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Suspension of female urethrovessical junction and anchoring means therefor.

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Description

The invention relates to apparatus for positioning anchoring means in living tissue suitable for suspending the female urethrovaginal junction.

Stress incontinence is caused by increased abdominal pressure. One surgical method for treating this condition involves suspension of the bladder neck for repositioning in the correct fixed retro pubic position such that there is no voiding of the bladder under stress and at the same time bladder outlet obstruction is avoided. Four relatively non-invasive surgical procedures for bladder neck suspension are described in Hadley et al., Urologic Clinics of North America, Vol. 12, No. 2, p. 291 (1985). In the original Pereyra method, a needle is passed from a suprapubic incision to an incision in the vagina near the bladder neck. Stainless steel suture wire is passed several times from the bladder neck to the suprapubic incision to suspend the bladder neck. The Cobb-Rudge method inserts the needle from below through the vaginal incision. The Stamey procedure uses an endoscope to prevent the surgical needle from puncturing the bladder. Dacron vascular graft is used to anchor nylon suture in the periurethral tissue. Finally, in the Raz method the surgeon inserts his finger through the vaginal incision to guide the suspension needle and avoid penetration of the bladder by the needle. The sutures are anchored by threading through tissue of the vaginal wall and tissue in the suprapubic area.

A major problem encountered during surgical needle suspension procedures such as described above is the correct positioning of the bladder neck and the urethra such that the position of the bladder neck with respect to the bladder is high enough to avoid incontinence under stress while not too high to prevent proper bladder voiding.

The invention is an improvement over the prior art by providing for easy adjustment of the suspending sutures to lower or raise the bladder neck during surgery, and for readjustment to lower or raise the bladder neck, if necessary, after the patient has benefited from the suspension procedure. The invention allows for more secure anchoring of the sutures without extensive tissue dissection required to place the tissue anchors in proper position.

A system for positioning of anchoring means used during surgical procedures is described in U.S. Patent 4,705,040 disclosing a hollow needle containing a retaining device attached to a filament. The retaining device after dislodging from the needle attaches to the interior wall of a body organ, and the filament is pulled to draw the device against the body wall. The filament is clamped outside the body to keep the organ in position.

U.S. Patent No. 4,166,469 describes placement of a pacemaker within a patient through a sleeve which is positioned in the body through a needle or over a guide wire which enters the patient within a needle and remains after the needle is removed.

The above prior art devices are helpful in introducing objects into the body, but do not have the versatility of the apparatus described below.

The invention is directed to an apparatus for positioning an anchoring means in living tissue, which comprises an insertion means primarily defined along a longitudinal axis to fit in a surgical needle, and an anchoring means having a substantially axial channel reversibly surrounding said insertion means in substantially axial alignment with said longitudinal axis of said insertion means. Said anchoring means is adapted to be flipped from said axial alignment to an angled position. Conveniently, said insertion means is a surgical guide wire threaded through said substantially axial channel of said anchoring means.

Anchoring means which may be employed for anchoring the suture in the tissue are described in more detail below by way of illustration.

Brief Description of the Drawings

Fig. 1 is a sectional view of a flip anchor with a placement means.

Fig. 2 is a sectional view of an adjustable tissue anchor placed in body tissue.

Fig. 3 is a perspective view of the externally adjustable tissue anchor of Fig. 2.

Fig. 4 is a perspective view of externally adjustable tissue anchor.

Fig. 5 is a sectional view of the tissue anchor of Fig. 4.

Fig. 1 shows flip anchor 28 and placement means 30. The flip anchor 28 has an axial channel 32 which snugly fits around the placement means 30. The anchor 28 includes a radial channel 34 allowing for passage of a suture 36. The flip anchor 28 conveniently is in the shape of a flat rectangle. The placement means 30 is a surgical guide wire which may be placed in position by a needle, or a needle extension. On pulling at both ends of the suture 36, the anchor 28 flips and becomes positioned substantially at right angles to the means 30. In an alternative embodiment, the flip anchor may have a means for attachment to a tool which is capable of flipping the anchor. Once the anchor 28 is in the flipped position, the suture 36 may be pulled from the suprapubic end.

Fig. 2 shows an adjustable tissue anchor 38 placed between the rectus muscle 40 and subcutaneous tissue 42. Suture 44 extends between the tissue anchor 38 and anchoring means 46 placed between periurethral fascia 48 and vaginal wall 50.
The anchoring means 46 may be properly positioned by introduction through a small incision of the vaginal wall. Alternatively, the anchoring means 46 may be introduced through a puncture of the vaginal wall by a needle. Thus, the flip anchor 26 of fig. 1 may be positioned on a needle, as described above. Alternatively, a padlike tissue anchor may be inserted in a needle and pushed through the needle, for instance with an obturator. The needle is subsequently withdrawn. The needle may have an extension known to have a certain length equal to the length between the desired position of the pad and the vaginal wall. This extension helps the surgeon in determining the distance which the needle has traveled through the vaginal wall, and the distance at which the anchoring means may be dropped.

Another method for positioning the anchoring means below the urethra between the vaginal wall and the periurethral fascia makes use of a solid needle having a sleeve. The needle punctures the vaginal wall when the proper position is attained, the needle is withdrawn leaving the sleeve behind in the tissue of the body. An anchoring means may then be inserted through the sleeve, and the sleeve withdrawn.

Fig. 3 shows the adjustable tissue anchor 38 of Fig. 2 in a perspective view. The tissue anchor 38 comprises substantially cylindrical anchor body 52 having snapping lip 54 to snap on cover lid 56. Anchor bottom 58 connects anchor body 52 with inner cylinder 60. Suture 62 is wrapped around inner cylinder 60, guided through channel 66 under suture-clamping screw 64 and through outer hole 68 which in Fig. 3 extends from the top 70 of the inner cylinder 66 through the anchor bottom 58. Suture 62 is clamped to the inner side of anchor bottom 58 by screw 64 when the anchor 38 is placed in the body. On removal of cover lid 56, screw 64 may be adjusted with a screwdriver. Thus, by screwing the screw 64 upwards, suture 62 is free for wrapping around inner cylinder 66 to shorten the length of the suture in the body, or the suture 62 is free for unwrapping from inner cylinder 66 to lengthen the suture in the body.

Figs. 4 and 5 show an externally adjustable tissue anchor 72. The tissue anchor 72 comprises substantially cylindrical anchor body 74, snappings lip 76 to snap on cover lid 78 having access hole 79, bottom 80, tissue anchor wall 82 and rotating spool 94 on which suture 106 is wound. The spool 84 may be rotated with the aid of driving gear 84. Driving gear 84 is situated in opening 86 of the bottom 80. The driving gear 84 comprises funnel 88 leading to hex driving hole 90, and driving gear teeth 92. Rotating spool 94 has inside gear teeth 92 of driving gear 84. The rotating spool 94 is locked in place between bottom edges 98 and 100 of the rotating spool bottom 80. Wave spring 102 is located under the driving gear 94. When the driving gear 84 is pushed downwards, e.g. by hand, the wave spring 102 allows the driving gear 94 to move down so disengaging ratchetting pawl 104. When the paw 104 is disengaged, the rotating spool 94 can be rotated to release suture 106 from the spool 94. Rotation of the rotating spool 94 is with an external tool such as an Allen wrench, capable of puncturing through the skin into access hole 79 in cover lid 78 engaging the hex driving hole 90. On release of the driving gear 84, the wave spring 102 returns the driving gear 84 to its original position in engagement with ratchetting pawl 104 allowing for rotation of the rotating spool 94 for uptake of suture 106 on the spool 94. The ratchetting pawl 104 is attached to rotating spool bottom 80 through pawl spring 106 and spring post 108 and pivots on pawl pin 110 which is attached to pawl post 112. The pawl post 112 in turn is attached to bottom 80 or is part of bottom 80.

The suture 106 is spooled on rotating spool 94, channeled through hole 114 in bottom 80, and led through ridges or holes in extensions 116 and 118 at the bottom 80 to the center of the anchor 72.

Claims

1. Apparatus for positioning an anchoring means (28) in living tissue, comprising placement means (30) primarily defined along a longitudinal axis and adapted to be placed in position by a surgical needle, characterized by said anchoring means being a flip anchor (28) having an axial channel (32) which snugly fits around said placement means in substantially axial alignment with the longitudinal axis of the placement means, the flip anchor being adapted to rotate from the axial alignment to a position in which the channel is angled from said longitudinal axis.

2. Apparatus according to claim 1, in which the placement means (30) is a surgical guide wire threaded through the axial channel (32) of the flip anchor (28).

Patentansprüche

1. Vorrichtung zum Positionieren einer Verankerungseinführung (28) in Lebendgewebe, umfassend eine Plaziereeinrichtung (30), die primär entlang einer Längssachse begrenzt und so angepaßt ist, daß sie sich mit einer chirurgischen Nadel in einer vorgesehenen Lage plazieren läßt, dadurch gekennzeichnet, daß die besagte Verankerungseinführung ein Klappanker (28) mit einem axialen Kanal (32) ist, welcher in ir
wesentlichen axialer Ausrichtung mit der Längsachse der Plaziereinrichtung eng anliegend um die besagte Plaziereinrichtung paßt, wobei der Klappanker so angepaßt ist, daß er sich aus der axialen Ausrichtung in eine Lage drehen läßt, in welcher der Kanal gegenüber der besagten Längsachse angewinkelt ist.

2. Vorrichtung nach Anspruch 1, bei welcher die Plaziereinrichtung (30) ein chirurgischer Führungsdraht ist, der durch den axialen Kanal (32) des Klappankers (28) gefädelt ist.

Revendictions

1. Appareil pour positionner un organe d’ancrage (28) dans du tissu vivant, comprenant un moyen (30) de mise en place (30) essentiellement délimité le long d’un axe longitudinal et conçu pour être mis en place par une aiguille chirurgicale, caractérisé en ce que ledit organe d’ancrage est un élément d’ancrage orientable (28) ayant un canal axial (32) qui s’ajuste à frottement doux autour dudit moyen de mise en place, sensiblement à l’alignement axial de l’axe longitudinal du moyen de mise en place, l’élément d’ancrage orientable étant conçu pour tourner de l’alignement axial à une position à laquelle le canal fait un angle avec ledit axe longitudinal.

2. Appareil selon la revendication 1, dans lequel le moyen de mise en place (30) est un fil métallique chirurgical de guidage enfilé dans le canal axial (32) de l’élément orientable de fixation (28).