wide	8 cm long 3.5 cm wide
Arms		
Apical Arm (B) Length Apical Arm (B) Width	15 to 22 cm long (each arm) 1 to 2 cm wide (each arm)	15 cm long (each arm) 1.5 cm wide (each arm)

Example 5—Versatile Graft and Method for Graft Placement to Address Anatomical Variation

Anterior Graft. In this embodiment, four individual sutures are attached to four bone anchors **60**. The individual sutures may be permanent (non-absorbable) or absorbable. Preferably, the sutures are permanent. The bone anchors **60** and sutures are placed in the previously described (anterior) fixation location at the ischial spines (IS) **40**, or the surrounding bone from which the IS **40** project, and posterior pubic bone. The sutures, functioning as apical and proximal arms **18**, **19**, **20**, **21** and referred to herein as "suture arms", are attached (preferably threaded, *i.e.*, woven) **70** through the graft body **13** (A) and preferably tied or otherwise attached together (*i.e.*, ischial spine suture arm to ischial spine suture arm; and pubic bone suture arm to pubic bone suture arm), to support the anterior graft **10**, as shown in Figure 9.

Table 7 shows exemplified and preferred dimensions for this embodiment of the anterior graft **10**. In Table 7, "B" (apical suture arms) refers to the apical arms **18** and **19** in Figure 9. In Table 7, "C" (proximal suture arms) refers to the proximal arms **20** and **21** in Figure 9. A_1 refers to the section of the body portion **13** between the second end **17** and the interface **26** and **27** with the apical arms **18** and **19**. A_2 refers to the section of the body portion **13** between the first end **15** and the interface **26** and **27** with the apical arms **18** and **19**. These dimensions are intended to be non-limiting.

Table 7. Anterior Graft		
Body Portion ($A=A_1+A_2$)	**Exemplified Dimension**	**Preferred Dimension**
Length Width	6 to 12 cm long 3.5 to 5 cm wide	8 cm long 4 cm wide
Suture Arms		
Apical Suture Arm (B) Length	20 to 40 cm long (each arm)	30 cm long (each arm)
Apical Suture Arm (B) Width	0 to 000 gauge	0 gauge
Proximal Suture Arm (C) Length	20 to 40 cm long (each arm)	30 cm long (each arm)
Proximal Suture Arm (C) Width	0 to 000 gauge	0 gauge

Posterior Graft. Two individual sutures are attached to two bone anchors **60**. The individual sutures may be permanent (non-absorbable) or absorbable. Preferably, the sutures are permanent. The bone anchors **60** and sutures are placed in the previously described (anterior) fixation location at the ischial spines (IS) **40** or the surrounding bone from which the IS **40** project. The sutures, functioning as apical arms **18** and **19**, are threaded (*e.g.*, woven) through the graft body **13** (A) and tied or otherwise attached together **70** (*i.e.*, ischial spine suture arm to ischial spine suture arm), to support the posterior graft **12**, as shown in Figure 10.

Table 8 shows exemplified and preferred dimensions for this embodiment of the posterior graft **12**. In Figure 10 and Table 8, "B" (apical suture arms) refers to the apical arms **18** and **19**. "A" refers to the body portion **13**. A_1 refers to the section of the body portion **13** between the second end **17** and the interface **26** and **27** with the apical arms **18** and **19**. A_2 refers to the section of the body portion **13** between the first end **15** and the interface **26** and **27** with the apical arms **18** and **19**. These dimensions are intended to be non-limiting.

Table 8. Posterior Graft		
Body Portion ($A=A_1+A_2$)	**Exemplified Dimension**	**Preferred Dimension**
Length Width	6 to 12 cm long 3.5 to 5 cm wide	8 cm long 4 cm wide
Suture Arms		
Apical Suture Arm (B) Length	20 to 40 cm long (each arm)	30 cm long (each arm)
Apical Suture Arm (B) Width	0 to 000 gauge	0 gauge

All patents, patent applications, provisional applications, and publications referred to or cited herein are incorporated by reference in their entirety, including all figures and tables, to the extent they are not inconsistent with the explicit teachings of this specification.

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application.

CLAIMS

I claim:

1. An implantable graft comprising:

a body portion, comprising a planar section having a longitudinal axis, opposed first and second ends, and opposed first and second lateral edges that terminate at said first and second ends; and

opposed first and second apical arms, wherein said first apical arm extends from said first lateral edge at a first interface closer to said first end of said body portion than said second end, wherein said second apical arm extends from said second lateral edge at a second interface closer to said first end of said body portion than said second end.

2. The graft of claim 1, wherein said graft further comprises:

opposed first and second proximal arms, wherein said first proximal arm extends from said first lateral edge at a third interface closer to said second end of said body portion than said first end, wherein said second proximal arm extends from said second lateral edge at a fourth interface closer to said second end of said body portion than said first end.

3. The graft of claim 1 or 2, wherein said first apical arm extends from said first lateral edge at a first acute angle relative to said longitudinal axis of said planar section, and wherein said second apical arm extends from said second lateral edge at a second acute angle relative to said longitudinal axis of said planar section.

4. The graft of any preceding claim, wherein said first proximal arm extends from said first lateral edge at a third acute angle relative to said longitudinal axis of said planar section, wherein said second proximal arm extends from said first lateral edge at a fourth acute angle relative to said longitudinal axis of said planar section.

5. The graft of claim 3 or 4, wherein each of said acute angles are between 20 degrees and 70 degrees.

6. The graft of claim 3 or 4, wherein each of said acute angles are between 25 degrees and 65 degrees.

7. The graft of claim 3 or 4, wherein each of said acute angles are between 30 degrees and 70 degrees.

8. The graft of claim 3 or 4, wherein each of said acute angles are between 35 degrees and 55 degrees.

9. The graft of claim 3 or 4, wherein each of said acute angles are between 40 degrees and 50 degrees.

10. The graft of claim 3 or 4, wherein each of said acute angles are 45 degrees.

11. The graft of any preceding claim, wherein said first and second apical arms and said planar portion occupy the same spatial plane.

12. The graft of claim 3, wherein said first and second apical arms, said first and second proximal arms, and said planar portion each occupy the same spatial plane.

13. The graft of any preceding claim, wherein each of said arms comprises a fixation device capable of fixing said arm to bone.

14. The graft of claim 13, wherein said fixation device comprises a bone anchor.

15. The graft of claim 14, wherein said bone anchor is selected from the group consisting of a tack, screw, bone suture, stale, fastener, pin, nail, headless screw, and dart.

16. The graft of any of claims 13 to 15, wherein each of said arms further comprises a terminus, and wherein said fixation device is located at said terminus of each of said arms.

17. The graft of any preceding claim, wherein said first and second apical arms each comprise a fixation device capable of fixing said first and second apical arms to ischial spines or surrounding bone from which the ischial spines project.

18. The graft of claim 17, wherein each of apical said arms further comprises a terminus, and wherein said fixation device is located at said terminus of each of said arms.

19. The graft of any of claims 2 to 18, wherein said first and second proximal arms each comprise a fixation device capable of fixing said first and second proximal arms to the posterior surface of the public symphysis.

20. The of graft of claim 19, wherein each of said first and second proximal arms comprises a terminus, and wherein said fixation device is located at said terminus of each of said proximal arms.

21. The graft of any of claims 1 to 12, wherein each of said arms comprises one or more apertures of sufficient diameter to accommodate a fixation device.

22. The graft of claim 21, wherein each of said arms further comprises a terminus, and wherein said one or more apertures are located at each of said terminus.

23. The graft of any of the preceding claims, wherein said planar section includes markings that provide a cutting template.

24. The graft of any of the preceding claims, wherein one or more of said arms includes markings that provide a cutting template.

25. The graft of any of the preceding claims, wherein said planar section includes perforations that provide a cutting template.

26. The graft of any of the preceding claims, wherein one or more of said arms includes perforations that provide a cutting template.

27. The graft of claim 1, wherein said first apical arm, said second apical arm, or both said first and second apical arms are integrally attached to said planar portion.

28. The graft of claim 2, wherein said first proximal arm, said second proximal arm, or both said first and second proximal arms are integrally attached to said planar portion.

29. The graft of claim 1, wherein said first apical arm, said second apical arm, or both said first and second apical arms are non-integrally attached to said planar portion.

30. The graft of claim 29, wherein said first apical arm, said second apical arm, or both said first and second apical arms are attached to said planar portion by filament such as suture.

30. The graft of claim 2, wherein said first proximal arm, said second proximal arm, or both said first and second proximal arms are non-integrally attached to the planar portion.

31. The graft of claim 30, wherein said first proximal arm, said second proximal arm, or both said first and second proximal arms are attached to the planar portion by filament such as suture.

32. The graft of claim 1, wherein said first and second apical arms are formed by a first flexible strap having a first free end and a second free end, wherein said first free end functions as said first apical arm and second free end operates as said second apical arm, and wherein said first flexible strap has a segment between said first free end and said second free end that is non-integrally attached to said planar section.

33. The graft of claim 32, wherein said segment between said first and second free ends of said first flexible strap is sutured to said planar section.

34. The graft of claim 2, wherein said first and second proximal arms are formed by a second flexible strap having a first free end and a second free end, wherein said first free end of said second strap functions as said first proximal arm and second free end of said second strap operates as said second proximal arm, and wherein said second flexible strap has a segment between said first free end and said second free end that is non-integrally attached to said planar section.

35. The graft of claim 34, wherein said segment between said first and second free ends of said second flexible strap is sutured to said planar section.

36. The graft of claim 1, wherein said first and second apical arms are formed by a first filament having a first free end and a second free end, wherein said first free end functions as said first apical arm and second free end operates as said second apical arm, and wherein said first filament has a segment between said first free end and said second free end that is attached to said planar section.

37. The graft of claim 36, wherein said first filament comprises a suture.

38. The graft of claim 36 or 37, wherein said segment between said first free end and said second free end of said first filament is woven through said planar section.

39. The graft of claim 2, wherein said first and second proximal arms are formed by a second filament having a first free end and a second free end, wherein said first free end of said second filament functions as said first proximal arm and said second free end of said second filament operates as said second proximal arm, and wherein said second filament has a segment between said first free end and said second free end that is attached to said planar section.

40. The graft of claim 39, wherein said first filament comprises a suture.

41. The graft of claim 39 or 40, wherein said segment between said first free end and said second free end of said second filament is woven through said planar section.

42. The graft of any of any preceding claim, wherein said body portion comprises tissue-compatible synthetic material.

43. The graft of any preceding claim, wherein said body portion comprises tissue-compatible natural material.

44. The graft of any preceding claim, wherein said portion comprises a blend of tissue-compatible synthetic material and tissue-compatible natural material.

45. A method for treating or preventing organ prolapse within a female patient's pelvic cavity, comprising:

providing an implantable posterior graft, wherein said posterior graft comprises a body portion comprising a planar section having opposed first and second ends and opposed first and second lateral edges that terminate at said first and second ends, and opposed first and second apical arms;

introducing the graft into the pelvic region of the patient;

fixing said first and second apical arms to the ischial spine or the surrounding bone from which the ischial spines project; and

attaching said second end of said planar section to the perineal body and/or surrounding tissues.

46. The method of claim 45, wherein the posterior graft provides support to the posterior and posterior-apical vaginal wall.

47. The method of claim 45, wherein the posterior graft is introduced to treat or prevent prolapse of the posterior vaginal wall (rectocele), the uterus, or the vaginal vault (apex).

48. A method for treating or preventing organ prolapse within a female patient's pelvic cavity, comprising:

providing an implantable anterior graft, wherein said anterior graft comprises a body portion comprising a planar section having opposed first and second ends and opposed first and second lateral edges that terminate at said first and second ends, opposed first and second apical arms, and opposed first and second proximal arms;

introducing the anterior graft into the pelvic region of the patient;

fixing said first and second apical arms to the ischial spine or the surrounding bone from which the ischial spines project; and

fixing said first and second proximal arms to the posterior surface of the pubic symphysis.

49. The method of claim 48, wherein the anterior graft provides support to the anterior and anterior-apical vaginal wall.

50. The method of claim 48, wherein the anterior graft is introduced to treat or prevent prolapse of the anterior vaginal wall (bladder prolapse; cystocele), the uterus, or the vaginal vault (apex).

51. A method for treating or preventing organ prolapse within a female patient's pelvic cavity, comprising:

providing a graft body portion comprising a planar section having opposed first and second ends and opposed first and second lateral edges that terminate at said first and second ends;

providing a first apical arm and second apical arm, wherein each of said first apical arms has a first terminus and a second terminus;

introducing said body portion and said apical arms into the pelvic region of the patient;

fixing said first termini of said first and second apical arms to the ischial spine or the surrounding bone from which the ischial spines project;

attaching said second end of said planar section to the perineal body and/or surrounding tissues; and

attaching said second termini of said first and second apical arms to said planar section, thereby forming an anterior graft.

52. A method for treating or preventing organ prolapse within a female patient's pelvic cavity, comprising:

providing a graft body portion comprising a planar section having opposed first and second ends and opposed first and second lateral edges that terminate at said first and second ends;

providing a first apical arm and second apical arm, wherein each of said first and second apical arms has a first terminus and a second terminus;

providing a first and second proximal arm, wherein each of said first and second proximal arms has a first terminus and a second terminus;

introducing said body portion, said apical arms, and said proximal arms into the pelvic region of the patient;

fixing said first ends of said first and second apical arms to the ischial spine or the surrounding bone from which the ischial spines project;

fixing said first ends of said first and second proximal arms to the posterior surface of the pubic symphisis;

attaching said second ends of said first and second apical arms to said planar section; and

attaching said second ends of said first and second proximal arms to said planar section, thereby forming a posterior graft.

53. A kit for treating or preventing a prolapsed organ, comprising a graft of any of claims 1 to 44.

54. A kit for treating or preventing a prolapsed organ, comprising a disassembled anterior or poster graft, wherein said anterior graft comprises a graft body portion comprising a planar section having opposed first and second ends and opposed first and second lateral edges that terminate at said first and second ends; and first and second apical arms, wherein said apical arms are unattached to said graft body portion.

55. The kit of claim 54, wherein said kit further comprises first and second proximal arms, wherein said proximal arms are unattached to said graft body portion.

56. The kit of claim 54, wherein said kit comprises two or more of said body portions and four or more of said apical arms.

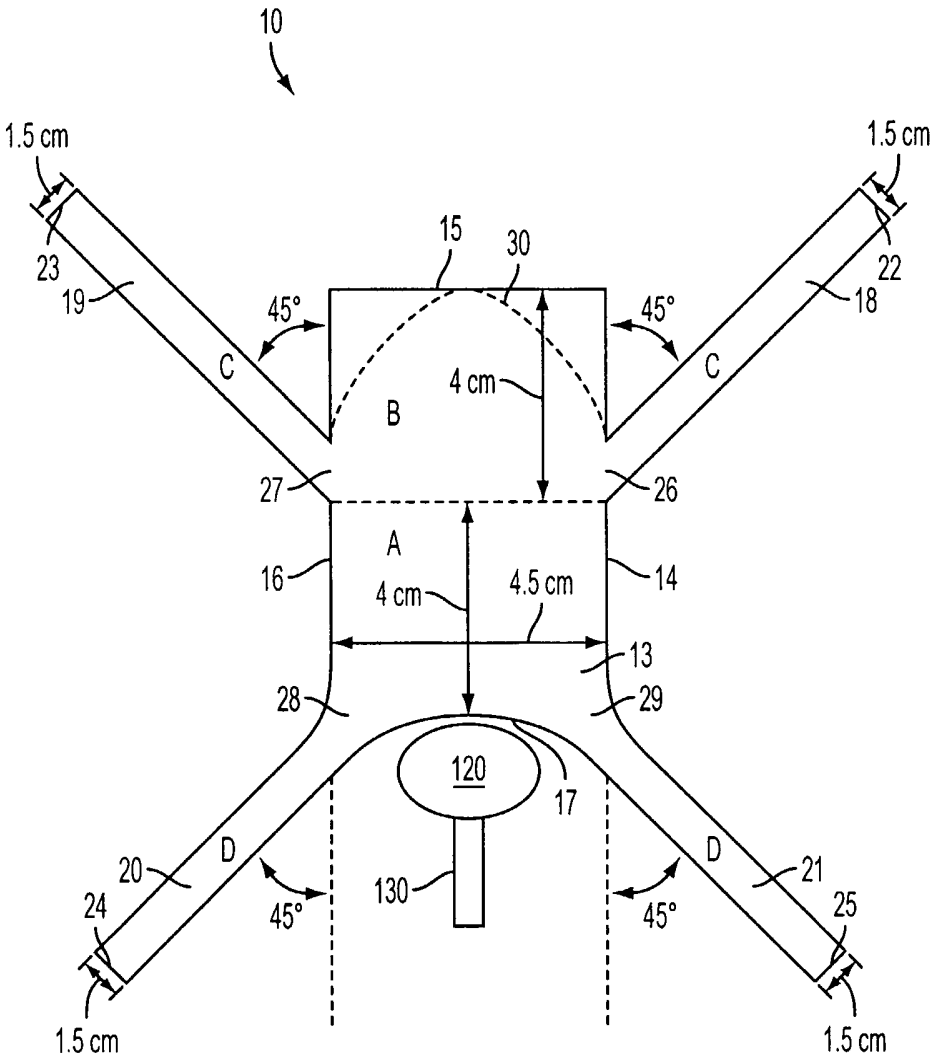
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FIG. 1

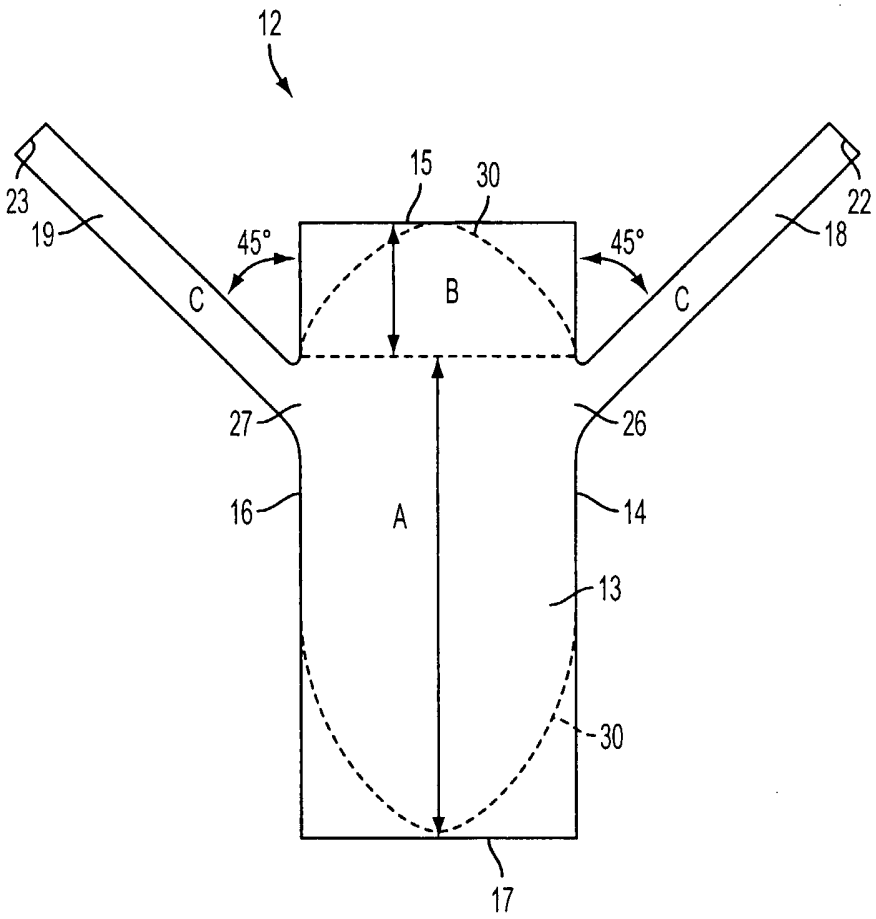

FIG. 2

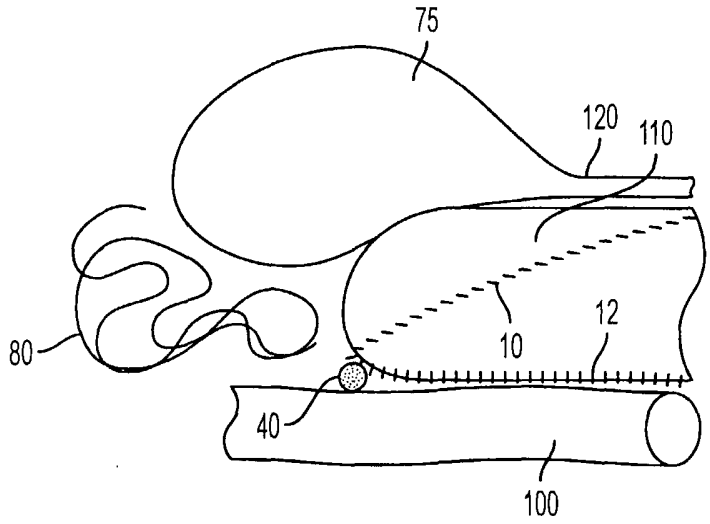

FIG. 3

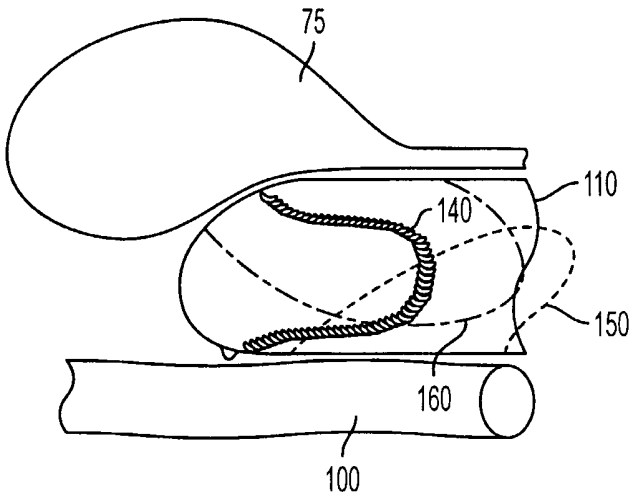

FIG. 4

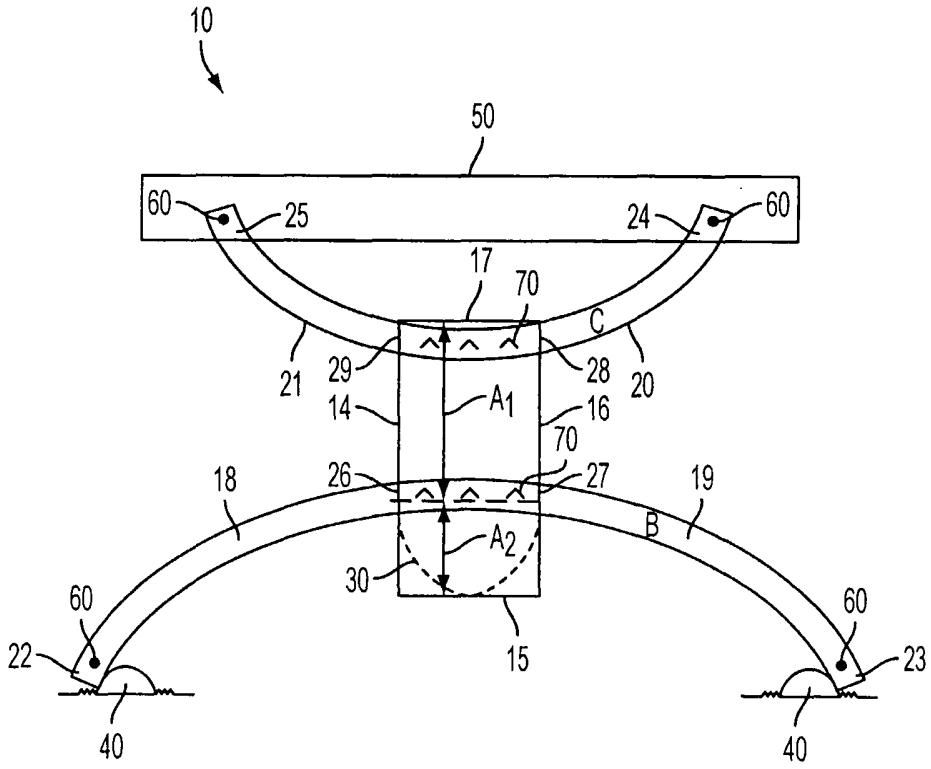
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FIG. 5

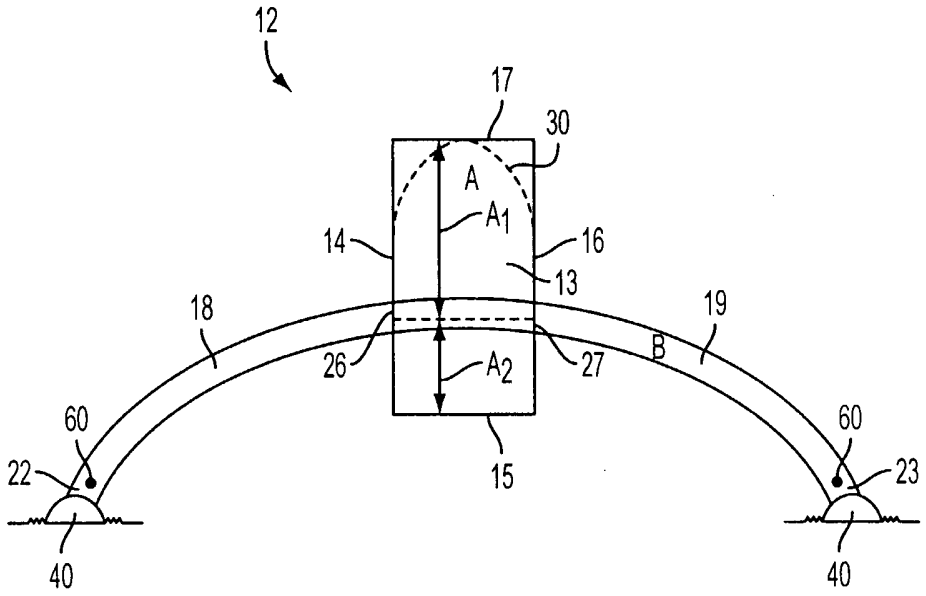

FIG. 6

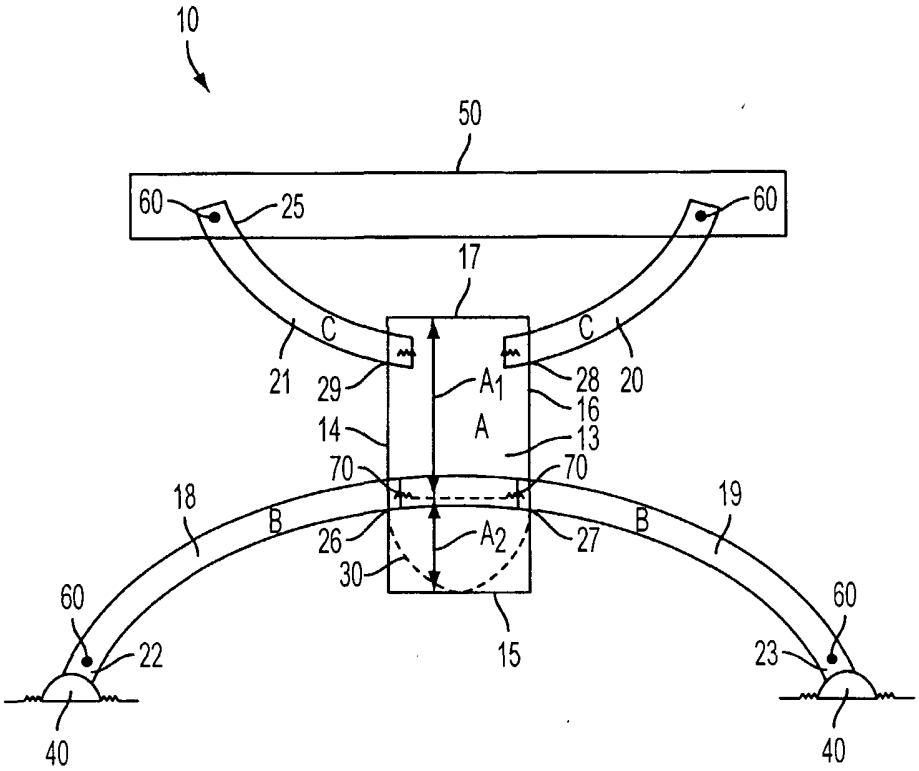
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FIG. 7

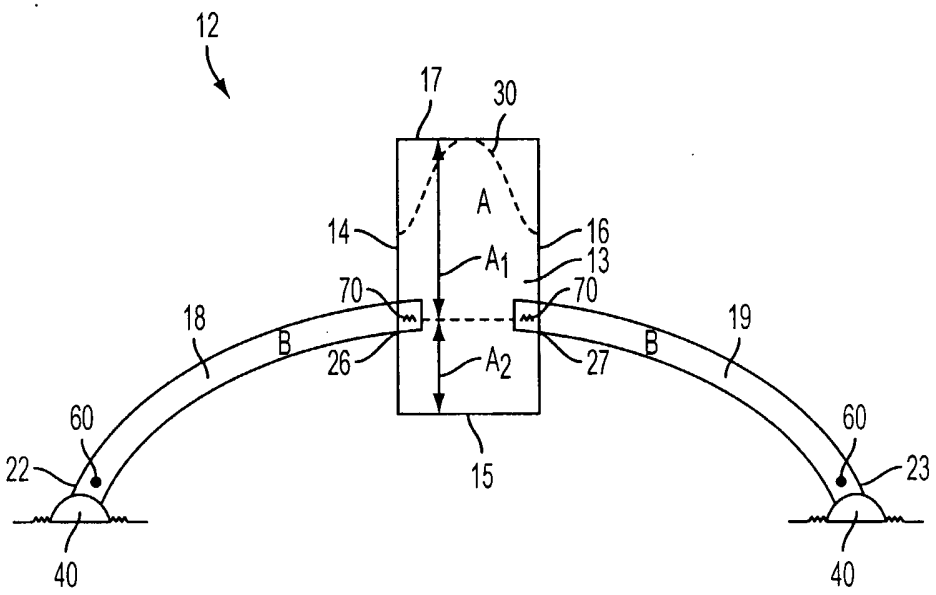

FIG. 8

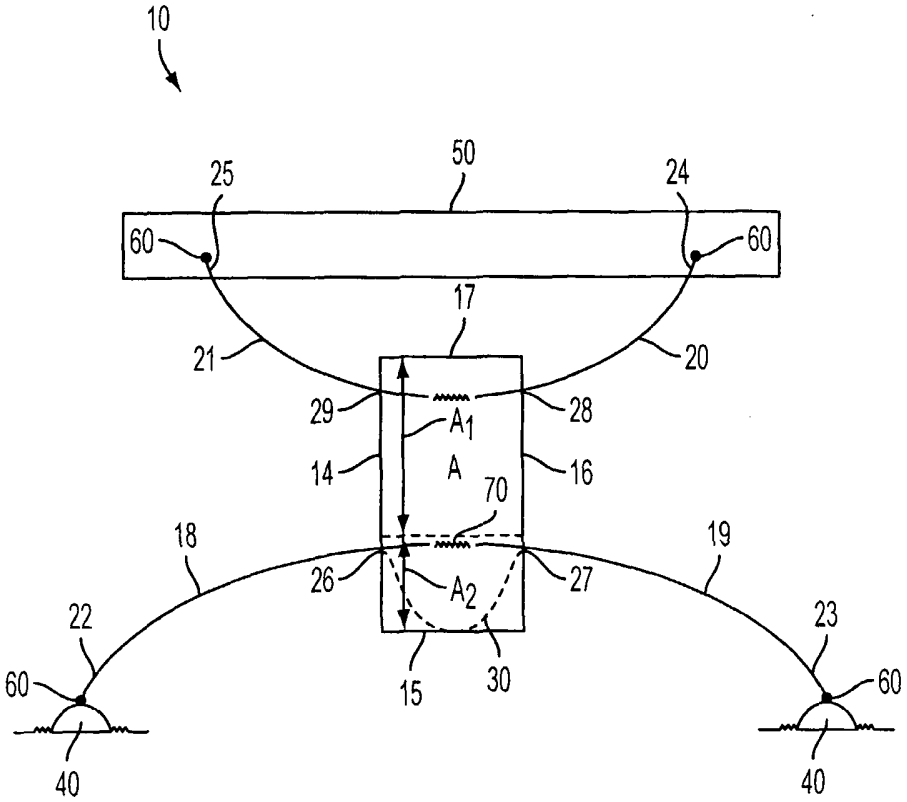
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FIG. 9

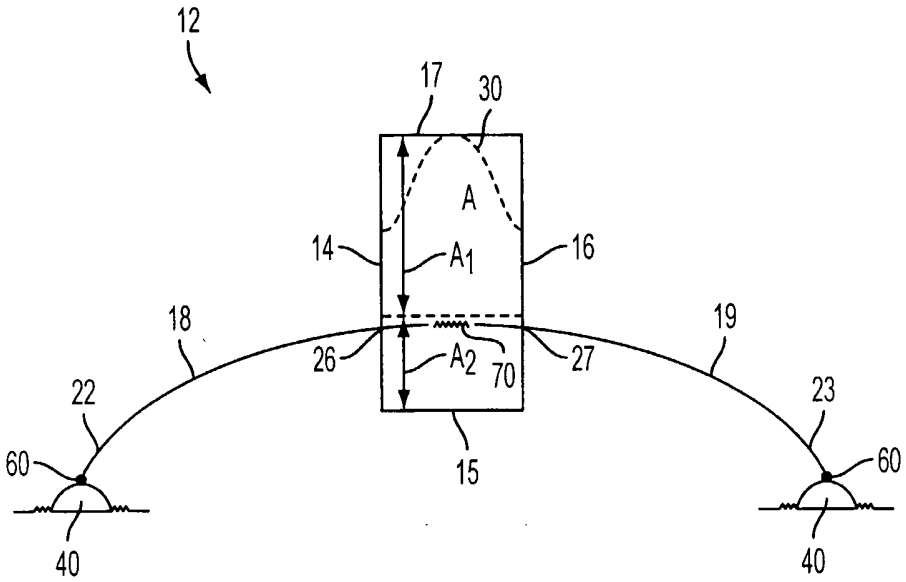

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/037888

A. CLASSIFICATION OF SUBJECT MATTER
A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/068107 A (ETHICON, INC) 21 August 2003 (2003-08-21) abstract; figure 9 page 19, line 4 - line 30	1-9, 11-13, 15-20, 27,28, 42-44,53
A		10,54-56

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 March 2006	16/03/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2005/037888

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/096929 A (AMS RESEARCH CORPORATION) 27 November 2003 (2003-11-27)	1-8, 11-13, 15-20, 23,24, 27,28, 42-44,53
	paragraph '0117! - paragraph '0119!; figure 14 paragraph '0090! paragraph '0074!	
A		9,10,29, 30,54-56

X	EP 0 774 240 A (ETHICON, INC) 21 May 1997 (1997-05-21)	1-4, 11-22, 27,28, 42,53
	column 2, line 27 - line 59; claims 6-12; figures	
A		5

X	WO 03/073960 A (JACQUETIN, BERNARD) 12 September 2003 (2003-09-12)	1,3,5, 13-15, 17,23, 24,27,53
	page 8, line 3 - line 20; figures 2,10 page 5, line 14 - line 20 page 17, line 15 - line 23	
A		25,26

X	WO 02/38079 A (ETHICON GMBH; MIGLIARI, ROBERTO) 16 May 2002 (2002-05-16) abstract; figures	54,55
A		1,2,11, 12,29, 30,32, 34,36, 38,39, 41,53,56

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/037888

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 45-52
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2005/037888

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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			CA	2475910 A1	21-08-2003
			EP	1474073 A1	10-11-2004
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			CA	2428652 A1	16-05-2002
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			US	2004116774 A1	17-06-2004