Project Statement

Accessible Incontinence Control Device

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Statement of Need

An accessible device needs to be developed that will help patients with disabilities control urinary incontinence. Urinary incontinence, the loss of ability to control the release of urine from the bladder, is a problem that affects about 12 million adults in the United States. Risk factors for urinary incontinence include age, obesity, sex, vascular disease, and other diseases such as diabetes and Parkinson’s disease. Urinary incontinence decreases a patient’s quality of life due to complications such as skin problems, urinary tract infections, embarrassment, and changes in personal life and activities.

There are currently several treatment methods available for patients with urinary incontinence. These treatments vary from behavioral changes to medical devices or surgical procedures depending on the cause of the incontinence. For patients whose incontinence cannot be controlled there are catheters and absorbent pads which are used to lessen the side effects of the incontinence. One problem with current incontinence control devices is that they tend to be very specific to a particular type of user; for example, specifically for a female with predictable incontinence due to high impact activities. It would be beneficial if a device could be developed that would help a wide array of patients or caregivers to control and manage urine flow, including patients with disabilities. Additionally, a patient would be able to assume greater control over urinary function if their incontinence control device had the ability to provide an indication of the status of the bladder.

Basic Preliminary Requirements

The goal of this project is to create a urinary control device that meets certain requirements. The device needs to be easily used by either a patient or a caregiver. Furthermore, it needs to be useable by a patient with disabilities including, but not limited to, partial paralysis, hearing loss, and restricted range of motion. The device needs to allow emptying of the bladder when desired and prevent emptying of the bladder otherwise. It should provide the user with a clear and understandable indication of the status of the bladder.

If the device developed is implantable it must be able to remain indwelling for thirty days, at which point it should be easily removed and replaced. Any material selected for the implantable device needs to be biocompatible. The material used cannot cause any adverse tissue reactions such as inflammation, irritation, or infection. It should be non-toxic, non-carcinogenic, and it should not cause an allergic reaction. If a metal material is selected the metal should not corrode in an in vivo environment.

Any incontinence control device that is designed needs to be tested in a simulated environment that is as close as possible to the environment in which the finished product would operate. It must comply with industry standards for any related urological medical devices. Brief descriptions of a few urinary incontinence devices that are currently on the market are included below.¹

- A urethral insert can be used by a woman with urinary incontinence on a limited basis. It is inserted into the urethra and functions similar to a tampon by preventing urine from leaking out. Urethral inserts are inserted before an activity

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that may cause loss of continence, and they are simply removed when the patient is ready to urinate.

• A pessary is a device that can be used by women who have urinary incontinence due to either a prolapsed bladder or uterus. It is a stiff ring that is inserted into the vagina and it needs to be removed regularly for cleaning.

• An artificial urinary sphincter can be used by men or women. It is a fluid filled ring that is implanted around the neck of the bladder. It is controlled by a valve implanted under the skin.

• A sacral nerve stimulator is implanted under the skin of your abdomen, and it resembles a pacemaker. The device emits electrical pulses through a wire that is connected to the sacral nerve. By stimulating the nerve the bladder can be better controlled.

• A catheter is a soft tube that can be used by a male or female. It is inserted into the urethra to drain the bladder. Male patients have the option of using external catheters which are attached around the penis similar to a condom.

**Basic Limitations**

- The first major limitation of this project is the time frame. The device must be completed by week 12 of the spring 2008 semester.
- Cost is another major limiting factor in the design of this device. The budget for this particular project is $2000.
- The environment in which the device will be tested is a limitation for this project. We do not have the resources or the experience required to be able to test this device in a real-life situation with actual incontinence patients. Despite limited testing abilities, the device needs to operate under standard temperature and pressure requirements for implantable devices.
- The equipment we can use for this project is limited to equipment and facilities on campus, specifically in the senior design lab and other School of Engineering facilities such as the machine shop.
- The device needs to be usable by patients with disabilities and symptoms that provide challenges beyond those provided by patients who suffer solely from incontinence.
- The size is a limiting factor; the device should be small, portable, discreet, and able to be hidden under clothes if applicable.
- The device must not affect other organs of the body outside of the organ(s) it is designed to effect.
- The device must comply with industry standards and FDA regulations. The device also needs to operate within safety standards, and safety regulations and quality requirements should be considered.

**Other Data**

There are three “clients” that this device would potentially able to help. They were selected from the list provided by the RERC-AMI National Student Design Competition. Brief profiles of the clients are shown below.
• Keisha is an 84-year-old female who suffers from hemiplegia on her dominant side sue to a stroke. She also has some hearing and memory loss.
• Jerry is an 82-year-old male with Parkinson’s and some recent Dementia.
• Jamie is a 42-year-old female with a T-11 spinal injury who is an avid wheelchair athlete.

Questions

• What is the physiology of the bladder?
• Would an implantable or external device be more reliable? Which would be more cost effective?
• Do any of the client’s conditions present specific related challenges we should be aware of?
• How will we simulate a testing environment?
• What are the operating principles of other devices currently used for incontinence?
• What are the size restrictions for the device?
• What type of biomaterials would be best for implantable catheter? Will this material cause any adverse effect?
• Will the materials chosen for the catheter interact with the medications used by the patients with different diseases?
• Is it possible to build the urinary device that will accommodate both male and female patients? What parameters should be taken into consideration so that it accommodates both?
• What are some restrictions should be taken into considerations when building this control device?
• How will the device monitor the patient(s) bladder control?
• What kind of software can be used to control the device?
• What kind of interface could be created for the user to control the device? (remote control, etc.)
• If an implantable device is used, where should it be implanted?
• What are the required strength properties? How much impact must it be able to withstand?
• What type of sensor would be available to indicate the status of the bladder?