NASA TECHNICAL MEMORANDUM

NASA TM-78255

PROSTHETIC DEVICE FOR CORRECTION OF URINARY INCONTINENCE

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December 1979

NASA

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TABLE OF CONTENTS

LIST OF ILLUSTRATIONS

TECHNICAL MEMORANDUM

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I. INTRODUCTION AND BACKGROUND

The National Aeronautics and Space Administration (NASA) encountered many biomedical problems by placing man in an alien environment. As these problems were resolved, it became apparent that much of the technology developed was almost directly applicable to biomedical problems existing on Earth. Not so apparent was the fact that the same technology requirements for high reliability, durability, and minimum size and weight for aerospace advanced the technology needed in biomedical innovations.

For these reasons, in 1966, NASA created the Biomedical Application Team Program, in which interdisciplinary teams actively seek out medical problems to which solutions may be found within the aerospace community. The teams interact with major medical institutions throughout the United States and define specific technological barriers to medical progress. The teams then propose solutions to these problems utilizing the technology which has been developed for the space program. This article is a typical outgrowth of that process.

Developing a device to be implanted inside the human body is a complex undertaking. Therefore, NASA's contribution was not only to provide the innovative concept and aerospace technology, but also to pull together the team of industries and institutions to take the project through design, development, manufacturing, animal trials, clinical trials, and marketing.

Urinary incontinence is one of the most difficult problems facing urologists today. It occurs in patients of both sexes and at all ages. For this article, incontinence can be defined as the involuntary loss of urine. The anatomy of the lower urinary tract consists of (1) the bladder which serves to store urine and forcibly expel it at regular and appropriate intervals and (2) the sphincter mechanism which surrounds and constricts the urethra, preventing urine from escaping when it should not. There is a balance between the mechanism for expulsion of urine and the mechanism necessary for its retention, and incontinents ensues when the balance is upset. Incontinence can thus be divided into two types:

a) Incontinence which occurs when the bladder is abnormal

b) Incontinence which occurs when the sphincter mechanism is incompetent.

The most common form of incontinence in young, healthy, and nulliporous (childless) women is stress incontinence which occasionally occurs in as many as 50 percent and frequently occurs in approximately 5 percent. This condition at times is worsened by child bearing [1]. Detrusor (bladder contraction muscle) abnormality is also common in women, and of those with stress incontinence 48 percent have an abnormal detrusor [2]. In men, sphincter incompetence sometimes follows prostatectomy, while detrusor dysfunction is most commonly caused by disseminated sclerosis, cerebrovascular accidents (stroke), and spinal trauma. Other causes such as spinal cord tumor, degenerative disease of the spinal cord, cervical spondylosis, head injury, herniated intervertebral disc, syringomyelis, and tabes dorsalis contribute a small but significant number of cases.

Table 1 indicates the large number of patients who lost bladder function as a sequel to a variety of diseases or injuries.

TABLE 1. MAJOR CAUSES OF INCONTENANCE [3]

Disease or Injury	Estimated total cases	Incidence of cases with bladder dysfunction (%)	Estimated total cases with neurologic dysfunction of urinary bladder
Multiple sclerosis	500,000	90	450,000
Spinal cord injury	100,000	75	75,000
Cerebrovascular disease	2,000,000	10	200,000
Parkinson's disease	1,000,000	25	250,000
Diabetes mellitus	3,000,000	10	300,000
Meningo myelocoele	1,000	75	750
Amyotrophic lateral sclerosis	6,000	10	600
TOTAL			1,276,350

The Rehabilitation Services Administration estimates that spinal cord injury cases alone are increasing at the rate of 8,000 to 10,000 each year with 80 percent of these in the 15 to 30 age range. Costs of care for spinal cord victims are estimated at $2.4 billion per year [4].

Current efforts to manage the incontinent patient consist of external collection devices or the use of an indwelling catheter. The most widely used external collection device at this time is the diaper. The obvious disadvantages of this system are (1) a social embarrassment as a result

of the odor (many patients avoid a return to working or social contacts as a result), and (2) the constant presence of urine results in skin rashes and severe skin ulcers.

The external collection device currently used for the male consists of a roll-on cuff with a connector to a leg bag for storage. As yet, no device is available for external collection of urine from the female. NASA is currently sponsoring research using aerospace technology to develop a method for externally collecting and storing urine for incontinent females. The major disadvantage of external collection devices is the constant presence of residual urine in the bladder and urethra, a condition that encourages bacterial growth. As a result, kidney failure resulting from urinary tract infections is a major cause of death in patients with spinal cord injury as well as others with severe urinary incontinence. Another means of managing urinary incontinence is through the use of indwelling catheters. This method has the disadvantages of requiring confinement to a bed as well as serving as a source of infection.

A need exists for a device that will allow the bladder to fill and then be emptied rapidly every 3 or 4 hours. This periodic voiding allows the bladder muscles to be exercised and, as a result, to remain healthy. In addition, the problem of residual urine is eliminated, and the urethra remains closed except during voiding so that the risk of urinary tract and kidney infections is greatly decreased. A prosthetic urinary sphincter being developed by NASA will fill this need. This sphincter will provide voluntary urination control to both male and female patients of any age 12 years and up who are healthy enough to undergo the implantation surgery.

II. PROBLEM STUDY

After receiving a problem statement from the Biomedical Applications Team, a MEDLINE search was made to determine all documented effort that had been expended on this problem. Some 30 related articles were thus obtained and evaluated providing an up-to-date background as a base from which to start. A survey was then made on NASA's programs to determine if any valves or systems that might be applicable to a prosthetic urinary sphincter were in existence. It was found that no hardware could be directly applied; however, there were miniature valves that could be used with modification. Qualified suppliers were then consulted with regard to their interest in participating in a development program and they were also asked for suggestions for applying their technology to assure a reliable producible unit. A study was then made on biocompatible materials. The development of polymeric materials compatible with a wide variety of acidic and caustic solutions used in the space program opened the potential for body implants.

After reviewing the prosthetic urinary sphincter designs described in the MEDLINE search articles and surveying the aerospace industries technology, it was concluded that NASA could make significant contributions toward an acceptable unit in two areas – first, by increasing the unit's reliability; second, by producing a simplified system that would reduce the trauma of implantation. The following design ground rules were then generated to help avoid the problems encountered by other attempts to restore urinary continence:

a) Minimize surgery for implantation – The implantation could be done perfectly, yet if the body is traumatized excessively, recovery will require much more time, or worse, implant removal might be required before the body would heal. Also, the longer the operation, the greater the chances of contracting a serious infection.

b) The design shall be simple for maximum reliability – Reduce friction and stiction by eliminating sliding parts. Minimum number of moving parts reduces the number of possible failure modes.

c) Design the urethral cuff so it will be adjustible after implantation – This reduces the time required for implantation and also eliminates chance of misfit. If this cuff is too large there will be no control. If the cuff is too small, blood circulation is cut off, resulting in necrosis (tissue death).

d) The design shall use only proven compatible materials to avoid the expense and time required for compatibility testing of a new material.

e) The design shall be such that the recipient's sexual activity will not be hampered.

f) Make design differences for male and female if necessary. Packaging differences may be necessary due to anatomy differences.

g) Consider both mechanical and hydraulic designs for putting the force on the urethra. The selection could be based on the other design ground rules with special emphasis on precise cuff pressure control and reliability.

h) The compression on the urethral cuff shall have minimum drift to avoid loss of urine over a long period of time such as sleep period.

i) The connecting tube between the cuff and the controls shall have maximum flexibility to allow it to conform, without kinking, to the body configuration.

j) The design shall be such that it can be manufactured by use of established technology.

k) The design shall be such that the critical functioning parts will not be contaminated with blood which is obviously present during implantation.

l) If tubing connections during the surgical procedure are required, they should be designed for minimum risk of contamination and minimum time required to perform. The implant ideally would not require any connections.

m) The urethral cuff shall be of minimum size thereby requiring the least disturbance and rearrangement of adjacent parts of the body. Trade-off shall be made, however, with contact area versus force required to establish continence.

n) The control actuator shall be sized to be cosmetically nonintrusive, yet large enough for easy through-the-skin finger thumb operation.

To accomplish the objectives, an encircling cuff will be implanted which will provide enough squeeze on the urethra to restore continence, yet remain below the pressure that would cause necrosis. The controls for the cuff will be located in the scrotum for the male and the labium major for the female (Figs. 1 and 2). The complete assembly will be totally implanted. Through-the-skin pressure will actuate valve for periodically voiding the bladder.

Many concepts evolved from which five of the most promising were selected. These concepts, which included using springs at the cuff and at the controls, were further developed. Novel ideas of how to get the cuff to conform to the configuration of the urethra were considered. These concepts which include two hydraulic designs and three all-mechanical designs are presented in Figures 3 through 7 with discussions in the following paragraphs. A matrix of these concepts comparing them with a product presently on the market is shown in Figure 8. The first concept, i.e., the "Press-Relieve Bulb" model, was selected because hydraulics appeared to be the most reliable means for precisely controlling the pressure on the urethra while maintaining minimum cuff size.

A. Press/Relief Bulb Concept of a Urinary Prosthetic Sphincter

The press/relieve bulb concept (Fig. 3) would use a formed cuff and tube with a large capacity bulb. As shown in Figure 3, to close the urethra, the bulb would be squeezed. The check valve holds the fluid in the cuff. Overpressure is relieved by a small relief valve mounted in the poppet head of the check valve and is bled back to the bulb through a small hole in the stim. To urinate, the check valve is "pinched" open as shown in Figure 3.

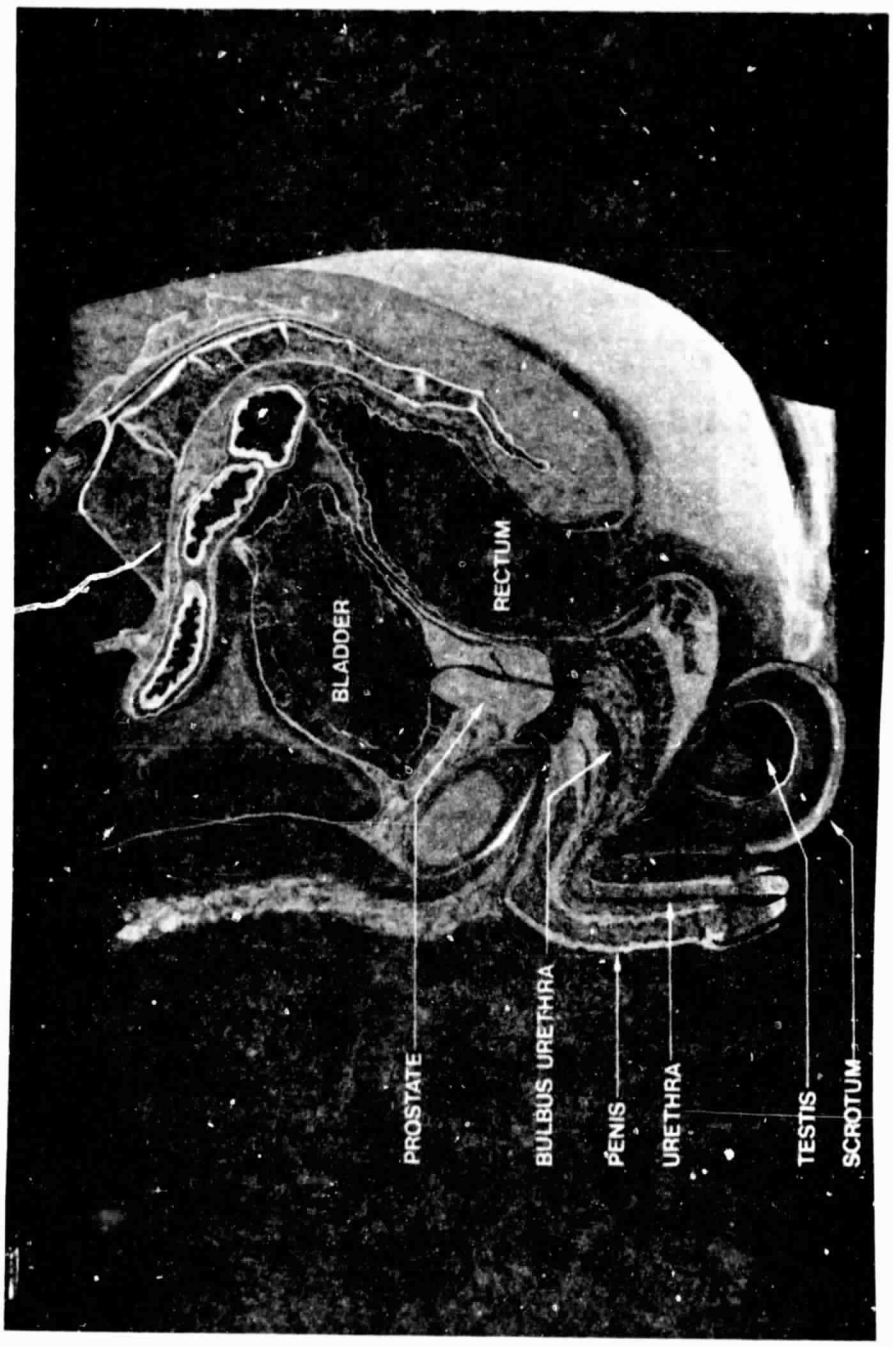

Figure 1. Lower urinary tract (male).

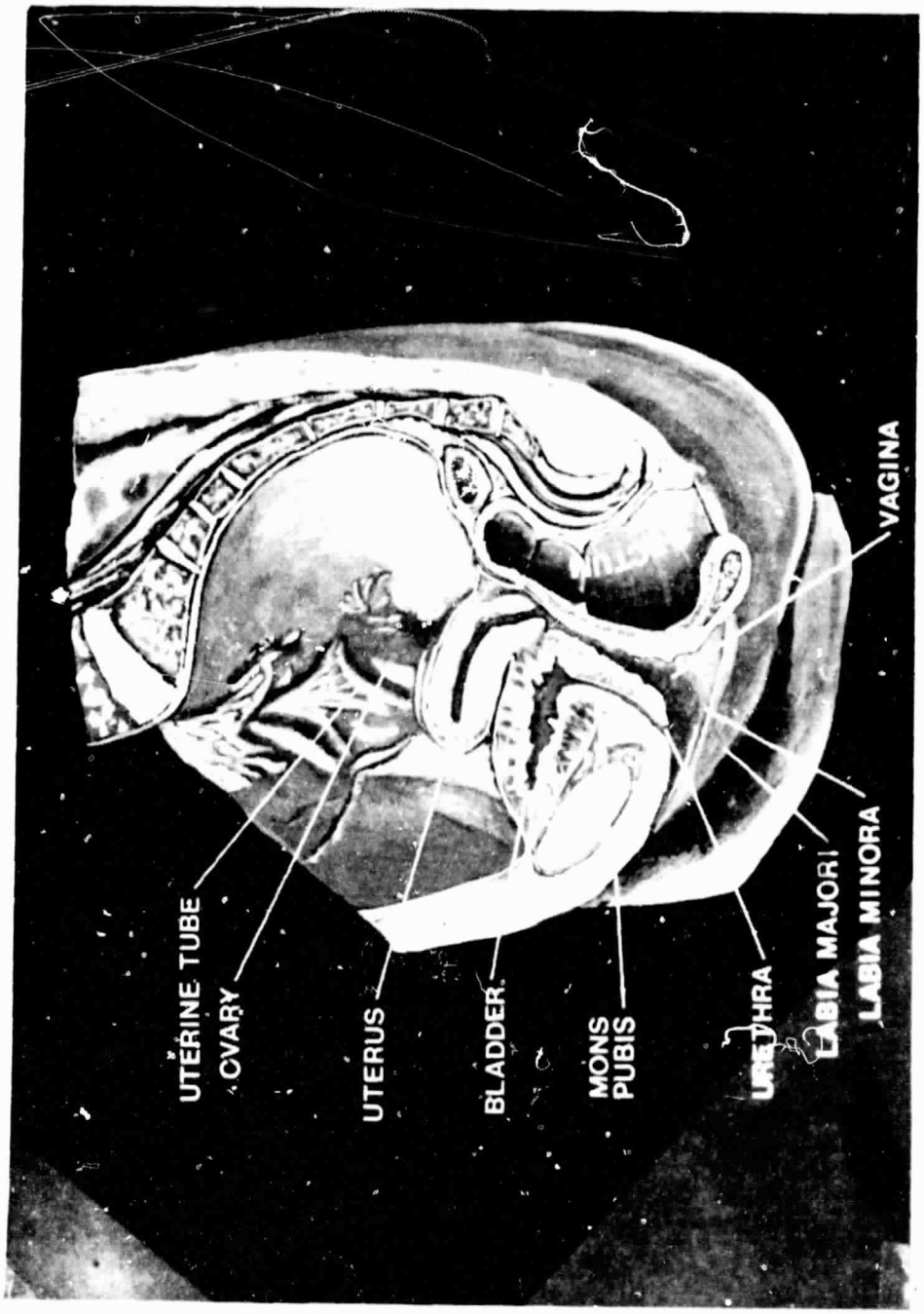

Figure 2. Lower urinary tract (female).

The main disadvantage of this concept is the relatively large bulb required to obtain the necessary volume. However, this does not appear to be a problem for the scrotum, but would definitely be a problem for the labia. A modification to the cuff could reduce needed volume.

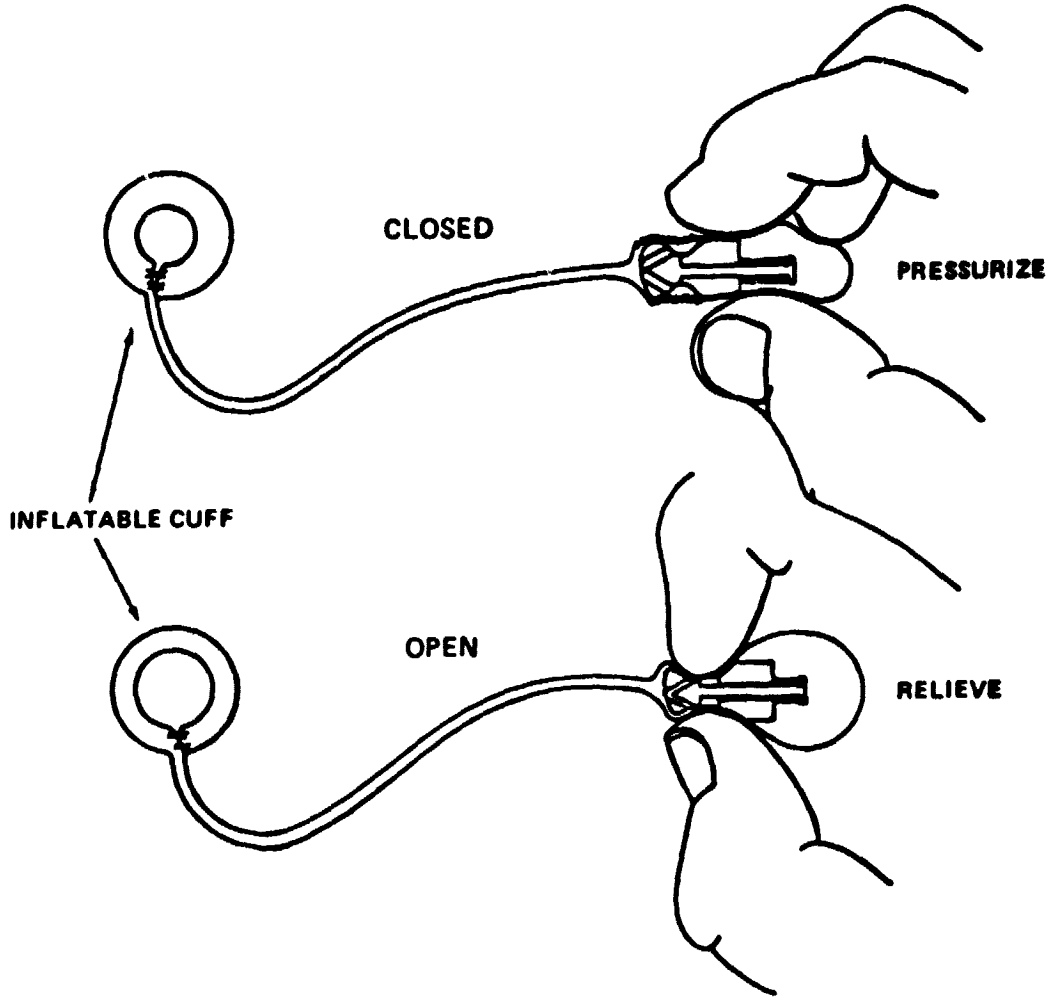

Figure 3. Press/relieve bulb concept of a urinary prosthetic sphincter.

B. Pressure Band Concept of a Urinary Prosthetic Sphincter

The pressure band concept (Fig. 4) uses a cuff filled with very small glass beads to evenly distribute the compression even over irregularities of the urethra. Glass beads are used in place of a fluid simply because this eliminates the failure mode of fluid leakage. To close

the urethra, a cord attached to the pressure band keeps the cuff compressed against the urethra by the "U" shaped spring. Proper urethral compression is set at time of installation.

To urinate, a finger and thumb will simply compress the "U" spring which releases the pressure on the urethra. Spring must be held for the duration of urination. A possible disadvantage is that tension in the cord would cause the tube to be somewhat stiffer than the tubing in other models, except during urination.

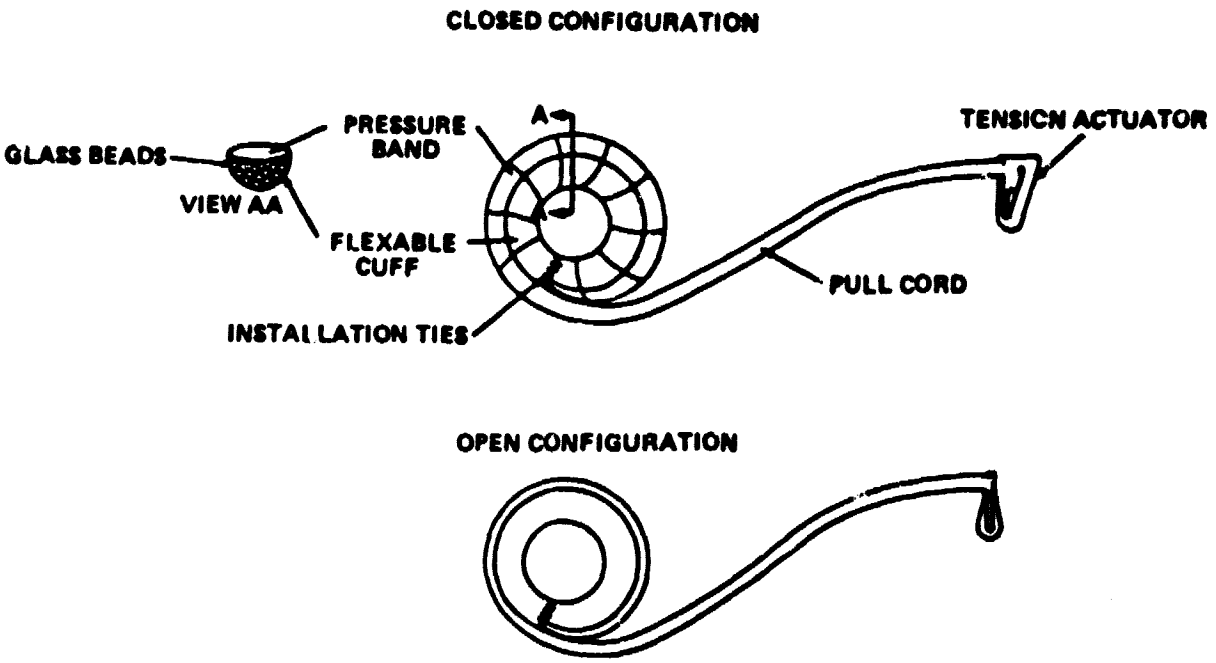

Figure 4. Pressure band concept of a urinary prosthetic sphincter.

C. Bourdon Tube Concept of a Urinary Prosthetic Sphincter

The bourdon tube concept (Fig. 5) uses a cuff filled with very small glass beads to evenly distribute the compression even over irregularities of the urethra. Glass beads are used in place of a fluid simply because this eliminates the failure mode of cuff fluid leakage. Due to the very low volume required to open the Bourdon tube, a small bulb can be used. The bulb must be squeezed for the duration of urination.

The main task to develop this concept is to obtain a Bourdon tube with correct spring rate for urethra compression in conjunction with variable size spacers for final setting of compression during installation.

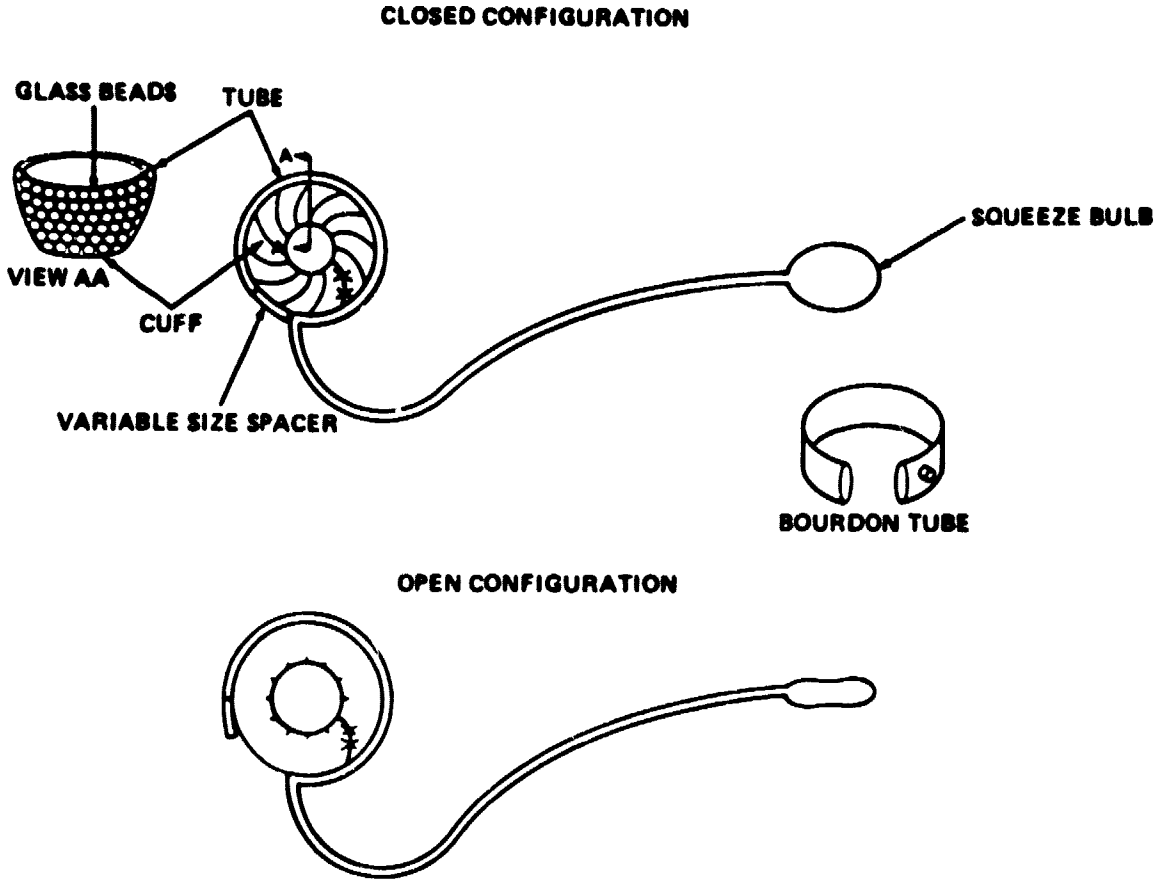

Figure 5. Bourdon tube concept of a urinary prosthetic sphincter.

D. Spring Cuff Concept of a Urinary Prosthetic Sphincter

The spring cuff concept (Fig. 6) uses a cuff filled with very small glass beads to evenly distribute the urethra compression even over irregularities. Glass beads are used in place of a fluid simply because this eliminates the failure mode of fluid leakage. A calibrated spring is used to hold the urethra closed. The compression is released by tension in the cord from the actuator mechanism. The tension starts to straighten out the cylinders thus opening up the spring band. Actuator mechanism is held in squeezed position for duration of urination.

Adjustment of urethral compression would be made during installation by selection of the right calibrated spring band and adjusting the cord to remove any excessive slack.

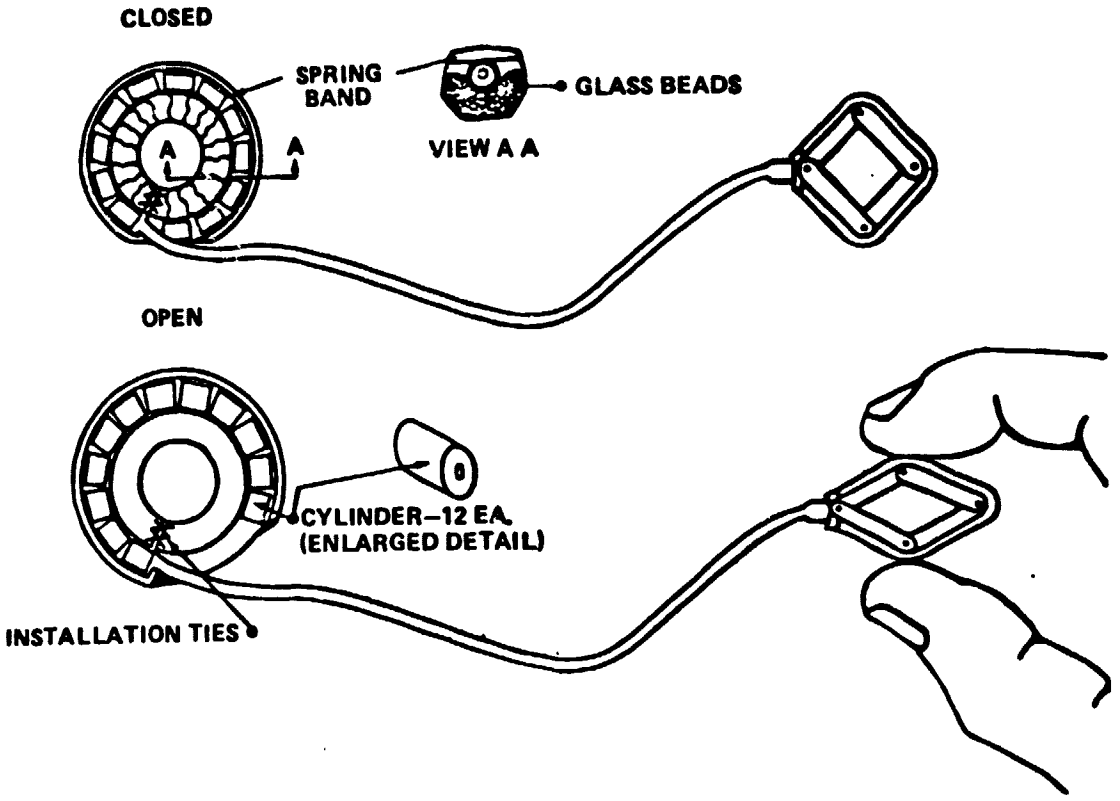

Figure 6. Spring cuff concept of a urinary prosthetic sphincter.

E. Vise Concept of a Urinary Prosthetic Sphincter

The vise concept (Fig. 7) uses a glass filled "pad" on the cuff housing and one on the piston. Urethral compression is provided by the calibrated coil spring. To urinate the activation mechanism pulls the piston off the urethra via the cord. Actuation mechanism must be held in the squeezed position for the duration of urination.

The main disadvantage is the relatively larger size of the cuff; however, it would be considerably smaller than shown in the figure. The cuff housing would need to be designed to allow quick change of the coil spring during installation to obtain correct urethral compression.

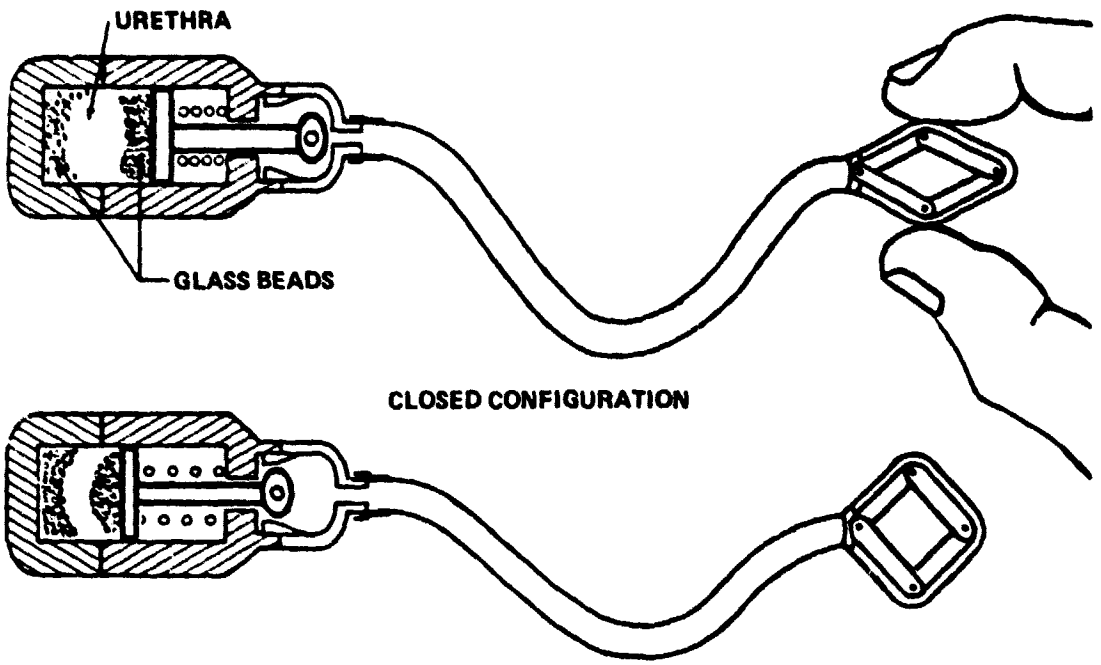

Figure 7. Vise concept of a urinary prosthetic sphincter.

III. HARDWARE DEVELOPMENT

The valving concept for the Prosthetic Urinary Sphincter was created by NASA/MSFC and given to Parker-Hannifin (PH) for their design and development because of their unique technology in miniature valves such as those already developed on the HEAO-B satellite and Viking space probe.

The Rochester General Hospital (RGH) was selected as systems contractor with the following general tasks:

a) Design cuff.

b) Design complete assembly (valving system provided by PH).

c) Write Product Development Protocol (PDP).

d) Manufacture prototype cuff.

e) Assemble complete prototype units.

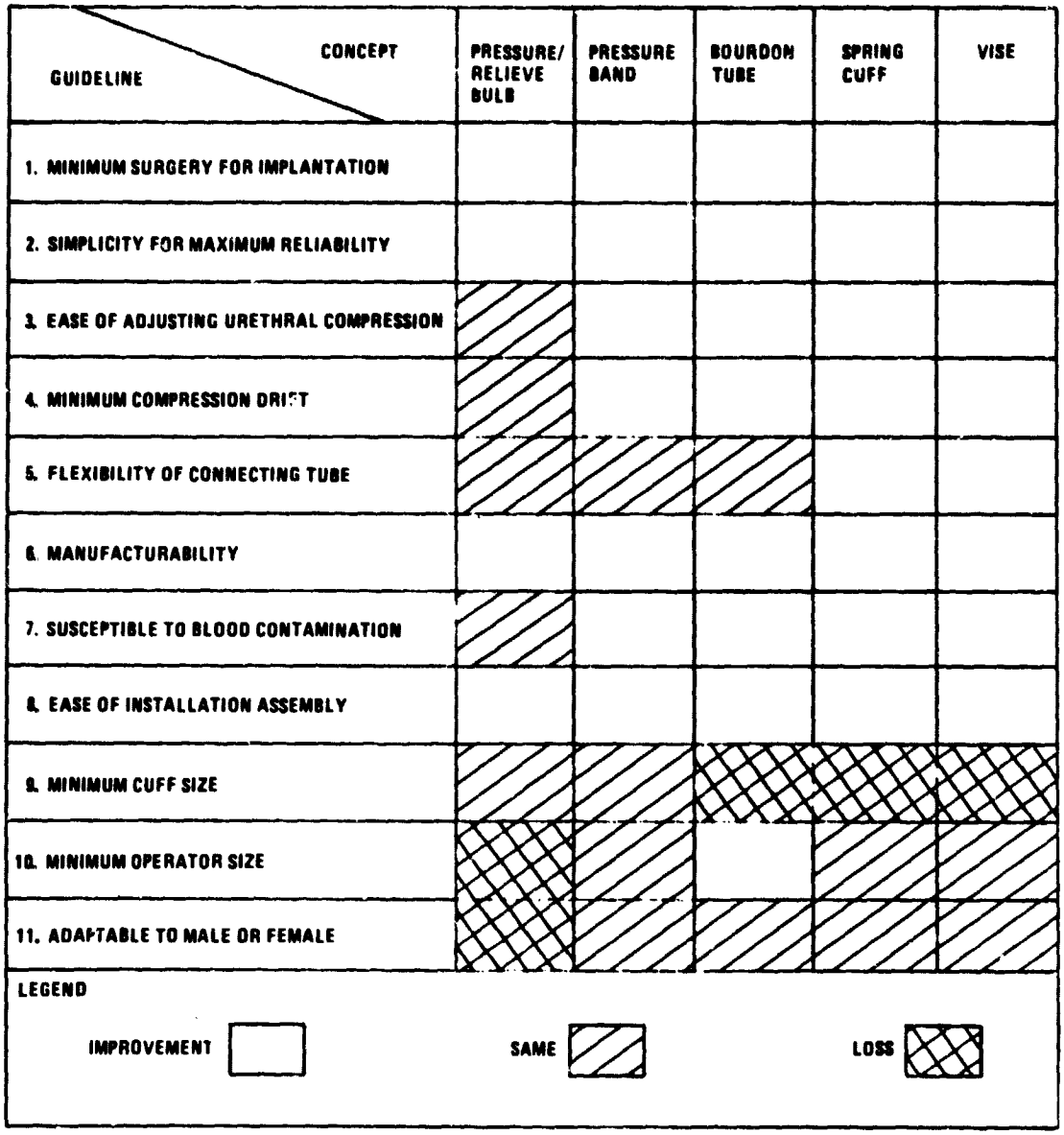

Figure 8. Potential improvement over product presently on the market.

f) Bench test units

g) Perform animal implants

h) Perform clinical implants.

RGH has contracted with Dow-Corning to be the System Manufacturer to provide the units to be used in the animal implants, with tentative plans for continued involvement during clinical implants and ultimately marketing the finished product. This forms the team which represents the best available technologies in each of the fields required to produce a marketable prosthetic urinary sphincter that will be accepted by urologists throughout the world.

Prototypes of the valving system have been manufactured by PH and have passed all required bench testing (Fig. 9). There have been no test failures, which speaks highly of Parker Hannifin's expertise in design and manufacturing. The simplicity aspect of reliability in the valve design is optimized in that one valve seat performs three functions, serving as a fill check, an over pressure relief, and a pressure release.

Figure 10 presents these functions. Thumb and finger squeeze bulb through the skin, producing pressure that lifts the ball off its seat allowing fluid to flow into the cuff which occludes the urethra. When the thumb and finger are removed, the ball reseats, holding the pressure in the cuff.

The pressure in the cuff must be enough to occlude the urethra, but must not be high enough to overcome the body's blood pressure. Should this occur the tissue under the cuff would die. To prevent such an unacceptable occurrence, the second valve function is accomplished by the over-pressure deflecting the diaphragm against the calibrated main spring to the point where the ball contacts the housing pedestal. This nudges the ball off its seat allowing fluid to pass back into the bulb. At the point where the cuff pressure reaches the calibrated setting (70 ± 5 inches of water), the cuff pressure/spring force reaches an equilibrium where the ball reseats and the valve is in a holding mode. The third function of the valve is to release the pressure in the cuff when the person chooses to void his or her bladder. This is accomplished by thumb/finger depressing the plunger which causes the pedestal to lift the ball off its seat allowing the fluid to flow from the cuff back into the bulb. The valving system is shown in more detail in Figure 9.

The main hardware design task facing RGH was the cuff, which had to interface with the human anatomy and be easy to install by the surgeon. Consideration of the effects of transient pressures caused by coughing and so forth was also required. The cuff that evolved is a two-compartment design, with a passive portion that is filled through a septum for precise fit after implant. The active compartment is connected to the valving system for pressurizing and releasing to accomplish

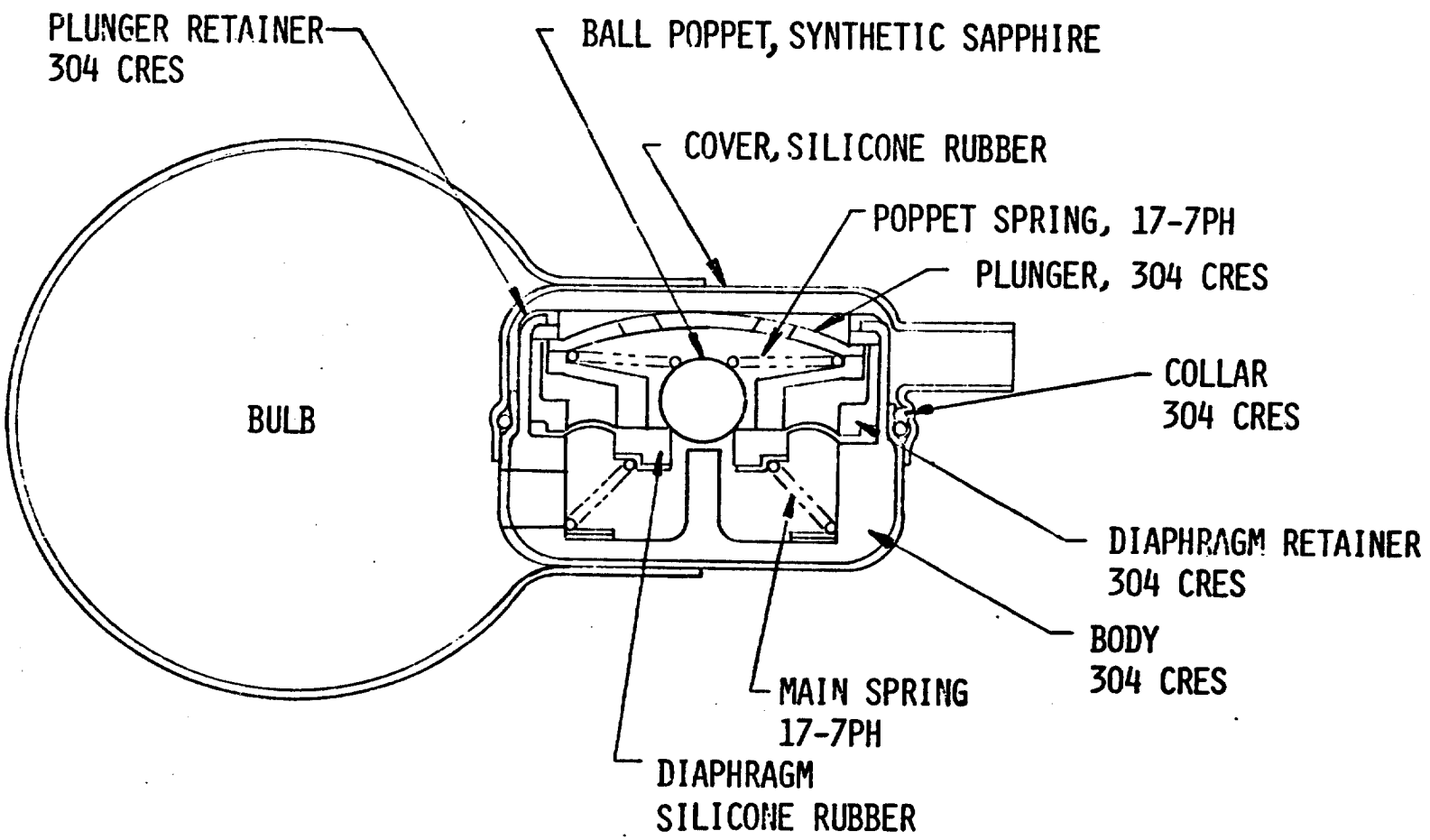

Figure 9. Valving system prototype.

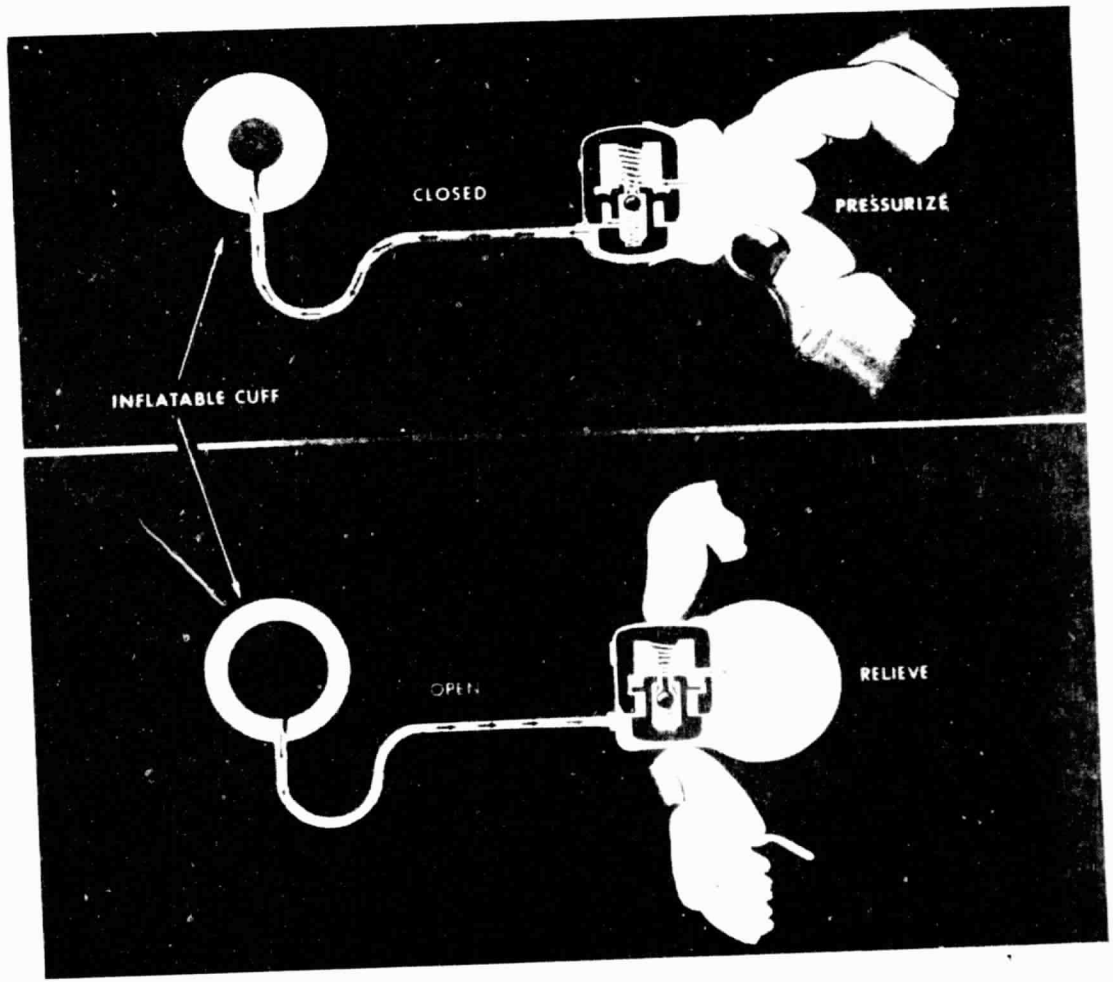

Figure 10. MSFC press/relieve bulb concept of a urinary prosthetic sphincter.

bladder control. RGH is also evaluating the amount of tissue ingrowth into the prosthesis required for anchoring and the potential operational interference it may cause as opposed to using materials that the body tends to encapsulate.

Cuff fit-up studies and implant procedures using cadavers, provide the checkout of prototype hardware and validation of generated implant techniques and procedures.

The first prototype cuffs were made by hand lay-up. Later, Dow-Corning manufactured from the basic RGH design a molded cuff which appears to be much more compatible with the human body because of its smooth contours when in the installed configuration.

RGH has written the Product Development Protocol (PDP) document to be submitted to the FDA for approval of this product. This document is intended to clear up any problems the FDA might have with the product so that when the development work is successfully completed, approval for marketing can be obtained without delay.

IV. CONCLUSION

In light of the satisfactory research and development effort conducted so far, indications are that a successful Prosthetic Urinary Sphincter will evolve. However, developing a satisfactory product is not enough to guarantee its use. Even though the potential market for a prosthetic urinary sphincter is considerably over a million, unless the product gains general acceptance by medical practitioners it will have only limited use. This is what happened in earlier attempts to market similar products. Although these early products had a lot of problems, in many cases they were very successful. Just as in aerospace, the medical community is very intolerant of failures. Once a product has had an unacceptable failure rate, the medical community is slow to give acceptance even after the product has been vastly improved.

The development process has been very gratifying in that so far the design ground rules have been met. Thorough testing and vigorous but responsible marketing procedures must be employed to ensure the ultimate success of this valuable product.

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APPROVAL

PROSTHETIC DEVICE FOR CORRECTION OF URINARY INCONTINENCE

By Ray Helms

The information in this report has been reviewed for technical content. Review of any information concerning Department of Defense or nuclear energy activities or programs has been made by the MSFC Security Classification Officer. This report, in its entirety, has been determined to be unclassified.

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