APPARATUS FOR CONTROL OF URINARY INCONTINENCE

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Filed Oct. 18, 1960, Ser. No. 63,388
3 Claims. (Cl. 128—1)

The present invention relates to the control of urinary incontinence, and, more particularly, is directed to a prosthesis and method of utilizing the same which will control undesirable leakages in the urethra of the human body.

In recent years an increasing amount of infection in the vicinity of the prostate gland has necessitated the removal of the same from the bodies of humans. In carrying out the operation by which the prostate or parts thereof are removed incisions are necessarily made which occasionally result in urinary incontinence after prostate removal. This urinary incontinence is inconvenient, unsanitary and often psychologically demoralizing and depressing to the patient.

Several operative techniques and methods have been proposed and carried out in attempts to correct urinary incontinence. None of these however has been completely satisfactory. Among the methods which have been used in attempts to control urinary incontinence are the operations of division, compression, constriction and support. In the revision technique a vesicle neck or urethral stenosis is created by incision or wedge excision. In the constriction method muscular constriction is used to create an artificial sphincter by Gracilis transplant or stenotic constriction. The operation of support utilizes implantation procedures in which the transverse perineal muscles, ischiocavernous and the levator ani muscles are used. The operation of compression applies a pressure to the urethra by means of a sling of muscular or fascial origin which does not completely surround the urethra. It is with this latter type of approach to correction of urinary incontinence that the present invention is directed, i.e., the application of pressure to the urethra by kinking and constricting.

According to the method of the present invention substantially improved control of urinary incontinence can be provided by the utilization of a new and novel prosthesis and method of utilizing the same. The prosthesis is of simple design, durable, comparatively easy to use and results in a substantially improved control of flow in the urethra. In carrying out the process of the present invention an unexpectedly high rate of complete cure has been obtained with very slight morbidity and minimal complications. The technique of the present invention is such that it can be repeated several times if the initial implant of the prosthesis is not completely satisfactory. Moreover, the technique of the present invention can be utilized in many instances where previous procedures have been tried to control incontinence and failed to produce the desired result.

It is accordingly an object of the present invention to provide a new method of controlling urinary incontinence.

It is another object of the present invention to provide a new and improved prosthesis for urinary incontinence control.

It is a still further object of the present invention to provide a prosthesis suitable for positioning in the bulbocavernous muscle in a manner that will provide complete control of the urethra.

It is a still further object of the present invention to provide a prosthesis suitable for kinking or angulating the urethra in a manner that will control urethral flow.

These and other objects and advantages are accom-

plished according to the present invention by positioning in a pocket created between the urethra and the bulbocavernous muscle and inserting therein the prosthesis of the present invention which may be generally described as a small, inflexible, biologically inert article, having in the plan view a generally rectangular shape which includes a bottom surface having a urethra bearing surface, parallel to the transverse axis of the urethra, when positioned adjacent thereto, a generally curved upper or top surface and means to permit the prosthesis to be fixedly positioned in the desired position adjacent to the urethra.

A more complete description of the prosthesis of the present invention and the manner in which it is used will be apparent from the drawings and description which follows in which:

FIGURE 1 shows the top view of one embodiment of the present invention.
FIGURE 2 is a cross sectional side view of the prosthesis shown in FIGURE 1 taken along the lines 3—2.
FIGURE 3 is a cross sectional side view of an alternate embodiment of the present invention.
FIGURE 4 is a cross sectional side view of another form of the present invention.
FIGURE 5 is a graphic showing of the initial steps taken in positioning the prosthesis.
FIGURE 6 is a descriptive showing of the pocket created for positioning the prosthesis.
FIGURE 7 shows the prosthesis positioned in a pocket fashioned between the urethra and the bulbocavernous muscle.
FIGURE 8 is a cross section of the lower extremities of the human body showing the prosthesis positioned in relation to the urethra.

The prosthesis of the present invention is constructed of hard, inflexible, biologically inert materials such as plastics, metals, alloys and the like which are more specifically described hereafter.

The prosthesis is shaped in one of several forms with variations depending on the particular shape of the anatomy in the vicinity in which the prosthesis is to be positioned.

In FIGURES 1-4 there are shown several forms of the prosthesis of the present invention. In FIGURE 1 one form of the prosthesis is shown in plan view. It will be noted that in this view the prosthesis 1 has a generally rectangular shape with curved surfaces and no sharp edges, including sides 2 which terminate in the curved end portion, generally shown at 3. Prosthesis 1 as shown in FIGURE 2 includes a base, or more particularly, a urethra bearing surface 4 and an upper curved surface 5 terminating at the base at 6. The upper curved surface 5 increases to a maximum at 8 at which point the prosthesis has its maximum thickness. To position the prosthesis a plurality of holes 10 extending from the upper curved surface through the urethra bearing surface 4, are positioned around the periphery of the prosthesis. Holes 10 vary in number, generally from a minimum of two to a maximum of about ten.

In FIGURES 3 and 4 alternate embodiments of the prosthesis of FIGURE 1 are shown. FIGURE 3 is a cross sectional side view, similar to the view of the embodiment shown in FIGURE 2. This form of the prosthesis is generally identified as 11. Prosthesis 11 includes a base or bottom 12, having fashioned thereon a generally curved urethra bearing surface 14. Bearing surface 14 extends across the width of prosthesis 11 so that when the prosthesis is positioned with its long axis parallel to the long axis of the urethra, bearing surface 14 will be perpendicular to the urethra.

Similar to the embodiment of FIGURES 1 and 2, pros-
thesis 11 of FIGURE 3 includes a generally upper curved surface 16, terminating in the curved ends 18. A plurality of holes 20, constructed similar to holes 19 of FIGURE 2 are positioned at the periphery.

The prosthesis 21 shown in FIGURE 4 in cross sectional side view includes a base or bottom surface 27 having a urethra bearing surface 28 thereon, which, similar to urethra bearing surface 14 of FIGURE 3, extends across the width of the prosthesis. It will be noted that the curvature of urethra bearing surface 28 is more gradual than the similar surface of the prosthesis of FIGURE 3. Varying degrees of curvature of the urethra bearing surface 28 can be provided in the body portion depending on the extent of coverage and application of pressure desired on the surface of the urethra. In any event, urethra bearing surface 28, similar to surfaces 14 and 4, must have sufficient width to extend across the kinked or distended width of the urethra when the prosthesis is firmly implanted against the same and exerting maximum pressure. Prosthesis 21 includes in the top thereof an indented or V shaped depression 24 to assist in seating prosthesis 21 around muscular extensions or protrusions that may exist at the site of prosthesis implantation. Similar to the embodiments shown in FIGURES 2 and 3, means are provided at 30 to permit positioning of the prosthesis in position in the manner described.

As has previously indicated it is necessary to fashion or shape the prosthesis in such a manner as to avoid sharp edges. It is also necessary that the prosthesis be prepared from materials which are biologically inert and provide sufficient strength to prevent the prosthesis from flexing once in position. Suitable materials include plastics of the methacylate type and metals such as gold, silver, and platinum, as well as other inert metal alloys. It is of course preferable that the prosthesis be light in weight without sacrificing strength so as not to unduly distort or distend the muscular structure in the vicinity of the urethra when the prosthesis is positioned. When using a methacylate type material to construct the prosthesis it may be desirable to impregnate the same with bisphenol or other similar materials to enhance radiologic visualization of the prosthesis when the same is positioned in the body.

In utilizing the prosthesis of the present invention it is necessary to insert the prosthesis in a pocket prepared between the bulbocavernous muscle and the urethra in a position substantially adjacent to the urethra. To accomplish this the patient is placed on the operating table in a Lithotomy position with the perineal region of the body prepared in a sterile manner as is accomplished in carrying out a conventional perineal operation including the positioning of a Lowryse Anterior Tractor. Referring now to FIGURE 5, a vertebral incision, generally identified as 42, is made in the middle of the perineum, extending from the scrotal margin to a point about 3 cm. above the anal margin. The incision is deepened through the skin 41, the subcutaneous tissues and fat 44, down to the colles fascia 48 which covers the bulbocavernous muscle 50. In accomplishing this and other incisions retractor shown at 54, 56, 57, 60 and 62 are used. Drains such as 58 are provided as needed.

By blunt dissection the ischiocavernous muscle 52 on either side of the bulbocavernous muscle is exposed. This exposure is more completely shown in FIGURE 6 in which the bulbocavernous muscle is identified as 50. In this further incision additional retractors or retractors 60 and drains 55 are used. After the ischiocavernous muscle 52 is exposed the fascia covering the bulbocavernous 50, hereafter referred to as the bulb, known as the colles fascia 48, is incised in the midline, vertically over the entire length of the bulb 50. A transverse incision is made in the bulb 50 about 1/2 cm. from its distal attachment to the urethra.

At this point, mainly by blunt dissection, a pocket 66 is formed between the bulb 50 and the urethra 76, as shown in FIGURE 8, using the colles fascia 48 to accomplishing the pocket formation it may be necessary to cut a few of the fibres of the decussation where they joint the urethra. The pocket 66 is made as deep as possible by carrying the dissection to the posterior insertion of the bulbocavernous muscle.

At this point the Lowayse Anterior Tractor is removed. A prosthesis is selected of the proper size and shape. The size and shape selected will of course depend on the size and shape of the pocket, the structure of the bulb muscle and its relationship and position to the urethra. The selected prosthesis identified as 68 in FIGURE 7 is then placed in pocket 68 oriented in such a way that the flat or bottom surface is positioned against the urethra with the longer axis of the prosthesis paralleling the urethra.

The selected prosthesis may utilize the embodiment such as FIGURE 3 when a very narrow point of contact between the urethra wall is available for pressure application. The embodiment shown in FIGURE 4 can be utilized when a broader area of contact between the prosthesis and the urethra is desired. However, the prosthesis generally shown in FIGURES 1 and 2 will be preferred since the maximum contact along the long axis of the prosthesis with the long axis of the urethra can be obtained.

Once in position and properly oriented with respect to the urethra, the prosthesis is fixed in position by means of four double strands of a suitable steel wire 70 with one strand looped through each hole 18 in the four corners of the prosthesis 68. The prosthesis is secured in the pocket 50 by passing the double suture of wire which is threaded on a curved needle through the bulb 50 out through the ischiocavernous muscle 52. One strand of wire is removed from the needle and passed through the ischiocavernous muscle at a lower point and tied to its fellow.

This procedure is repeated on each of the four corners of the prosthesis. It is essential that the prosthesis be firmly anchored and immobilized in position. It has been found that the use of steel wire in the manner described above accomplishes the permanent positioning most adequately. However, other suitable means if available such as clamps fashioned into the body portion of the prosthesis can conceivably be used. Experience has shown however that the plurality of holes at the periphery of the prosthesis provides a most adequate means for immobilizing the prosthesis in the desired position. Positioning the prosthesis in this manner will permit kinking and compression of the urethra in a manner that substantially restores the normal functioning of the external sphincter.

After the prosthesis has been positioned the transverse incision of the bulbocavernous muscle is closed in line with the incision using interrupted sutures of catgut in the conventional manner. Similarly the colles fascia 48 is closed in a vertical manner followed by closure of the subcutaneous tissues and finally the skin is closed. Suitable dressings and drains as necessary may then be applied.

As installed the prosthesis remains permanently fixed in the bulbocavernous muscle functioning in such a manner that pressure applied by the prosthesis to the urethra will substantially eliminate urinary incontinence.

While the description of this invention has been undertaken with respect to specific embodiments shown which will generally have a length of from 25 to about 40 mm, a width of from about 15 to 20 mm, and a thickness of from about 0.3 to about 1.5 mm, it is to be understood that many variations thereof can be made without departing from the essential nature of the invention. Such vari-
ations and departures are to be understood as coming within the scope of this invention and are to be limited only by the claims appended hereto.

I claim:

1. A prosthesis to prevent urinary incontinence by implanting the same in the human body adjacent to and in contact with the urethra, said prosthesis consisting of an inflexible, biologically inert, smooth surfaced solid having a generally rectangular base and continuously curved top and side surfaces terminating at the opposite ends and sides of said base, said base having a width equal to the width of the urethra and an integral raised urethra bearing surface centrally positioned therein, the main axis of which surface is transverse to the main axis of said base, said urethra bearing surface having a width equal to the width of said base and a height not greater than its width, said prosthesis having a plurality of positioning holes spaced about the periphery of the curved top surface extending from the curved surface downwardly through the base.

2. The prosthesis as claimed in claim 1 in which the continuously curved top surface is a concave surface.

3. The prosthesis as claimed in claim 1 in which the continuously curved top surface is a convex surface.

References Cited in the file of this patent

UNITED STATES PATENTS

699,025 Le Hardy -------------- Apr. 29, 1902
705,453 Sherman -------------- July 22, 1902
2,649,086 Sluijter -------------- Aug. 18, 1953
2,649,854 Salm -------------- Aug. 25, 1953