



(51) International Patent Classification:
A61F 2/00 (2006.01)

(21) International Application Number:
PCT/US2017/054240

(22) International Filing Date:
29 September 2017 (29.09.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/402,566 30 September 2016 (30.09.2016) US

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(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH,

(54) Title: A METHOD AND DEVICE FOR CLOSING THE UROGENITAL HIATUS IN THE ABSENCE OF OR DAMAGE TO THE PUBOVISCERAL MUSCLE FIELD

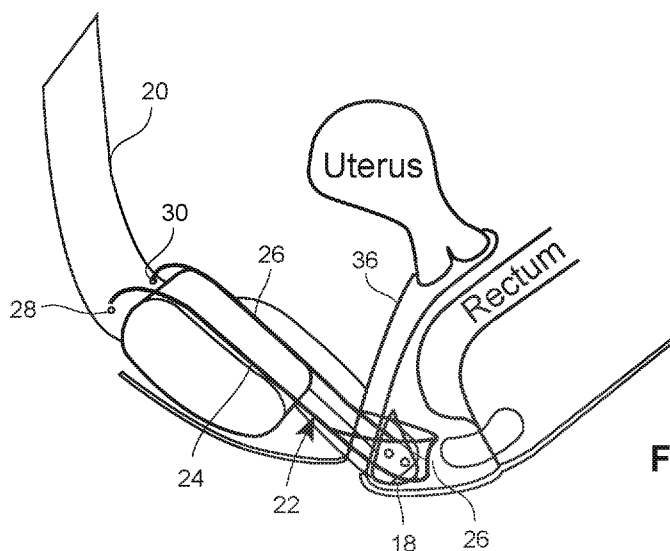


FIG. 6

(57) Abstract: A method of closing a urogenital hiatus in which a pubovisceral muscle (PVM) is damaged, and an implant for use in the method are disclosed. The implant includes two suspension arms that are generally flexible in bending but stiff in tension and form muscle-equivalent tensile load-bearing elements. An upper end of each suspension arm can be affixed on or near the pubic bone or rectus fascia near the origins of the PVM. A lower end of each suspension arm is configured to be operatively coupled to and/or support the perineal body so as to support the perineal body from the rectus fascia or pubic bone and close the urogenital hiatus. The lower ends of the suspensions arms can be directly secured to the perineal body, or the lower ends of the suspension arms may be connected to a support hammock that directly supports the perineal body.

GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

A METHOD AND DEVICE FOR CLOSING THE UROGENITAL HIATUS IN THE ABSENCE OF OR DAMAGE TO THE PUBOVISCERAL MUSCLE FIELD

Cross Reference To Related Applications

[0001] This application is a non-provisional and claims the benefit of the filing date of US Provisional Patent Application No. 62/402,566, filed September 30, 2016, entitled “A Method and Device for Closing the Urogenital Hiatus in the Absence of or Damage to the Pubovisceral Muscle Field.” The entire contents of US Provisional Application No. 62/402,566 is hereby incorporated by reference.

Statement of Government Interest

[0002] This invention was made with government support under grant AG024824 awarded by the U.S. National Institutes of Health. The government has certain rights in the invention.

Field of the Disclosure

[0003] This disclosure relates generally to methods of effecting urogenital hiatus closure in the absence of or damage to the pubovisceral muscles of to the levator ani muscles, and devices configured to effect urogenital hiatus closure in the absence of or damage to the pubovisceral muscles.

Background

[0004] Pelvic organ prolapse is one of the most common reasons for women to undergo surgery in their lifetime. Pelvic organ prolapse, also known as uterine prolapse, occurs when the pelvic organs fall from their normal position into or through the vagina. Pelvic organ prolapse is often caused by damage to levator ani muscles incurred during vaginal childbirth. Vaginal childbirth can cause tears to one or both sides of the pubovisceral (pubococcygeal) muscle portion (“PVM”) of the pelvic floor muscles (i.e., the levator ani muscle) in 10-15% of women. Typically, when a woman sustains a tear on one or both sides of the PVM, she loses the ability to prevent downward displacement of the perineal body (an important part of the “pelvic floor”) relative to the pelvic bones. Eventually, the torn PVM atrophies because it no longer carries active or passive muscle forces. This renders the woman susceptible to the development of a pelvic organ prolapse. In biomechanical terms this occurs because there is no longer any PVM muscle to close the urogenital hiatus (one of the openings in the female pelvic floor), and no other muscle is available to do this.

[0005] FIGS. 1A-1C schematically illustrate this scenario. FIG. 1A illustrates the typical condition of the levator ani 10 (i.e., the pelvic floor muscles) in a healthy woman. The

healthy levator ani 10 holds the urogenital hiatus 12 together and maintains a balanced pressure across the vaginal wall 14, which thereby holds the uterus 16 and other pelvic organs up and in place within the body cavity. FIG. 1B illustrates a rupture in the levator ani 10, which allows the urogenital hiatus 12 to open and thereby develop a pressure differential across the vaginal wall 14. FIG. 1C illustrates how the pressure differential across the vaginal wall 14 places an excessive force on the support structures for the pelvic organs, such as by creating excessive tension in the support ligaments for the uterus uterosacral ligament (“USL”) and the cardinal ligament (“CL”), leading to a uterine prolapse (e.g., hernia) through the urogenital hiatus 12.

[0006] Various health and/or lifestyle problems can be caused by a pelvic organ prolapse. Until now, however, there has been no commonly accepted procedure available to correct the critical loss of muscle control that causes pelvic organ prolapse.

Summary

[0007] The present disclosure provides new methods and devices for returning the urogenital hiatus to normal dimensions in women and men who have suffered injury and atrophy of the pubovisceral muscle (“PVM”) portion of their pelvic floor muscles.

[0008] In some arrangements, a method of closing a urogenital hiatus with a PVM implant includes affixing a support hammock to the perineal body to extend from the left side of the perineal body to the right side of the perineal body. Upper ends of a left suspension arm and a right suspension arm are passed on respective opposite left and right sides of the vagina and urethra from the perineal body to the pubic bone along the path of the healthy PVM. The upper ends of the left and right suspension arms are wrapped over the top of the pubic bone. The upper ends of the left and right suspension arms are fastened to the rectus fascia or other structure near the origin points of the PVM at the pubic bone. Left and right sides of the hammock are connected to lower ends of the respective left and right suspension arms. The lengths of the left and right suspension arms are adjusted so as to elevate the perineal body back up to its normal, healthy position relative to the pubic bone.

[0009] In some arrangements, a method of closing a urogenital hiatus with a PVM implant includes passing upper ends of a left suspension arm and a right suspension arm on respective opposite left and right sides of the vagina and urethra from the perineal body to the pubic bone along the path of the healthy PVM. The upper ends of the left and right suspension arms are affixed to the rectus fascia or other structure near the origin points of the PVM at the pubic bone. Lower ends of the left and right suspension arms are affixed to respective left and right sides of the perineal body. The lengths of the left and right suspension arms are adjusted

so as to elevate the perineal body back up to its normal, healthy position relative to the pubic bone.

[0010] In some arrangements, a PVM implant for closing a urogenital hiatus according to any one of the methods disclosed herein includes a left suspension arm and a right suspension arm. The left suspension arm has a length that extends from an upper end to a lower end, the length extending at least from an origin point of the PVM at the pubic bone to the perineal body the first suspension arm. The right suspension arm has a length that extends from an upper end to a lower end, the length extending at least from an origin point of the PVM at the pubic bone to the perineal body the first suspension arm. The PVM implant has means for affixing the upper ends of the left and right suspension arms to the pubic bone or other tissue near the origin points of the PVM and means for coupling the lower ends with the perineal body to support the perineal body and close the urogenital hiatus.

[0011] The PVM implant may include a tissue fixation device is disposed at the upper end of each of the left and right suspension arms. The PVM implant may include tissue fixation devices disposed at the lower ends of each of the left and right suspension arms. One or both of the upper ends of the left and right suspension arms may have a hooked shape configured to wrap over an upper edge of the pubic bone.

[0012] At least one of the left and right suspension arms may be formed of multiple, separable strands of tensile load-bearing elements. At least one of the left and right suspension arms may be formed of only a single strand that has an elongate shape extending from the upper end to the lower end and is flexible in bending but stiff in tension and forms a muscle-equivalent tensile load-bearing element. At least one of the left and right suspension arms may be a suture, wire, or cable. At least one of the left and right suspension arms may be flexible and may have a resilient tensile strength similar to that of a typical healthy PVM.

[0013] The PVM implant may include a support hammock extending between the lower ends of the left and right suspension arms. The support hammock may be the form of a flexible, thin, sheet. The support hammock may have the form of a wide band of flexible material with opposite left and right ends that are configured to extend from a left side to a right side of a perineal body and a width that is configured to extend at least partly from a bottom to a top of the perineal body. Preferably, the support hammock may be configured to provide a suitable surface area for supporting the perineal body without forming excessive pressure points or lines against the perineal body.

[0014] One or more of the left and right suspension arms and the support hammock may be formed of synthetic mesh, active biocompatible tissue-engineered elements, and/or passive

[0001] biocompatible tissue-engineered elements. One or more of the left and right suspension arms and the support hammock may be formed of synthetic mesh comprising polypropylene, autograft, allograft, and/or xenograft.

[0002] In some arrangements, a method of closing a urogenital hiatus with a PVM implant according to any arrangement described herein includes implanting the PVM implant to extend along the normal direction of a healthy PVM from an origin point of the PVM at the pubic bone to the perineal body, affixing an upper end of the implant to the pubic bone or adjacent tissues near the origin point, and coupling a lower end of the implant to support the perineal body so as to close the urogenital hiatus.

[0003] Any one or more of these aspects, arrangements, and/or features may be combined with any one or more of the other aspects and/or additional aspects, arrangements, features, and/or technical effects that are apparent upon detailed inspection of the figures and the following description.

Brief Description of the Drawings

[0004] FIG. 1A is a schematic illustration of a typical healthy pelvic region of a woman along the sagittal plane;

[0005] FIG. 1B is a schematic illustration of the pelvic region similar to FIG. 1A, but in which the levator ani is ruptured;

[0006] FIG. 1C is a schematic illustration of the pelvic region similar to FIG. 1B, but with pelvic organ prolapse through a ruptured levator ani;

[0007] FIG. 2A is another a schematic illustrations of the levator ani muscles in a typical healthy female pelvic region from below;

[0008] FIG. 2B is another a schematic illustrations of the levator ani muscles in a typical healthy female pelvic region from above;

[0009] FIG. 3 is another schematic illustration of a typical healthy pelvic region of woman along the sagittal plane illustrating various organs and muscle groups;

[0010] FIG. 4 is a similar view as FIG. 3 with the puborectal muscle removed to show underlying structures and illustrating how the perineal body falls away from the pubic bone; and

[0011] FIG. 5 is a similar view as FIG. 3, and also illustrating an exemplary implant device for repairing the ruptured PVM according to aspects of the present disclosure;

[0012] FIG. 6 is a similar view as FIG. 5 and illustrating the implant device implanted to repair the ruptured PVM;

[0013] FIG. 7 illustrates another exemplary implant for repairing the ruptured PVM;

[0027] FIG. 8 illustrates yet another exemplary implant for repairing the ruptured PVM; and

[0028] FIG. 9 illustrates a further exemplary implant for repairing the ruptured PVM.

Detailed Description

[0029] In general, pubovisceral muscle implants (hereinafter, “PVM implants”) are disclosed that can be surgically implanted to correct the critical loss of muscle control in the levator ani that causes pelvic organ prolapse. A PVM implant includes two suspension arms, a left suspension arm and a right suspension arm. Each a suspension arm has an elongate shape, such as that of a suture, wire, or cable, and is generally flexible in bending and stiff in tension and forms a muscle-equivalent tensile load-bearing element. An upper end of each suspension arm is configured to be attached to target points on or near the pubic bone or rectus fascia: a first target point on the left side of the vagina and urethra and a second target point on the right side of the vagina and urethra. A lower end (i.e., the opposite end) of each suspension arm is configured to be operatively coupled to and/or support respective left and right sides of the perineal body so as to support the perineal body from the rectus fascia or pubic bone. The lower ends of the suspensions arms can be unconnected to each other and directly secured to opposite left and right sides of the perineal body with a tissue fixation device, such as with hooks, suture pads, or other biomechanical fasteners. The lower ends of the suspension arms may be connected with each other, for example by a support hammock that directly supports the perineal body.

[0030] To implant a PVM implant that includes the support hammock, the support hammock is tunneled through or wrapped around the lower side of the perineal body from one side to the other (i.e. anatomical left side and right side). The left and right sides of the hammock are connected to the lower ends of the respective left and right suspension arms of the PVM device. The upper ends of the left and right suspension arms are passed on each side of the midline (i.e., the sagittal plane) up alongside the vagina and urethra, for example with a trocar, and then wrapped over the pubic bone and fastened to the rectus fascia or other nearby structure. The lengths of the two suspension arms are adjusted by the surgeon so as to elevate the perineal body back up into its normal, healthy position relative to the pubic bone, thereby returning the urogenital hiatus to its normal size and maintaining that closure during normal activity of daily living so as to prevent prolapse. Alternatively, if the support hammock is not to be used, then the lower end of each suspension arm is attached to the sides of the perineal body with a tissue fixation device, such as, hook, suture pad, or other biomechanical fastener sufficient to grip or fasten to soft tissue and support the expected loads thereon.

[0031] In a typical healthy woman, there are two anatomical openings in the pelvic floor, the urogenital hiatus and the levator hiatus. The urogenital hiatus lies between the pubic bone ventrally and the perineal body dorsally. The levator hiatus occurs between the pubic bones and the anorectal angle where the puborectal muscle loops behind the rectum. Both the urogenital hiatus and the levator hiatus are bordered laterally by the medial margin of the levator ani muscle.

[0032] As depicted in FIGS. 2A and 2B, studies of magnetic resonance imaging of the pelvic floor muscles (i.e., the levator ani) in healthy women have been used to quantify the muscle fiber orientations of three major divisions: the pubovisceral muscle (“PVM”) (also called the pubococcygeal muscle), the iliococcygeal muscle (“ICM”), and the puborectal muscle (“PRM”). From a biomechanical perspective, because these are all parallel-fibered muscles, the muscle orientation reflects the mechanical line-of-action of that muscle subdivision between its origin and insertion. The results of the MRI studies showed that the mean fiber directions for each of the PVM, ICM and PRM, respectively, were +41 degrees, +33 degrees, and -19 degrees with respect to the horizontal. From these results, it appears that the PVM is a “lifter” of the perineal body and thereby a “closer” of the urogenital hiatus. In contrast, the PRM, which acts at an angle of 60 degrees to the PVM, does not “lift” the perineal body vertically, although it does help “close” the levator hiatus.

[0033] FIG. 2A is a schematic view of the lower pelvic region from below, after the vulvar structures and perineal membrane have been removed. This view shows the arcus tendineus levator ani (ATLA), the external anal sphincter (EAS), the puboanal muscle (PAM), the perineal body (PB) uniting the two ends of the puboperineal portion (PPM) of the pubovisceral (PVM)?], the iliococcygeal muscle (ICM), and the puborectal muscle (PRM). In this view, the urethra and vagina have been transected just above the hymenal ring. FIG. 2B shows the pubovaginal portions of the levator ani muscles seen from above, looking over the sacral promontory (SAC). This view shows the pubovisceral muscle, sometimes called the pubococcygeal muscle, and the puboanal muscle (“PAM”). The internal obturator muscles have been removed to clarify levator muscle origins, and the urethra, the vagina, and the rectum have been transected just above the pelvic floor.)

[0034] As shown more clearly in in FIG. 3, in a standing woman, the PVM 16 prevents the perineal body 18 and pelvic floor from being pushed downward and backward by ubiquitous downward intra-abdominal pressure and superincumbent inertial forces. The PVM 16 is illustrated here as having a left side PVM 16a and a right side PVM 16b, which are connected at their lower (or distal) ends to respective opposite left and right sides of the

perineal body 18 and originate at the pubic bone 20 at origin points 17a and 17b, respectively. Under those same forces, the PRM, on the other hand, maintains closure of the levator hiatus, thereby preventing the female organs from prolapsing (herniating) under that downward loading but cannot exert any lifting force. During defecation, both the PVM 16 and the PRM relax to allow passage of stool to the anal sphincter, which also relaxes so stool is passed out of the body. Following defecation, the muscles contract to maintain levator hiatus closure again. Thus, the inventors have found that the PVM 16 and the PRM work together to achieve these goals during normal activities.

[0035] The normal geometric relationships between the perineal body 18 and pubic bone 20 shows downward and backward displacement in women with prolapse. This includes in rectilinear coordinates the distance and angle subtended by the perineal body relative to a coordinate system origin placed on the arcuate pubic ligament (immediately under the pubic symphysis) and the sacrococcygeal junction in the mid-sagittal plane. The inventors have found that knowing the normal variation in this distance and angle subtended by the perineal body in a healthy woman can provide a geometric goal for the surgeon to return a fallen perineal body in cases with prolapse. The inventors have also found that by returning the perineal body 18 to the location it usually has in healthy women, a surgeon can help eliminate or reduce the risk of a future vaginal wall prolapse, as described hereinafter.

[0036] As illustrated in FIG. 3, a normal intact Pubic bone-PVM-perineal body-PVM-pubic bone system includes generally: (a) left and right attachments sites of the PVM to the pubic bone; (b) the left and right side tensile load-bearing elements that are the PVM muscles themselves that develop contractile force along lines-of-action given by the +41 degree angle noted herein; (c) the left and right attachments sites of the PVM to the perineal body behind the urethra and vagina; and (d) the perineal body 18, which is a passive collagenous structure of connective tissue which lies between the distal vagina and rectum and links the two distal ends of the PVM together as a mechanical link across the midline in the frontal and transverse planes. The perineal body 18 is a mobile, roughly triangular, structure relative to the pubic bone. When the PVMs contract, the PVMs lift the perineal body toward the pubic bone, thereby closing the urogenital hiatus 12, an opening in the pelvic floor.

[0037] The left side PVM 16a and the right side PVM 16b take origin from boney support points, which are illustrated in FIG. 4 as the origin points 17a and 17b, at the rear of the pubic bone 20 on opposite left and right sides of the midline, respectively. (For purposes of this discussion, the pubic bone can be regarded as being fixed in space.) The origin points 17a and 17b are the upper support points of the respective left side PVM 16a and right side PVM 16b

on the bony pelvis. In essence, the pelvic organs and other tissues that the left and right side PVMs support hang from these bony support points. The PVMs are formed from parallel-fibered striated muscle. As illustrated in FIG. 3, the PVM 16 passes downward and backward (i.e., posteriorly) from the origin points in the sagittal plane at an average angle of about 41 degrees below the horizontal on opposite left and right sides of the vagina to attach to the perineal body. This attachment point of the PVM 16 to the perineal body is the lower fixation point of the PVM.

[0038] In FIG. 4, the pubovisceral muscles (PVM) are omitted to show how the perineal body 18 “falls” away from the pubic bone when the PVM are damaged, thereby causing the urogenital hiatus 12 to gape open. It has been found that the PVM 16 is the only pelvic floor muscle that can close the urogenital hiatus 12, and that no other pelvic floor muscle has this biomechanical role. Superincumbent intra-abdominal pressure exceeds the atmospheric pressure acting on the underside of the front vaginal wall. If the urogenital hiatus 12 is allowed to gape open because of insufficient strength of the PVM 16, then a pressure differential acts across the front vaginal wall 14, which causes the front vaginal wall to tend to herniate in the downward direction under the action of the superincumbent intra-abdominal pressure. If this pressure differential is allowed to persist, for example because the PVM 16 is not maintaining closure of the urogenital hiatus 12, then a prolapse (herniation) of the front vaginal wall 14 can result. The inventors have found that by maintaining closure of the urogenital hiatus, a pressure differential can never begin to act across the vaginal wall because both sides of the vaginal wall are maintained in equipoise within the abdominal cavity. The inventors have also found that a PVM implant or replacement as disclosed herein can function to elevate the perineal body 18 so that it maintains closure of the urogenital hiatus 12. However, until now, no existing surgical operation or device has been directed toward this goal.

[0039] FIG. 5, illustrates an exemplary PVM implant device 22 prior to implantation that is configured to correct or mitigate problems associated with a rupture of the pubovisceral portion of the levator ani muscle, i.e., the PVM 16. The PVM implant 22 is designed to provide similar structural elements as the natural PVM 16 on both left and right sides of the sagittal plane. The PVM implant 22 includes two suspension arms, a left suspension arm 24 and a right suspension arm 26. The PVM implant 22 also includes an optional support hammock 26 (also called a perineal body sling). The upward arrow A indicates the direction in which the PVM implant 22 is to elevate the perineal body 18 to close the urogenital hiatus 12. Upper ends of the suspension arms 24, 26 of the PVM implant 22 are affixed to the pubic

bone 20 at upper left and right fixation points 28, 30, as illustrated by the dots. Lower ends of the suspension arms 24, 26 of the PVM implant 22 may be affixed to the perineal body 18 at possible lower fixation points 32, 34 shown by the dots.

[0040] The PVM implant 22 is designed to provide similar structural elements as the natural PVM 16 on the opposite left and right sides 16a and 16b of the sagittal plane. These structural elements are the left and right fixation points 28, 30 near to where the normal PVM muscle originates, the left and right tensile load-bearing members or suspension arms 24, 26 that serve the carrying functions of the respective left and right PVM muscles 16a, 16b, and the left and right attachment points 32, 34 to the perineal body 18 on opposite sides of the vagina 36. The most convenient locations from a surgical perspective are to attach the upper ends of the suspension arms 26 and 26 to two fixation points 28, 30 on the rectus abdominis sheath, or other convenient soft tissue point in that region, such as the tissues in the obturator foramen region, on either side of the sagittal plane. Attaching the upper ends of the suspension arms 24, 26 to the pubic bone 20 itself via bone screws is possible. However, it may be preferable to avoid fixation to the pubic bone 20 because of possible risk of bone infection. The suspension arms 24, 26 pass up and over the top edge of the pubic bone and wrap downward around the pubic bone until they extend at an angle of +41 degrees to the horizontal to connect to the perineal body 18 via the central hammock 26. The central hammock 26 may be tunneled through the perineal body 18, such as through bilateral points of entry at the fixation points 23 and 24 to link the distal ends of the arms together. Alternatively, the central hammock 26 may be wrapped around the lower side (i.e., distal from the fixation points 28, 30) of the perineal body 18 rather than be tunneled through the perineal body. In order to successfully implant the PVM implant 22, it is important to know where the upper fixation points 28, 30 and the lower fixation points 32, 34 are to be located anatomically in order to create the appropriate mechanical action to close the urogenital hiatus 12.

[0041] Alternatively, if the central hammock 26 is not used, the mechanical attachment of the lower ends of the left and right suspension arms 24, 26 of the PVM implant 22 may be made directly to the perineal body 18 at the fixation points 32, 34 by soft tissue anchors, such as standard pads, hooks or other anchors, as described hereinafter. Because the perineal body might 18 stretch under loads imposed by the activities of daily living with this direct fixation, it may be preferably to use hammock 26 passed through or wrapped around the perineal body 18.

[0042] FIG. 6 shows the PVM implant 22 fully implanted. The support hammock 26 of the PVM implant 22 is tunneled through the perineal body 18, and the suspension arms 24, 26 are brought up on opposite left and right sides of the vagina 36 and urethra 38 to wrap around the back and top of the pubic bone 20. The upper ends of the suspension arms 24, 26 are fastened to the rectus fascia at fixation points 28, 30 on opposite sides of the midline (i.e., the sagittal plane). The lengths of the suspension arms 24, 26 are adjusted, for example by the surgeon during the implant operation, so as to elevate the perineal body 18 towards the pubic bone 20 into its normal, healthy position. So installed, the PVM implant 22 maintains closure of the urogenital hiatus 12 in the face of increases in intra-abdominal pressure loading and superincumbent inertial loading.

[0043] Next, biomechanical functions of the PVM implant 22 are discussed. The two fixation points 28, 30 at the top of the pubic bone 20 at or near the rectus fascia serve as the main support points for the PVM implant. The left and right side suspension arms 24, 26 are preferably strong enough to carry the largest tensile force that would ever be carried by a PVM 16 in any activity of daily living without undue stretch that would allow the urogenital hiatus to open. The suspension arms 24, 26 preferably have similar tensile and flexural stiffness properties as the normal PVM 16. Once adjusted by the surgeon, the function of the PVM implant 22 is to act as a hammock and with pair of checkreins that prevent the perineal body 18 from displacing downwardly relative to the pubic bone 20 under ubiquitous superincumbent loads, thereby preventing the opening of the urogenital hiatus 12 under the downward mechanical action of intraabdominal pressure or superincumbent inertial loads associated with activities of daily living. Preferably, the hammock 26 is designed to spread the upward support load on the perineal body 18 over a large enough area that the hammock does not cut through the perineal body 18 (for example, like a wire through cheese) when the perineal body is loaded by superincumbent pressures and forces.

[0044] FIG. 7 illustrates another exemplary PVM implant 40, which generally embodies many of the characteristics of the PVM implant 22. The PVM implant includes a left suspension arm 42 and a right suspension arm 44. Each suspension arm has an upper end 46, which is configured to be affixed to a fixation point at or near the pubic bone as described previously, and a lower end 48. The upper end 46 may include a bio-compatible fastener 50 for attachment to the pubic bone or rectus fascia as described hereinafter. In some arrangements, the upper end 46 may have a hooked shape that hooks over an upper edge of the pubic bone 20 and may or may not hook into the bone, as illustrated schematically in FIGS. 5 and 6. The suspension arms 42, 44 have a length sufficient to extend from the

fixation points 28, 30 near the pubic bone 20 to the distal or lower side of the perineal body 18, as illustrated schematically in FIGS. 5 and 6. The suspension arms 24, 26 are preferably flexible and have a resilient tensile strength similar to that of a typical healthy PVM, as described herein. Exemplary size and strength parameters are discussed elsewhere herein.

[0045] A support hammock 52 extends between and connects the lower ends 48 of the left and right suspension arms 42, 44. The lower ends 48 of the suspension arms 42, 44 may be integrally formed with the support hammock 52, or the lower ends 48 of the suspension arms 42, 44 may be separately formed and subsequently connected to opposite left and right ends of the support hammock 52, for example with separate fasteners and/or tying the lower ends 48 to the support hammock 52. The support hammock 52 preferably has the form of a flexible, thin, sheet. Preferably, the support hammock 52 is shaped and sized to provide a suitable surface area for supporting the perineal body 18 without forming excessive pressure points or lines against the perineal body. For example, the support hammock 52 may have the shape of a wide ribbon or band of flexible material with opposite left and right ends that extend from the left side to the right side of the perineal body 18 and a height or width that extends at least partly from the bottom to the top of the perineal body. The support hammock 52 may be made of any suitable material for implanting in the body that provides the tensile strength, and preferably flexibility, to pull the perineal body 18 toward the pubic bone and support the perineal body so as to prevent the urogenital hiatus 12 from gaping, as described herein.

[0046] FIG. 8 shows yet another exemplary arrangement of the PVM implant 40 of FIG. 7 illustrating that either or both of the suspension arms 42, 44 may be formed of a single strand tensile load-bearing element or of multiple strands of tensile load-bearing elements. In this exemplary arrangement, the left suspension arm 42 is formed of multiple separable strands, such as sutures, wires, bands, or cables, and the right suspension arm 44 is formed of a single strand. The left suspension arm 42 is shown to be formed of two separate strands 54, 56. However, either or both of the suspension arms 42, 44 may be formed of more than two strands. Further, both the left and the right suspension arms 42, 44 may be formed of multiple strands, or both of the left and right suspension arms may be formed of a single strand as exemplified in FIG. 7. The support hammock 52 and tissue fixation devices 50 may be as described elsewhere herein.

[0047] FIG. 9 shows another PVM implant 60 that does not include the support hammock 52, but which otherwise embodies many of the characteristics of the PVM implants 22 and 40. In this arrangement, the PVM implant 60 includes the left and right suspension arms 42

and 44, in which each suspension arm includes at least one tissue fixation device 50 at each of the lower end 48 of the suspension arm 42, 44. In this arrangement, the lower ends 48 of the suspension arms 42 and 44 are formed by multiple different strands 62, with a tissue fixation device 50 affixed to the lower end of one or more, and preferably each of the different strands 62. Three different strands 62 are exemplified, however, more or fewer than three strands 62 could be provided. Similarly, either or both of the upper ends 46 of the suspension arms 42, 44 could also be formed of more than one strand 62, similar to the lower ends 48. Further, either or both of the suspension arms 42, 44 could be formed of a single strand 62 at either or both of the upper and lower ends. In any event, each suspension arm 42, 44 includes at least one section that has only a single strand or the strands are bundled together, such as by wrapping, weaving, in a casing, and/or with an adhesive, to form a single elongate body. For example, in FIG. 9, the portion of the suspension arm extending from the upper end 46 to where the three strands 62 separate forms a single elongate suspension member, whereas the strands 62 extending on to the lower ends 48 form separate elongate suspension members.

[0048] The tissue fixation devices 50 may take any form suitable for affixing the suspension arms to the fixation points. Preferably, the upper ends 46 of the suspension arms are configured to be wrapped over the pubic bone 20 and fastened to the rectus fascia or other nearby structure as described herein. Tissue fixation devices 50 may optionally be attached to the upper ends 46 for connecting the upper ends 46 to the rectus fascia, pubic bone, or other tissue. The lower ends 48 of the suspension arms also have tissue fixation devices 50 for affixing the lower ends directly to the perineal body 18. In this arrangement, a tissue fixation device 50 is disposed at the distal end of each of the strands 62 so that each strand can be individually affixed to the perineal body 18. The tissue fixation devices 50 may be any suitable device for coupling the ends to the respective tissues of the rectus fascia or the perineal body. For example, the tissue fixation devices 50 may be suture pads 50a or hooks, such as single-prong hooks 50b or multiple prong hooks 50c. However, other types could also be used for the tissue fixation devices 50. In this arrangement, suture pads 50a are disposed at the upper ends 46 of the suspension arms 42, 44, but any suitable type of tissue fixation device 50 could be used. Similarly, an exemplary one of a suture pad 50a, a single-prong hook 50b, and a multiple-prong hook 50c is disposed at the distal ends of each of the strands, but any arrangement and combination of different or the same types of tissue fixation devices 50 could be used.

[0049] Generally, it is believed to be preferable to elevate the perineal body 18 rather than some other point or structure in the pelvic region, such as the mid urethra 38. In addition to counteracting the pressure differential in preventing prolapse, as discussed previously, the perineal body 18 is also the confluence, i.e., nexus or central connecting location, of a number of important lower pelvic floor structures, including the distal ends of the PVM, the distal vagina 36, and the anal sphincter. In effect, the perineal body 18 is a tensile element that mechanically binds together these structures using a tough, stiff, and inelastic collagenous tissue in the non-pregnant state. If the perineal body 18 were to be removed, these structures would simply separate under the influence of the downward superincumbent pressure loads causing the female organs to prolapse through the resulting opening because the arms of the PVM would have nothing to grasp in order to prevent the prolapse of the distal urethra 38, vagina 36, and anal sphincter.

[0050] Furthermore, the exact size and shape of the PVM implant 22, 40, and/or 60 may be customized to meet any of many different in-situ design criteria. Based on testing and theory, however, the inventors have found that the following strength factors and characteristics of the PVM implant appear to be generally important. First, MRI measurements lead the inventors to believe that, in young women who have not given birth vaginally, the PVM cross-sectional area ranges from 0.79 to 1.8 cm², with a mean 1.22 and standard deviation of 0.25 cm². Second, biomechanical analysis suggests that the maximum unilateral force the PVM implant 22, 40, and/or 60 must carry is 29, 46, and 60 N of force in the 5th, 50th and 95th percentile woman under static conditions, and 48, 78 and 98 N of force under dynamic conditions. Third, muscle physiological arguments lead one to an alternative method for estimating the maximum unilateral PVM force: this is derived from multiplying the MRI cross-sectional area measurements by the maximum specific tension of striated muscle, which is known by muscle physiologists to be 28 N/cm² in a maximum contraction. Furthermore, these resulting forces proved to be consistent with the biomechanical predictions of PVM forces using a free body diagram to estimate the forces acting on the pelvic floor. The MRI measurements therefore validate the biomechanical predictions. Fourth, measurements from an instrumented speculum in women asked to contact their pelvic floor muscles eight months post-partum resulted in forces that are only 20% of those that potentially can be developed according to the biomechanical and physiological calculations. From these findings, the inventors conclude that if one designs the ultimate tensile strength of the implant to have a safety factor of 2.0, each arm of the PVM implant 22, 40, 60 preferably should to be able to withstand repeated tensile loading of two times 98 N, or 196 N for the

large woman. Under this load, one would preferably not want the suspension arms 24, 26, 42, 44 to extend, i.e., stretch and/or elongate axially, by more than a few mm, for example, about 5 mm, which would yield a linear tensile stiffness on the order of approximately 40 N/mm for the two suspension arms 24/26 or 42/44 combined, or approximately 20 N/mm for each arm. (By way of contrast and comparison, at a load of 150 N, the calf muscles have been measured to have an active linear tensile stiffness of about 50 N/mm, and a passive muscle stiffness of about 6 N/mm, and the Achilles tendon has a passive stiffness of about 27 N/mm.) The PVM implant 22, 40, 60 preferably has a flexural stiffness generally equivalent (e.g., at least the same order of magnitude or closer) to the biomaterials being repaired or replaced, such as human tensor fascia lata or lumbodorsal fascia, which are strong type-1 collagen structures with a highly organized fibrillar structure, approximately 0.5 to 1 mm thick that flex relatively easily and are relatively stiff in tension (because of their highly organized collagen architectures) with an elastic tensile modulus in the range of 20-100 MPa. The PVM implants 22, 40, 60 however are not limited to these design criteria, and other design criteria and factors may be considered.

[0051] The arrangements in the drawings are meant to be exemplary only, and it is understood that all different arrangements of the components and features described therewith that would be technically suitable for are to be part of this disclosure. For example, the PVM implant 22, 40, 60 can be made of many different materials. Typical candidate PVM implant materials are preferably bio-compatible materials suitable for implantation in the body. In one arrangement, the suspension arms 24, 26, 42, 44 and/or the support hammock 26, 52 are formed of synthetic mesh, such as polypropylene, autograft, allograft, xenograft (such as ACell matrix), active biocompatible tissue-engineered elements, and/or passive biocompatible tissue-engineered elements. Each suspension arm 24, 26, 42, 44 could be formed of a single strand (e.g., a suture), or two or more strands (e.g., sutures), as discussed previously. Forming the suspension arms 24, 26, 42, 44 of multiple strands (e.g., sutures) provides redundancy to help prevent ultimate failure in case any one of the strands fails. The attachment point between the suspension arm 24, 26, 42, 44 and the support hammock 26, 53 is preferably a failsafe surgical knot or attachment with the part of the hammock involved in the knot able to withstand the stresses and strains without tearing. Alternatively, the two suspension arms 24, 26, 42, 44 and the support hammock 26, 52 could be fashioned as a single unit, with the properties of the suspension arms and the support hammock being engineered for different properties. Preferably, the suspension arms 24, 26, 42, 44 can withstand high tensile loads, and the support hammock 26, 52 is able to deploy

and gather as much of the perineal body 18 as possible and load the perineal body as evenly as possible across its upper contact area with the tissue. This could be achieved by encouraging rapid connective tissue ingrowth while the support hammock 26, 52 is in an open unfurled configuration that would permanently prevent it from furling or rolling up into an (undesirable) cylinder in the frontal or transverse planes, for example by providing reinforcing elements to prevent bending and/or attachment and fixation strategies that would cause the support hammock 26, 52 to remain generally flat.

[0052] Fixation or attachment of the upper ends 46 of the suspension arms 24, 26, 42, 44 may be actualized in any medically sufficient manner. Friction between the suspension arms 24, 26, 42, 44 through the tissues and where the upper ends 46 of the suspension arms wrap over the pubic bone should suffice to fix the suspension arms. However, the upper ends of the suspension arms could also be sutured to the rectus fascia if desired.

[0053] Fixation or attachment of the lower ends 48 of the suspension arms 24, 26, 42, 44 may be actualized in any medically sufficient manner. When the support hammock 26, 52 is not used, the lower ends 48 of the suspension arms may be attached directly to the perineal body 18 with tissue fixation devices 50, such as grappling hooks or pads made, for example, of polydioxanone or other biocompatible synthetic or partially absorbable materials. However, other bio-compatible fasteners may be used.

[0054] Next, possible methods of surgically implanting the PVM implant to correct a ruptured levator ani, and in particular, a ruptured or weakened PVM (also called “perineal body fixation”) are described. In this description, the perineal body fixation will be approached from the perineum in the context of vaginal or abdominal operations for prolapse. However, other contexts are also possible. With reference again to FIG. 5, the suspension arms 24, 26, 42, 44 can be tunneled from below the pelvic floor using trocars or other needle-like devices to pass them behind the pubic bone 20 along the original path of the PVM 16 to reach the desired upper fixation points 28, 30. The method of upper fixation will determine the exact technique to be used in this part of the procedure. However, as described previously, any suitable method of fixing the upper ends 46 of the suspension arms is acceptable. Once the PVM implant 22, 40, 60 is in place with the lower portion fixed in or to the perineal body 18, the length of the suspension arms 24, 26, 42, 44 may be adjusted to bring the perineal body 18 into contact with the anterior vaginal wall, thereby closing the urogenital hiatus 12. To ensure proper adjustment, a spacer may be placed in the vagina during the adjustment step to determine the minimum diameter between the underside of the pubic bone and the front of the perineal portion of the PVM implant 22, 40, 60. The target

location of the perineal body 18 relative to the pubic symphysis and pubic bone 20 may be as described previously herein or otherwise known.

[0055] The PVM implant 22, 40, 60 would be appropriate in women (and possibly men) where elevation of the perineal body 18 is needed to return it to its normal, healthy location relative to the pubic bone. For example, women who have failed normally successful operations for prolapse where the downward displacement of the perineal body is considered to be the reason for operative failure and who were not planning to be sexually active may be suitable candidates for receiving the PVM implant. Other medical, quality of life, and safety factors may also be considered in identifying appropriate candidates for having the PVM implant implanted as described herein.

[0056] This detailed description is to be construed as exemplary only and does not describe every possible embodiment or combination, as describing every possible embodiment and combination would be impractical, if not impossible. One could implement numerous alternate embodiments and combinations, using either current technology or technology developed after the filing date of this application. Thus, while specific exemplary forms are illustrated and described herein, it is to be understood that any of the various aspects, arrangements, and/or features disclosed herein may be combined with any one or more of the other aspects, arrangements, and/or features disclosed herein in a manner that would be understood by a person of ordinary skill in view of the teachings of this disclosure.

Claims

We claim:

1. A method of closing a urogenital hiatus in which a pubovisceral muscle (PVM), which extends from a perineal body to a pubic bone so as to suspend the perineal body from the pubic bone with a PVM implant, is damaged, the method comprising:

affixing a support hammock to the perineal body to extend from the left side of the perineal body to the right side of the perineal body;

passing upper ends of a left suspension arm and a right suspension arm on respective opposite left and right sides of the vagina and urethra from the perineal body to the pubic bone along the path of the healthy PVM;

wrapping the upper ends of the left and right suspension arms over the top of the pubic bone;

fastening the upper ends of the left and right suspension arms to the rectus fascia or other structure near the origin points of the PVM at the pubic bone;

connecting left and right sides of the hammock to lower ends of the respective left and right suspension arms; and

adjusting the lengths of the left and right suspension arms so as to elevate the perineal body back up to its normal, healthy position relative to the pubic bone.

2. A method of closing a urogenital hiatus, in which a pubovisceral muscle (PVM), which extends from a perineal body to a pubic bone so as to suspend the perineal body from the pubic bone, is damaged, the method, the method comprising:

passing upper ends of a left suspension arm and a right suspension arm on respective opposite left and right sides of the vagina and urethra from the perineal body to the pubic bone along the path of the healthy PVM;

affixing the upper ends of the left and right suspension arms to the rectus fascia or other structure near the origin points of the PVM at the pubic bone;

affixing lower ends of the left and right suspension arms to respective left and right sides of the perineal body; and

adjusting the lengths of the left and right suspension arms so as to elevate the perineal body back up to its normal, healthy position relative to the pubic bone.

3. A PVM implant for closing a urogenital hiatus in which a pubovisceral muscle (PVM), which extends from a perineal body to a pubic bone so as to suspend the perineal body from the pubic bone, is damaged, the PVM implant comprising:

a left suspension arm having a length to extend at least from an origin point of the PVM at the pubic bone to the perineal body, wherein the left suspension arm extends from an upper end to a lower end;

a right suspension arm having a length to extend at least from an origin point of the PVM at the pubic bone to the perineal body, wherein the right suspension arm extends from an upper end to a lower end;

means for affixing the upper ends of the left and right suspension arms to the pubic bone or other tissue near the origin points of the PVM; and

means for coupling the lower ends with the perineal body to support the perineal body and close the urogenital hiatus.

4. The PVM implant of any one of the previous claims, wherein a tissue fixation device is disposed at the upper end of each of the left and right suspension arms.

5. The PVM implant of any one of the previous claims, wherein at least one of the left and right suspension arms comprises multiple, separable strands of tensile load-bearing elements.

6. The PVM implant of any one of the previous claims, wherein at least one of the left and right suspension arms is formed of only a single strand that has an elongate shape extending from the upper end to the lower end and is flexible in bending but stiff in tension and forms a muscle-equivalent tensile load-bearing element.

7. The PVM implant of any one of the previous claims, wherein at least one of the left and right suspension arms is a suture, wire, band, or cable.

8. The PVM implant of any one of the previous claims, further comprising a support hammock extending between the lower ends of the left and right suspension arms.

9. The PVM implant of any one of the previous claims, further comprising tissue fixation devices disposed at the lower ends of each of the left and right suspension arms.

10. The PVM implant of any one of the previous claims, wherein at least one of the left and right suspension arms is flexible and has a resilient tensile strength and stiffness similar to that of a typical actively contracting healthy PVM.

11. The PVM implant of any one of the previous claims, wherein each of the upper ends of the left and right suspension arms has a hooked shape configured to wrap over an upper edge of the pubic bone.

12. The PVM implant of any one of the previous claims, wherein at least one of the left and right suspension arms and the support hammock is formed of synthetic mesh,

active biocompatible tissue-engineered elements, and/or passive biocompatible tissue-engineered elements.

13. The PVM implant of any one of the previous claims, wherein at least one of the left and right suspension arms and the support hammock is formed of synthetic mesh comprising polypropylene, autograft, allograft, and/or xenograft.

14. The PVM implant of any one of the previous claims, wherein the support hammock has the form of a flexible, thin, sheet.

15. The PVM implant of any one of the previous claims, wherein the support hammock has the form of a wide band of flexible material with opposite left and right ends that are configured to extend from a left side to a right side of a perineal body and a width that is configured to extend at least partly from a bottom to a top of the perineal body

16. The PVM implant of any one of the previous claims, wherein the support hammock is configured to provide a suitable surface area for supporting the perineal body without forming excessive pressure points or lines of indentation against the perineal body.

17. A method of closing a urogenital hiatus in which a pubovisceral muscle (PVM), which extends from a perineal body to a pubic bone so as to suspend the perineal body from the pubic bone, is damaged with a PVM implant according to any one of the previous claims, the method comprising:

implanting the PVM implant to extend along the normal direction of a healthy PVM from an origin point of the PVM at the pubic bone to the perineal body;

affixing an upper end of the implant to the pubic bone or adjacent tissues near the origin point; and

coupling a lower end of the implant to support the perineal body so as to close the urogenital hiatus.

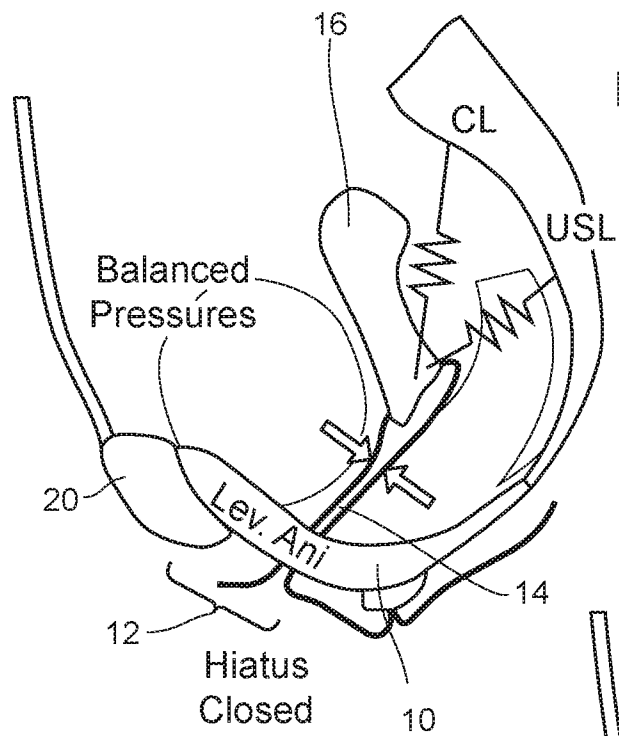


FIG. 1A

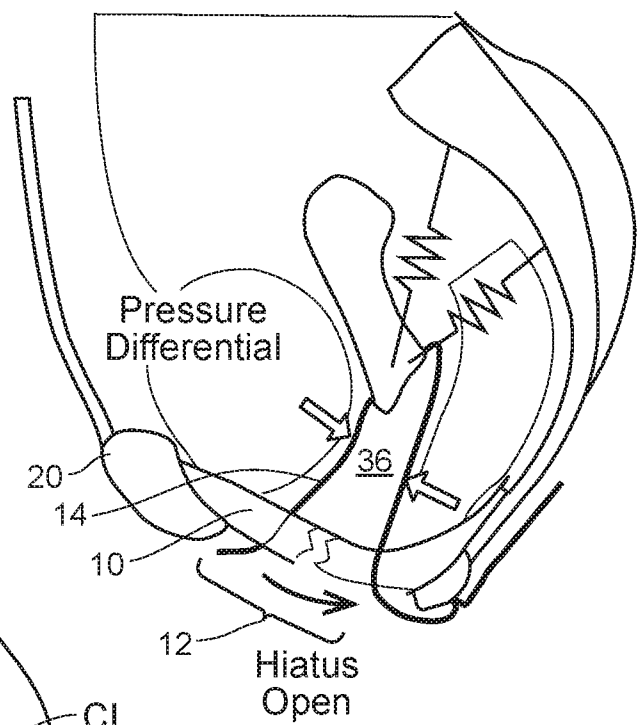


FIG. 1B

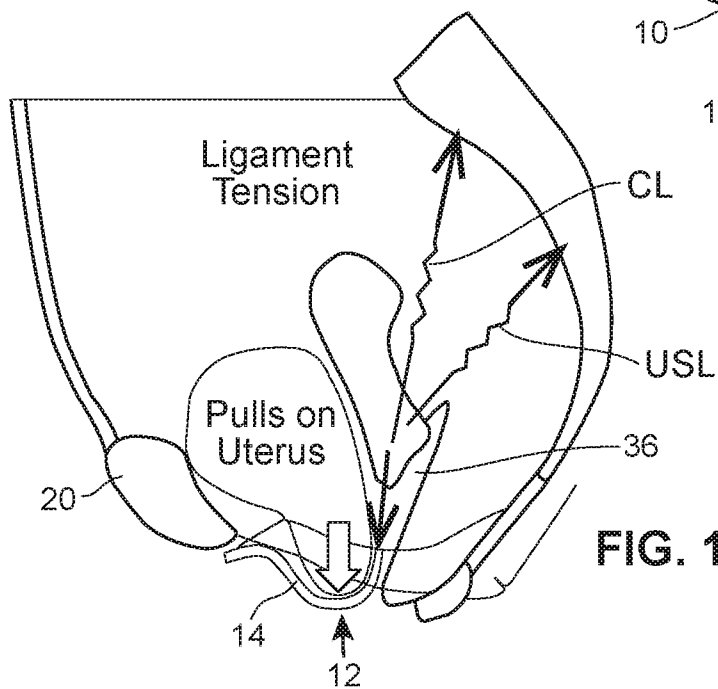


FIG. 1C

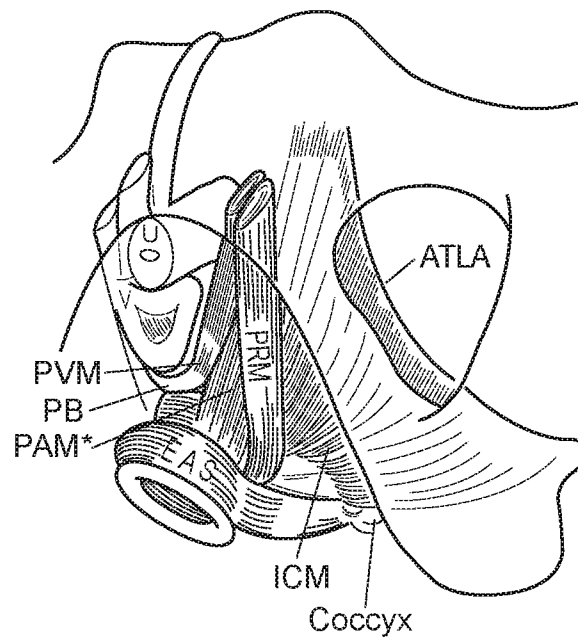


FIG. 2A

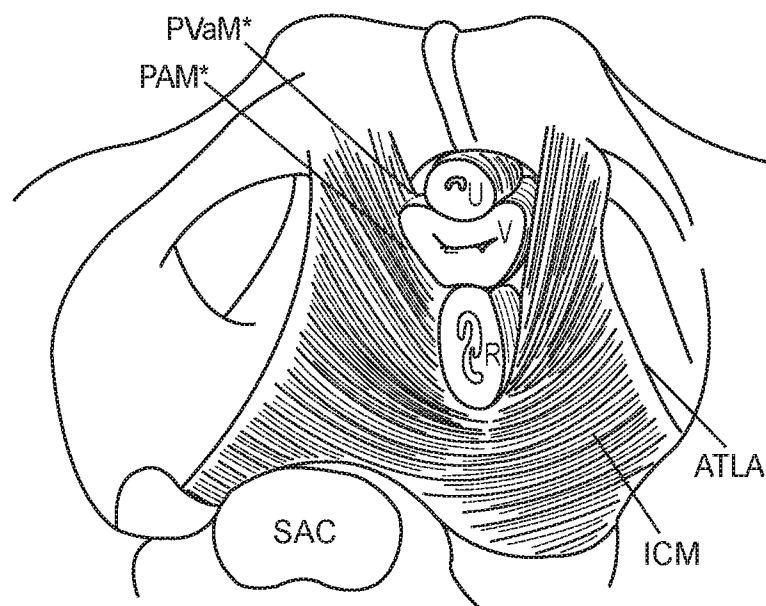


FIG. 2B

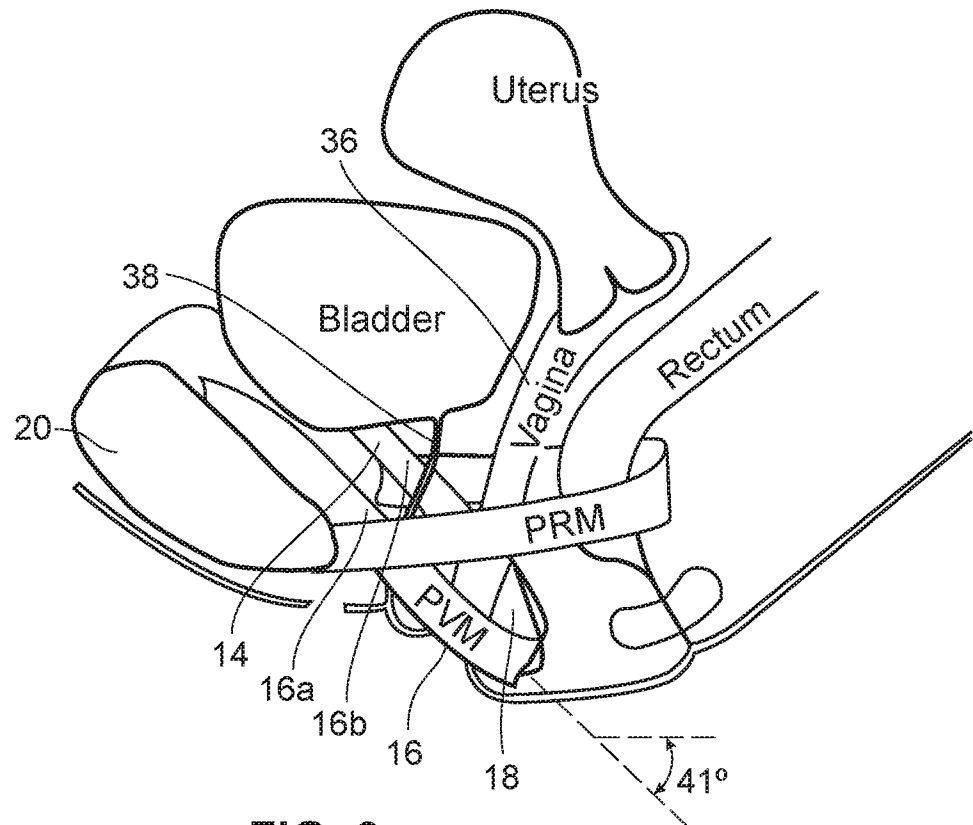


FIG. 3

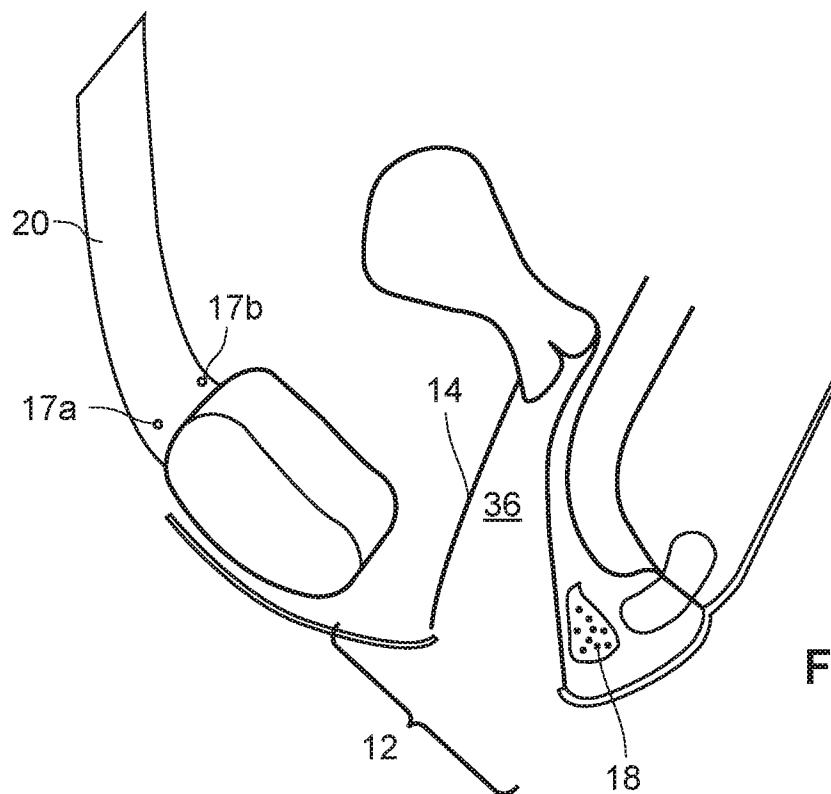
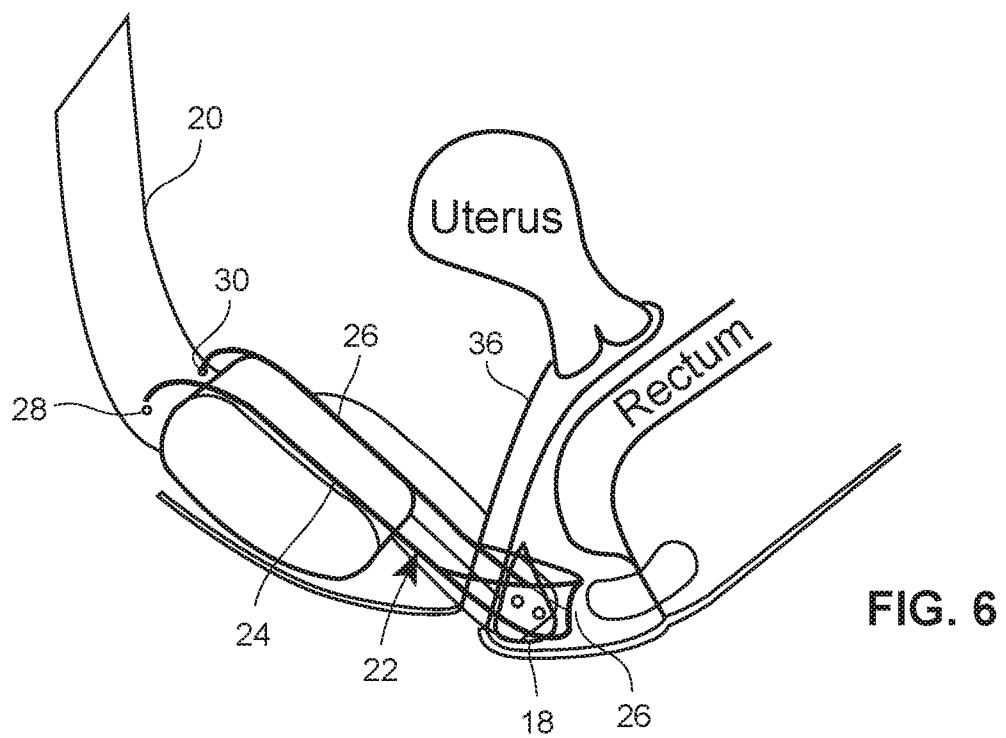
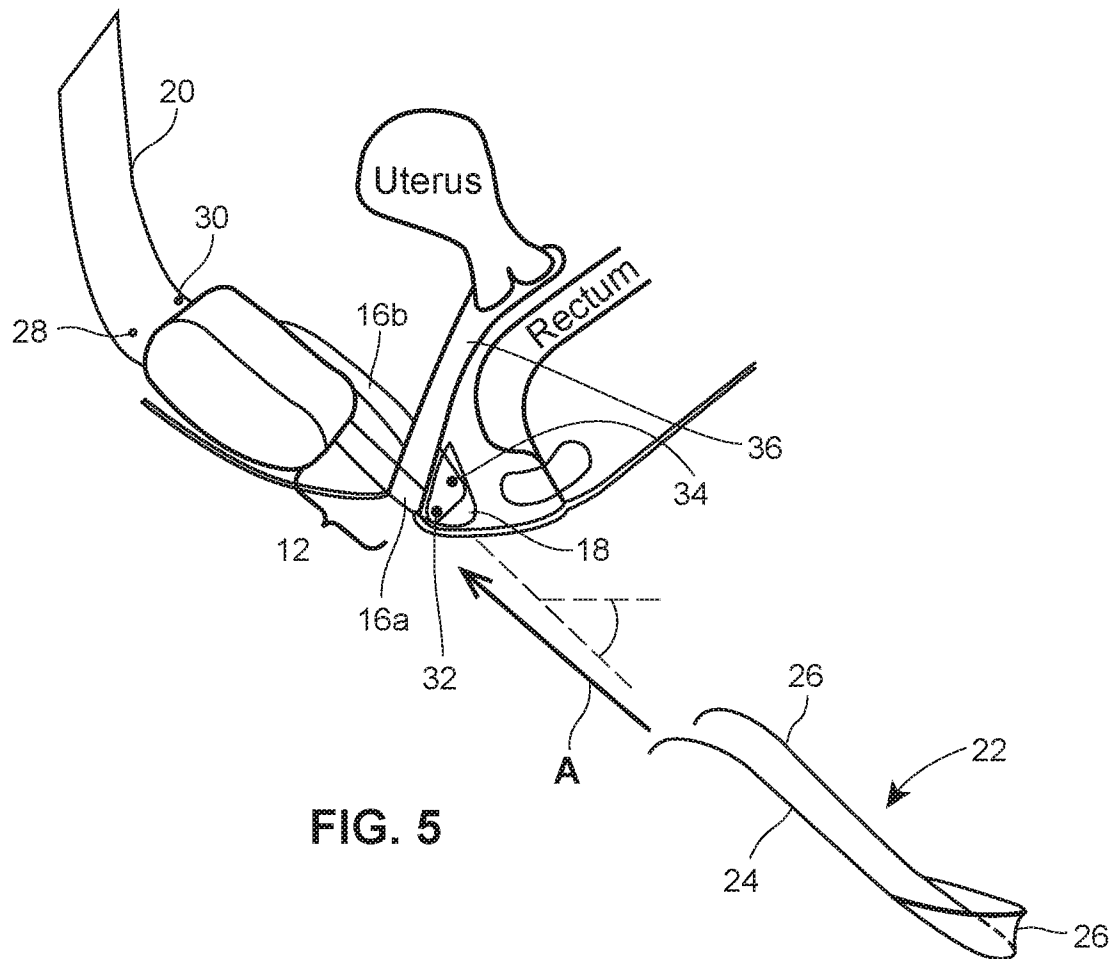


FIG. 4



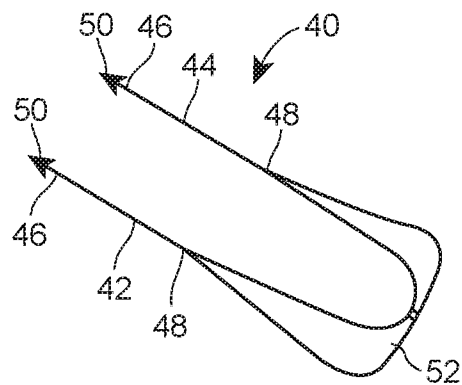


FIG. 7

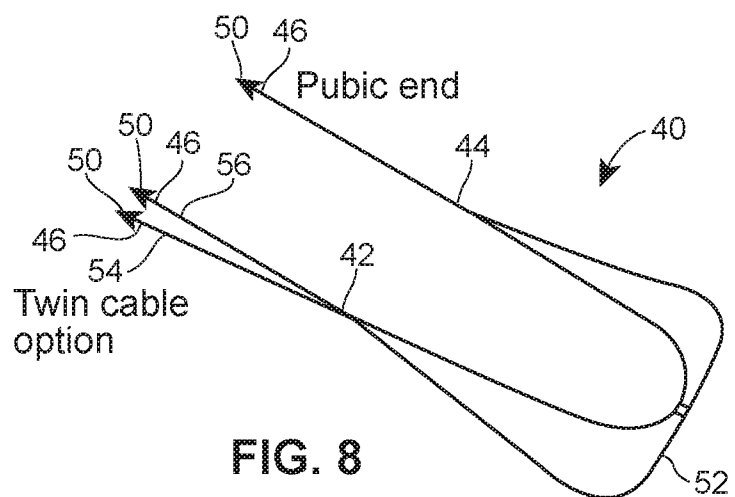


FIG. 8

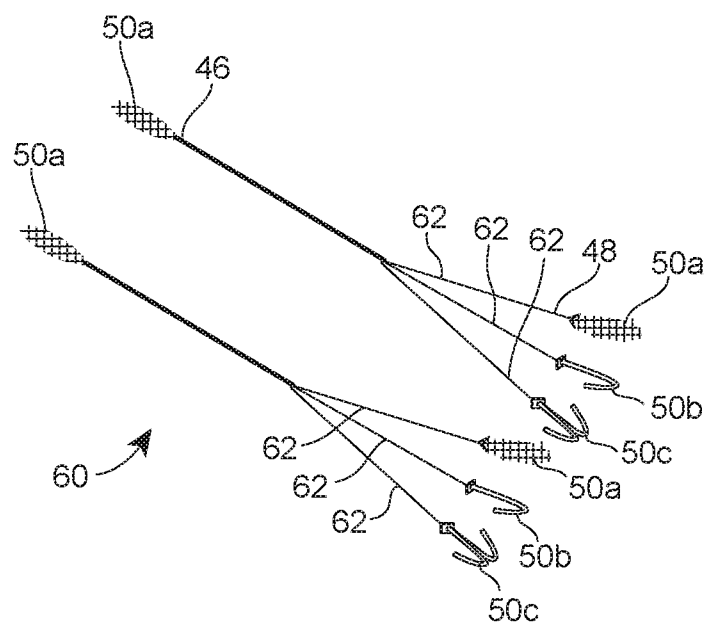


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/54240

Box No. 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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
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.: 6-17
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. 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 additional fees, this Authority did not invite payment of additional fees.
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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/54240

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/00 (2017.01)

CPC - A61F 2/0063, A61F 2/0004, A61F 2/0031, A61F 2/0045, A61F 2/005

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)

See Search History Document

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

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- A	US 6,042,534 A (GELLMAN et al.) 28 March 2000 (28.03.2000) Entire document, especially Abstract, col 9, ln 42-56, col 14, ln 10-13, col 14, ln 54- col 15, ln 12, col 16, ln 20-42 and FIGS. 10-11.	3-5 ---- 1
X -- A	US 2011/082328 A1 (GOZZI et al.) 07 April 2011 (07.04.2011) Entire document, especially Abstract, para[0018], para[0048], para[0064]-[0066] and FIGS. 4-5. yes perineal body.. sort of along proper muscle	2 -- 1
A	US 2011/0015477 A1 (MONTPETIT et al.) 20 January 2011 (20.01.2011) Entire document.	1-5
A	US 7,79,4385 B2 (ROSENBLATT) 14 September 2010 (14.09.2010) Entire document.	1-5
A	US 6,221,005 B1 (BRUCKNER et al.) 24 April 2001 (24.04.2001) Entire document.	1-5
a	US 8,371,998 B2 (HAVENFIELD) 12 February 2013 (12.02.2013) Entire document.	1-5

☐ Further documents are listed in the continuation of Box C.☐ 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 application or patent 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

16 November 2017

Date of mailing of the international search report

12 JAN 2018

Name and mailing address of the ISA/US

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