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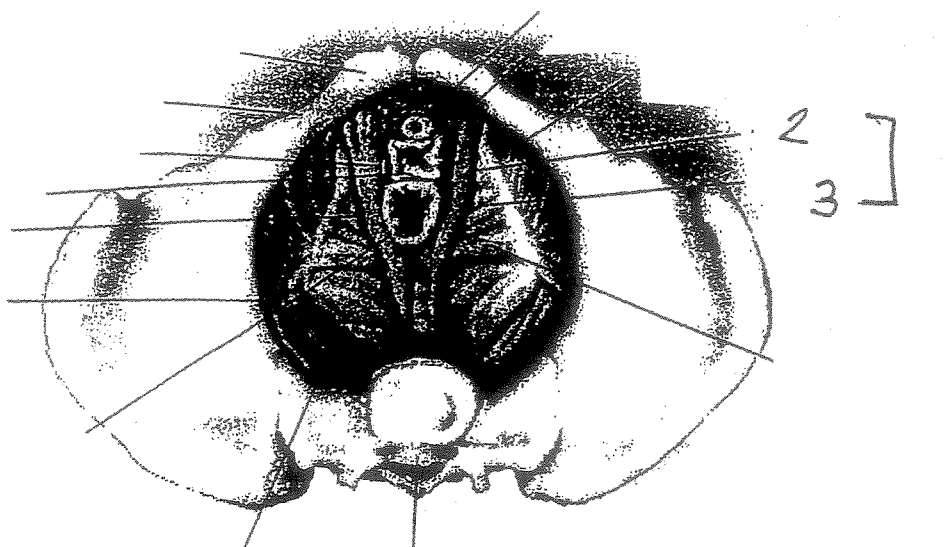
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(54) Title: METHOD AND APPARATUS FOR LEVATOR DISTENSION REPAIR



(57) Abstract: Improved methods and apparatuses for treatment of pelvic organ prolapse are provided. A specialized mesh having a shape for convenient subcutaneous placement to support the levator ani muscles is provided, as is a method of use of such a device. Appropriate devices for introducing such a mesh implant are also disclosed.

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## TITLE OF THE INVENTION

## METHOD AND APPARATUS FOR LEVATOR DISTENSION REPAIR

## BACKGROUND OF THE INVENTION

## FIELD OF THE INVENTION

[0001] This invention relates to urogenital surgery.

## DESCRIPTION OF THE RELATED ART

[0002] Female genital prolapse has long plagued women. It is estimated by the U.S. National Center for Health Statistics that 247,000 operations for genital prolapse were performed in 1998. With the increasing age of the U.S. population, these problems will likely assume additional importance.

[0003] The common clinical symptoms of vaginal prolapse are related to the fact that, following hysterectomy, the vagina is inappropriately serving the role of a structural layer between intra-abdominal pressure and atmospheric pressure. This pressure differential puts tension on the supporting structures of the vagina, causing a "dragging feeling" where the tissues connect to the pelvic wall or a sacral backache due to traction on the uterosacral ligaments. Exposure of the moist vaginal walls leads to a feeling of perineal wetness and can lead to ulceration of the exposed vaginal wall. Vaginal prolapse may also result in loss of urethral support due to displacement of the normal structural relationship, resulting in stress urinary incontinence. Certain disruptions of the normal structural relationships can result in urinary retention, as well. Stretching of the bladder base is associated with vaginal prolapse and can result in complaints of increased urinary urgency and frequency. Other symptoms, such as anal incontinence and related bowel symptoms, and sexual dysfunction are also frequently seen with vaginal prolapse.

[0004] Anterior vaginal wall prolapse causes the vaginal wall to fail to hold the bladder in place. This condition, in which the bladder sags or drops into the vagina, is termed a cystocele. There are two types of cystocele caused by anterior vaginal wall prolapse. Paravaginal defect is caused by weakness in the lateral supports (pubourethral ligaments and attachment of the bladder to the endopelvic fascia); central defect is caused by weakness in the central supports. There may also be a transverse defect, causing cystocele across the vagina.

[0005] Posterior vaginal wall prolapse results in descent of the rectum into the vagina, often termed a rectocele, or the presence of small intestine in a hernia sac between the rectum and vagina, called an enterocele. Broadly, there are four types based on suspected etiology. Congenital enteroceles are thought to occur because of failure of fusion or reopening of the fused peritoneal leaves down to the perineal body. Posthysterectomy vault prolapses may be “pulsion” types that are caused by pushing with increased intra-abdominal pressure. They may occur because of failure to reapproximate the superior aspects of the pubocervical fascia and the rectovaginal fascia at the time of surgery. Enteroceles that are associated with cystocele and rectocele may be from “traction” or pulling down of the vaginal vault by the prolapsing organs. Finally, iatrogenic prolapses may occur after a surgical procedure that changes the vaginal axis, such as certain surgical procedures for treatment of incontinence. With regard to rectoceles, low rectoceles may result from disruption of connective tissue supports in the distal posterior vaginal wall, perineal membrane, and perineal body. Mid-vaginal and high rectoceles may result from loss of lateral supports or defects in the rectovaginal septum. High rectoceles may result from loss of apical vaginal supports. Posterior or posthysterectomy enteroceles may accompany rectoceles.

[0006] Several factors have been implicated as being involved in genital prolapse in women. It is thought that individual women have differing inherent strength of the relevant connective tissue. Further, loss of connective tissue strength might be associated with damage at childbirth, deterioration with age, poor collagen repair mechanisms, and poor nutrition. Loss of muscle strength might be associated with neuromuscular damage during childbirth, neural damage from chronic straining, and metabolic diseases that affect muscle function. Other factors involved in prolapse include increased loads on the supportive system, as seen in prolonged lifting or chronic coughing from chronic pulmonary disease, or some disturbance in the balance of the structural support of the genital organs. Obesity, constipation, and a history of hysterectomy have also been implicated as possible factors.

[0007] As noted, vaginal prolapse and the concomitant anterior cystocele can lead to discomfort, urinary incontinence, and incomplete emptying of the bladder. Posterior vaginal prolapse may additionally cause defecatory problems, such as tenesmus and constipation. Furthermore, apart from the physical symptoms, vaginal prolapse has been shown to result in a lower quality of life for its sufferers, including feeling less attractive, less feminine, and less sexually attractive.

[0008] Vaginal prolapse develops when intra-abdominal pressure pushes the vagina outside the body. In a normal situation, the levator ani muscles close the pelvic floor. This results in little force being applied to the fascia and ligaments that support the genital organs. Increases in abdominal pressure, failure of the muscles to keep the pelvic floor closed, and damage to the ligaments and fascia all contribute to the development of prolapse. In addition, if a woman has a hysterectomy, the vaginal angle may be altered, causing increased pressure at a more acute angle, accelerating the prolapse.

[0009] There are generally two different types of tissue that make up the supportive structure of the vagina and uterus. First, there are fibrous connective tissues that attach these organs to the pelvic walls (cardinal and uterosacral ligaments; pubocervical and rectovaginal fascia). Second, the levator ani muscles close the pelvic floor so the organs can rest on the muscular shelf thereby provided. It is when damage to the muscles opens the pelvic floor or during the trauma of childbirth that the fascia and ligaments are strained. Breaks in the fascia allow the wall of the vagina or cervix to prolapse downward.

[0010] As noted above, the levator ani muscles close the pelvic floor so the organs can rest on the muscular shelf thereby provided. The levator ani muscles arise from the pubis, the pelvic fascia, and the ischial spine. They insert on the pelvic viscera, coccyx, and the fibrous raphe of the perineum.

[0011] When damage has occurred in the levator muscle, most commonly as a result of obstetric injury, the anatomical defect is noted as a tendency towards a vertical elongation of the levator plate. This downward sagging of the levator plate results in the longitudinal enlargement of the levator hiatus with secondary placement of the cervix and upper vagina upon the levator hiatus. With increased intra-abdominal pressure the defective levator plate is no longer supportive of the downward movement of the uterus, cervix and upper vagina, which are resting upon the levator hiatus, and genital prolapse develops. Over a period of time elongation of the uterosacral and cardinal ligaments will result.

[0012] The cardinal and uterosacral ligaments form a suspensory mechanism that suspends the vaginal apex but allows for some vertical mobility. In the normal woman the cervix will descend to but not below the plane of the ischial spines. Damage to the cardinal uterosacral ligament complex permits the uterus and upper vagina to telescope downwards, like an inverted sock. Complete failure of the cardinal uterosacral ligament complex will result in a "cervix-first" prolapse.

[0013] Anteriorly, the continence mechanism is maintained by the integrity of the sub-urethral hammock and the insertion of pubo-urethral ligaments into the mid urethra.

Posteriorly, the perineal body needs to be firm and substantial in size to allow stretching and angulation of the vagina around it. Levator muscle distension can have a significant effect on perineal body descent and future pelvic prolapse, as well as prolapse recurrence.

[0014] Treatment of vaginal prolapse is uncertain, and generally based on the symptoms of the prolapse. If symptoms are more severe, treatment is commonly by either surgery or pessary. Surgical options might include hysterectomy or by uterus-saving procedures. Such procedures may include abdominal or vaginal access routes. Sacralcolpopexy or sacrospinous fixation may be used. Anterior colporrhaphy is often utilized for treatment of anterior vaginal prolapse. In addition, methods of surgical repair using mesh or biological implants, or a combination thereof, to support the prolapsed organ in its appropriate position, have been developed, and may use either a transobturator or vaginal approach.

[0015] Traditional anterior prolapse repairs have a relatively high failure rate. Consequently, mesh or grafts have been used to provide additional support for a traditional repair. However, the typical placement of such augmentation of the levator muscle is through a transvaginal approach, with transvaginal dissection. Such transvaginal dissection can be more difficult for the surgeon and may lead to further failures. Consequently, there is a need for alternative methods and apparatus for augmentative support of repaired levator muscle in cases of pelvic organ prolapse.

#### SUMMARY OF THE INVENTION

[0016] The present invention includes surgical instruments and implantable articles for urological applications, particularly levator muscle repair as supportive treatment for other repairs of pelvic organ prolapse, or as a standalone treatment for prolapse.

[0017] The present invention comprises placing mesh subcutaneously against the levator muscle, rather than transvaginally, requiring no vaginal dissection in a preferred embodiment.

[0018] In a preferred embodiment the mesh apparatus of the present invention is trapezoid-shaped. The mesh is placed surgically bilaterally on each side of the body between the levator muscle and associated fatty tissue. The mesh is placed such that the base of the trapezoid-shaped mesh runs from the obturator to the ischial spine, with the top of the trapezoid tucked under the rectum.

[0019] The mesh apparatus is implanted subcutaneously with a novel introducer. The introducer inserts the mesh, spreads it, and opens it in the proper orientation and location.

Following such implantation, the mesh apparatus may be secured with sutures or staples in a preferred embodiment.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0020] A more complete appreciation of the invention and many of the attendant advantages thereof will be readily obtained as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

[0021] Fig. 1 shows the anatomy of the pelvic floor, including the pubococcygeus muscles and illiococcygeus muscles that make up the levator ani muscles.

[0022] Fig. 2 shows a schematic illustrating the general condition of healthy levator muscles.

[0023] Fig. 3 shows a schematic illustrating the general condition of levators associated with prolapsed pelvic organs.

[0024] Fig. 4 shows a plan view of the mesh apparatus of the present invention.

[0025] Fig. 5 shows the approximate location of insertion of the mesh of the present invention.

[0026] Fig. 6 shows a schematic illustrating the appropriate orientation of the mesh in vivo.

[0027] Fig. 7 shows a schematic illustrating an alternative orientation of the mesh in vivo.

[0028] Figs. 8-13 show an embodiment of an introducer for use in the present invention.

[0029] Figs. 14-18 show an alternative embodiment of an introducer for use in the present invention.

[0030] Fig. 19 shows flaps on the leading end of the introducer.

[0031] Fig. 20 shows an alternative embodiment of the mesh placement of the present invention.

[0032] Fig. 21 shows an alternative site of incision for the present invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0033] Referring now to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views. The following description is meant to be illustrative only, and not limiting other embodiments of this invention will be apparent to those of ordinary skill in the art in view of this description.

[0034] The relevant anatomy is illustrated in Fig. 1. As can be seen, the levator ani muscles 1, including the pubococcygeus 2 and illiococcygeus muscles 3, are a significant

portion of the pelvic floor and provide support for the pelvic viscera. Fig 1 and 2 show the normal condition of the levator muscles, while Fig. 3 shows the posture of levator muscles associated with prolapsed pelvic organs. As can be seen, such muscles offer less support for the pelvic viscera and may benefit from additional support as provided in the present invention.

[0035] In the present invention, the mesh implant, an embodiment which is illustrated in Fig. 4, is placed external to the levator muscles. Such placement reinforces the muscle. Tissue ingrowth during the normal healing process will further support the muscle, and the mesh implant will prevent over-distension of the muscles. It is noted that the top edge of the mesh apparatus can be reinforced with plastic or other similar materials to provide spring and to hold the mesh in the desired shape in vivo, allowing for improved ease in placement. The mesh apparatus may also comprise rivets or some similar palpable marker in certain locations, such as on the corners, in order to provide additional ease and certainty in terms of appropriate placement of the device.

[0036] In a preferred embodiment, the mesh implant is placed bilaterally on each side on both the right and left side of the patient's body, and is placed in a subcutaneous location between the levator muscle and the overlying fatty tissue.

[0037] Fig. 5 shows a preferred approximate location of insertion of the mesh apparatus of the present invention. As illustrated, a small incision 4 is made on each side of the rectum approximately 3 cm lateral and 3 cm posterior to the anus 5. Instead of dissecting through the muscle, the surgeon creates a space by bluntly moving along the belly of the muscle to the ischial spine, sweeping off the ischial spine. Another embodiment may use pillow dissection with placement of a balloon device, followed by inflation of such a balloon to create the required space. An example of proper placement is illustrated schematically in Fig. 6. As illustrated, the upper edge of the mesh apparatus runs from the ischial spine 6 to the obturator foramen 7. The lower edge (ie, the base of the trapezoid) is curled under the rectum 8 .

[0038] A small tail of mesh 9 can be used to support the perineal body 10 in an embodiment of the present invention. Such placement is illustrated schematically in Fig. 7. Fig. 7 also illustrates an embodiment of the mesh of the present invention in which the upper edge of the mesh comprise arms 11 and 12. These arms allow for transvaginal placement of the mesh as an alternative procedure. Such an alternative may be especially beneficial in instances where the patient is in need of other surgical treatment, such as placement of urethral support devices.

[0039] Appropriate insertion devices, or introducers, which allow for correct placement of the described mesh are within the scope of the present invention. Some embodiments are illustrated in Figs. 8-13 and 14-18, though other embodiments are possible.

[0040] Figs. 8-13 illustrates embodiments of the introducer of the present invention. These embodiments comprise a thimble tunneling device to which the mesh implant is attached. The thimble portion 13 is inserted via the surgeon's finger. After insertion to the proper location, the attached mesh implant portion 14 is unrolled to its proper orientation. Devices to assist in the deployment of the mesh, such as mesh perforations 15, push buttons, needles, or staples are within the scope of the present invention. An example of an embodiment in which the thimble portion comprises a needle 16 is seen in Fig. 12. The needle allows for a small bite of tissue is illustrated to secure placement of the mesh. The thimble may also comprise a button 17, an embodiment of which is illustrated in Fig. 13. In an embodiment, such button could be engaged to release suture or staple to secure the mesh.

[0041] Figs. 14-18 illustrate another embodiment of the introducer of the present invention. In this embodiment, the mesh apparatus 18 may be rolled around a device 19 having the capability of spreading, with the mesh not attached to the spreader but covered by a protective sheath 20. As seen in Fig. 15, upon insertion by the surgeon, and appropriate location of the mesh, the protective sheath 20 may be removed. In Fig. 16, the spreaders 19 are spread by actuating spreader controls 25, releasing the mesh to its appropriate orientation. The mesh apparatus is then stabilized in its proper location and orientation with staples or tacks, for example. Following such stabilization, the spreaders 19 are retracted to the un-spread condition, as in Fig. 17. The sheath is replaced, as in Fig. 18, and the introducer is withdrawn. Appropriate safety features such as flaps 21 on the leading end of the introducer to prevent catching tissue inadvertently are also within the scope of the present invention, as shown in Fig. 19.

[0042] Alternatively, a mesh implant to effect support of distended levator ani muscle may be implanted, as illustrated in Fig. 21, by first making an approximately 3 cm long Krasky incision 22 beginning at a point approximately 2 cm inferior to the anus 5. Following such an incision, the surgeon may bluntly dissect a location for the placement of the mesh implant by inserting a finger into the incision and tunneling toward the ischial spine on the left side of the patient. Using blunt dissection, the surgeon uses his finger to open the space to the spine. In this position, the finger lies in the space between the levator muscle medially and the fatty tissue laterally. By making a sweeping motion with



his finger, the surgeon creates a space, until both the ischial spine and the inferior pubic ramus are palpable.

[0043] Following creating of the space by blunt dissection, the mesh can be placed with a needle in an embodiment of the present invention. The needle may be inserted through an anchor 23,24 or other tissue fixation structure disposed on an arm 11,12 on the mesh, as illustrated in Fig. 20. The surgeon places his finger on the ischial spine, then runs the needle along his finger until the end of the anchor pushes into the tissue, which will be adjacent the ischial spine in the levator muscle (i.e., at the sacrospinous ligament, the ischiorectal fossa, or the iliococcygeus muscle). The anchor engages the tissue at this point, and the needle is removed by withdrawing from the incision. The needle is then inserted into an anchor or other tissue fixation structure on the other arm of the mesh implant. The surgeon then places his finger on the pubic ramus, runs the needle along his finger, thereby pushing the anchor into the obturator internus muscle, engaging that tissue. The needle is removed by withdrawing from the incision. The surgeon then sweeps along the mesh, smoothing the area between the anchors and sweeping the tail end of the mesh beneath the rectum.

[0044] The dissection and mesh placement is repeated on the right side of the patient. The tail ends of the two implants may overlap beneath the rectum or anococcygeal body following placement, or may be sutured together. Following placement of the mesh implants, the Krasky incision is closed.

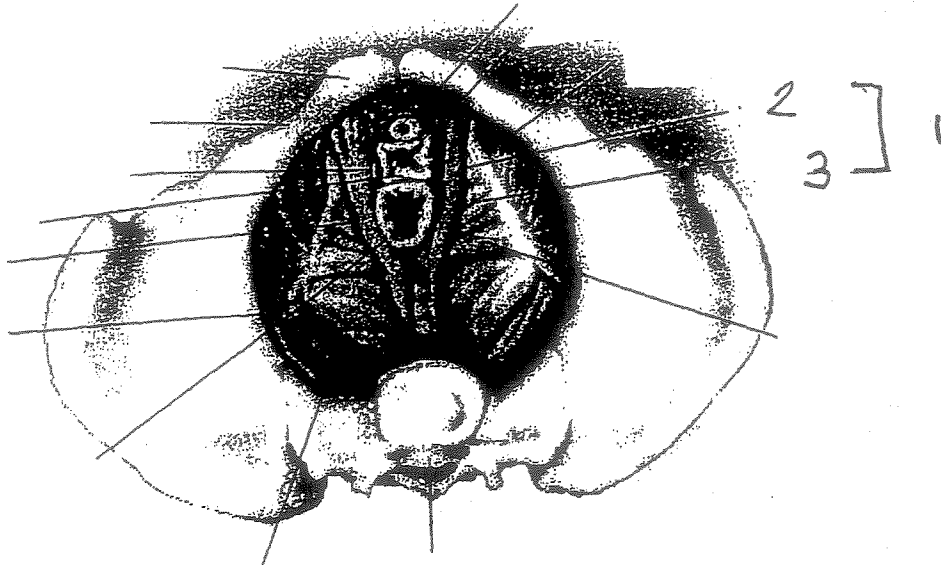
[0045] Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein for both female and male patients.

## CLAIMS:

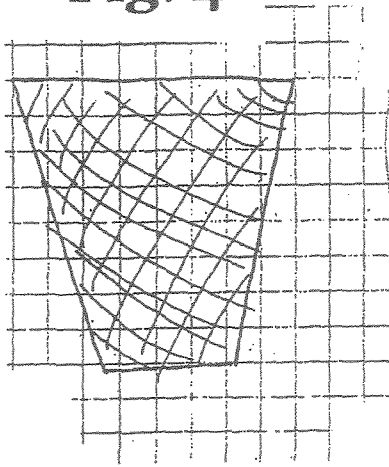
1. A surgical kit for the treatment of pelvic organ prolapse, said kit comprising:
  - a. A mesh portion having a trapezoidal shape having a top edge and a bottom edge opposite said top edge; and
  - b. An introducer for placement of such mesh portion in an appropriate anatomical location.
2. The kit of claim 1, wherein said mesh portion comprises at least one arm adjacent the top edge of said mesh portion.
3. The kit of claim 2, wherein said at least one arm comprises a tissue fixation mechanism.
4. The kit of claim 3, wherein said tissue fixation mechanism comprises an anchor.
5. The kit of claim 1, wherein said mesh portion comprises a tail of mesh adjacent a bottom edge of said mesh portion.
6. The kit of claim 1, wherein said mesh portion comprises rivets or other palpable structures located at the corners of said mesh portion.
7. The kit of claim 1, wherein said top edge of said mesh portion is reinforced with plastic.
8. An introducer for inserting an implant, comprising a thimble portion to which an implant is detachably connected.
9. The introducer of claim 8, comprising perforations adapted to facilitate detachment of said implant from said thimble portion.
10. The introducer of claim 8, said thimble portion comprising a needle.

11. The introducer of claim 9, said thimble portion comprising a push button mechanism adapted to deploy said implant.
  
12. An introducer for inserting an implant, comprising a spreader device about which said implant may be rolled when the spreader device is in its unspread condition.
  
13. The introducer of claim 12, further comprising a protective sheath covering said implant rolled about said spreader device in its unspread condition.
  
14. The introducer of claim 12, said introducer comprising a control mechanism adapted to adjust said spreader device from an unspread condition to a spread condition.
  
15. A method of treating levator distension comprising placing a mesh implant between the levator muscle and the overlying fatty tissue on at least one side of a patient.

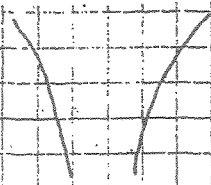
**Fig. 1**



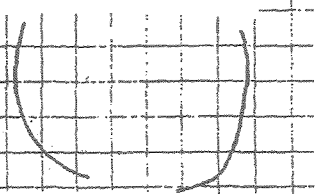
**Fig. 4**



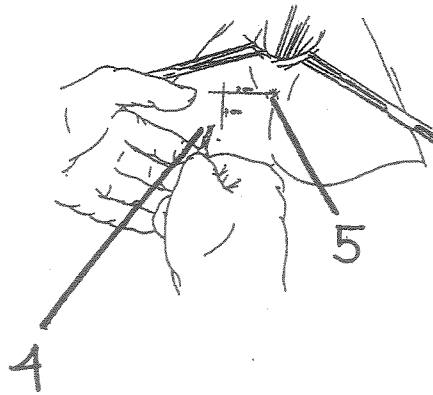
**Fig. 2**

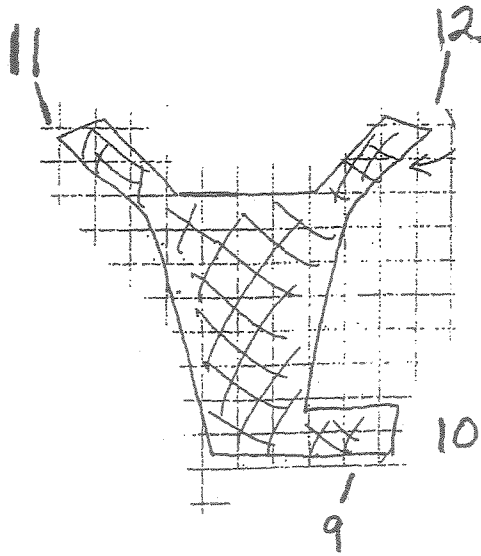
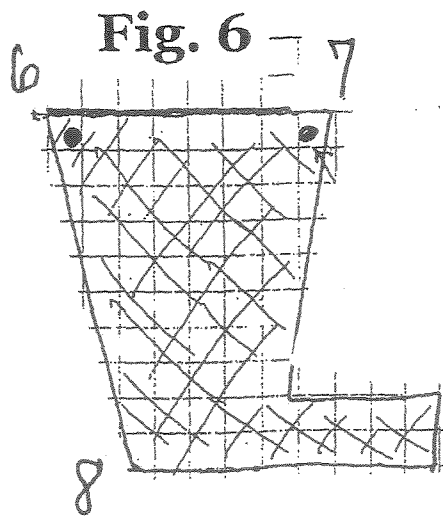


**Fig. 3**



**Fig. 5**





**Fig. 7**

Fig. 8

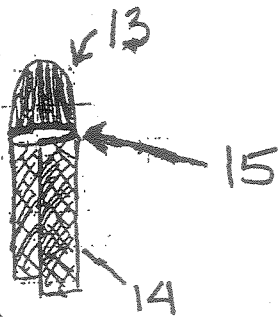


Fig. 9

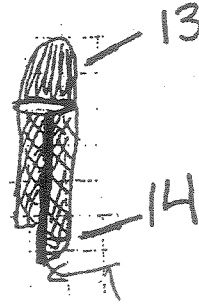


Fig. 10

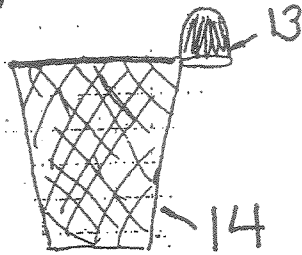


Fig. 11

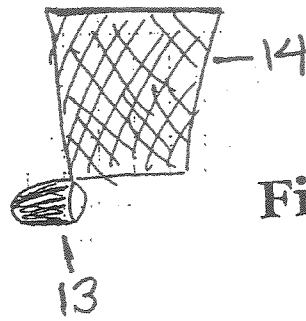


Fig. 12

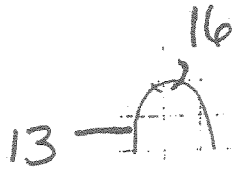


Fig. 13

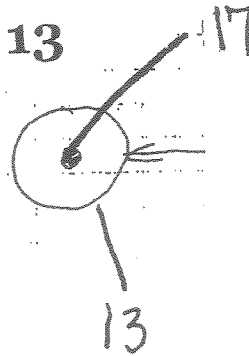




Fig. 14

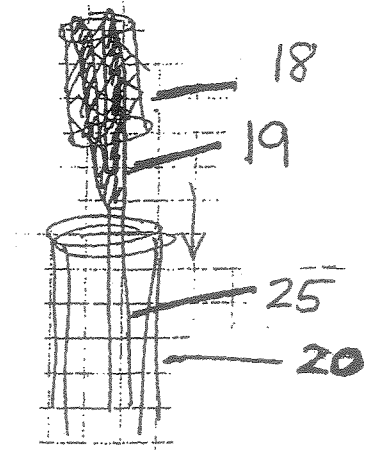
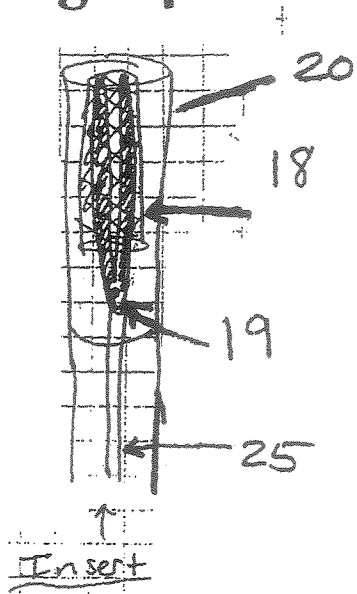


Fig. 15

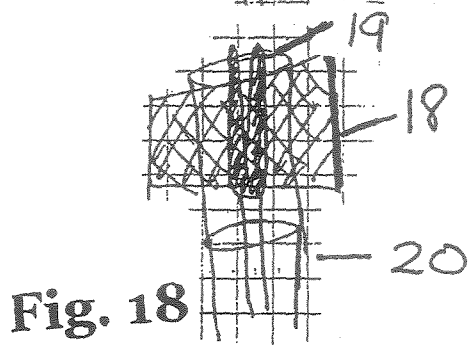
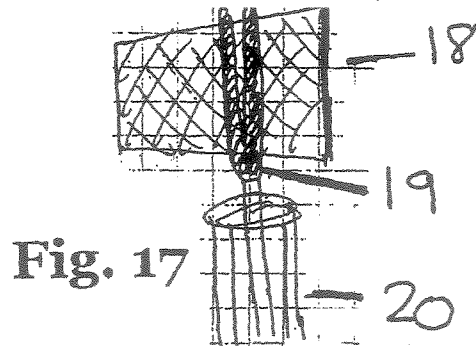
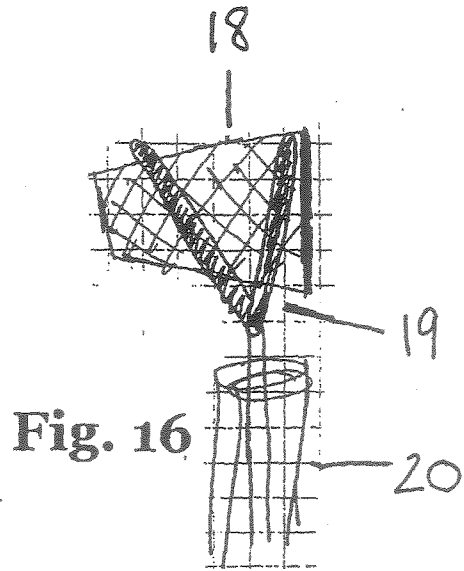


Fig. 19

