Design of Wireless Real Time Artificial Sphincter Control System for Urinary Incontinence

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Abstract— **Urinary Incontinence is the most common health problem in old people, autistic kids and diabetic patients with significant social and economic impact in the quality of life. According to WHO, 20 million people are affected by Urinary Incontinence. This paper proposes an integrated architecture to continuously monitor the patients' bladder and remotely trigger the wireless artificial sphincter system using wireless power transfer in real time. After analysis, a few Ionic Electro Active Polymers (EAP) were selected to physically control the urethra. Possible designs using EAP polymer for urethra control are elaborated in this paper. This paper analyzes the major challenges of wireless power and data transfer and its impact on the design of the complete system. The proposed system provides a solution to continuously monitor the bladder and send alert messages to the control system that's on the patient's body. On receiving these alerts, patients' will remotely trigger the artificial sphincter control system to release the urine from their bladder. Thus the patients or caregivers can monitor the pressure inside their bladder and control urinal flow remotely by opening and closing the ionic EAP clip from outside. The system design has been simulated and tested with its different parameters and its results are discussed in this paper.**

Keywords—Urinary Incontinence, Ionic ElectroActive Polymer(EAP) polymer, Wireless power communication, Sphincter control, Transcutaneous Power

I. INTRODUCTION

Urinary Incontinence (UI) is the fortuitous leakage of urine or uncontrolled loss of urine from the bladder. Urinary Incontinence occurs if the sphincter muscles are not able to hold back urine. Patients may keep away from community events or else change their way of life as they need to wear pads to avoid leakage of urine. This will restrict their hobbies, work environment, and social settings that will propel them towards depression.

Mostly these patients will be given care in nursing homes or in their own homes. Providing care for patients who have UI is more time consuming than with patients with other diseases. They will have to be attended to more frequently, to avoid bad odor, leakage, and uneasiness for them and others.

This paper describes our objective to develop a system that will ease the life of patients and caregivers. The main challenges are monitoring the bladder pressure, the mechanical design of artificial sphincter system, operating the system remotely and the challenges in-body wireless communication. The major causes of this problem are nerve failure, loss of sphincter muscle control etc. To address both the problems we have designed two systems. The first one is a continuous bladder pressure monitoring system to monitor the bladder and issue an alarm when the bladder reaches above a threshold. The second one is an artificial sphincter control system that activates the sphincter functions remotely. This system is able to open and close the urethra from a remote location based on the messages received from the pressure monitoring system. Patients and caregivers can activate this system on a need basis.

The rest of the paper is organized as follows: Section II explains the current research to treat UI, devices that are used to manage UI, and some of the challenges faced by them. Section III explains the need for an EAP polymer to treat UI. Section IV describes the challenges in creating an artificial urinary sphincter system using EAP polymer and types of polymer that can be used for making actuators. Section V and VI describes the proposed architecture and the electrical modeling of the sensor and control system respectively. Section VI concludes with a summary of the invention as well as improvements that can be implemented using real time configurations.

II. RELATED WORKS

Currently products that are sold to manage UI is based on artificial control devices, electronic stimulation to stimulate sphincter muscles, or a simple catheter that feeds into a bag. Still in many hospitals, a mechanical catheter device is widely used that is bulky, unpleasant, and embarrassing for the patients. AMS 800^{TM} an artificial urinary control system is used for UI which is purely a mechanical device. In many cases, these devices have led to

978-1-4799-3704-2/14/$31.00 ©2014 IEEE

mechanical/non-mechanical failures that had caused urethral atrophy and erosion. This is a major embarrassment for patients. The problem here could be the cuff pressure that has to be decided at the stage of implantation.

Hached et al. developed an artificial urinary control system based on hydraulic and control modules and used Bluetooth for wireless communication [2]. They also tried to deploy ultra low power RF link in MICS band for better performance. However, their prototype is still based on manual pump and a modified AMS 800. This system is still uncomfortable for patients. To provide comfort, we use wireless modules in flexible devices. This system still causes discomfort and uneasiness for the patient. We address the above mentioned issue by providing maximum comfort and flexible device using wireless modules.

Another treatment option for UI is male InVance/AdVance [3]. However, this option is limited if patients have restrained incontinence or blood coagulation disorders. Although AMS 800 is successful, it could still be improved. If the device is not fitted properly, during the catheter surgery, it causes urethral erosion due to too much restriction. We use biocompatible EAP material to provide a solution for urethral erosion as well as wireless devices that are long lasting and less complex. The sacral nerve stimulator device is used to treat UI that involves complex implanting procedures with high cost of surgery. Sometimes the device can cause nerve pain and allergy for the patients [4]. While proposing the design, we consider the above issues and try to address them in this research paper. To solve the problem of UI and offer maximum comfort to patients, we suggest a new EAP based wireless, artificial, sphincter control system.

III. DESIGN CHALLENGES

Fig 1: shows the basic urinary bladder system.

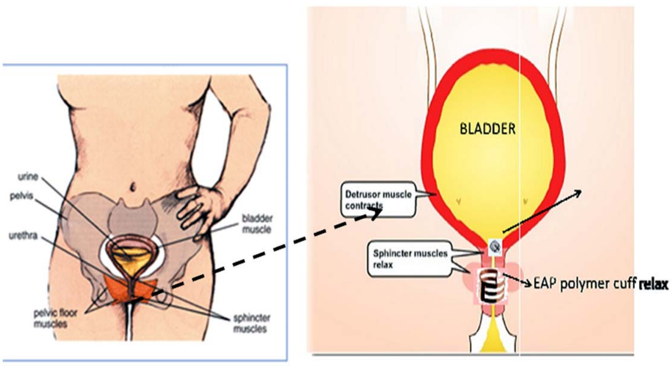

Fig 1: Overview of Artificial Sphincter Design

The two main reasons for using an UI device is the brain does not send status messages about the bladder and sphincter muscles don't work well anymore. Already existing devices are very cumbersome to use. Hence the first and the foremost requirement of our system are to make it easy for patients and caregivers to use. They should not experience any discomfort, and it should be compact and flexible. Second, the device should have near real time responses in order to empty the bladder when it is triggered remotely. Third, the artificial sphincter should be able to close and open remotely. Keeping that in mind, an artificial sphincter should be designed using flexible materials that are capable to handle very low voltages. The device should monitor and measure the pressure of the bladder continuously to determine the capacity of the bladder and its status. Fourth, the device should have a long battery life or another suitable wireless device should be considered. It is very important to design a device that does not damage the urethra or cause stress due to high voltage.

B. Challenges of Sphincter Design

It's necessary to design the EAP polymer actuator that does not interfere with blood through the tissue [8]. According to Cohen et al, bio compatible polymers should have special bio-active surfaces facilitating cellular proliferation, in soft tissue applications especially in EAP polymer [9]. Selecting a suitable EAP polymer is a great challenge as different ionic EAP polymer exhibits different properties and responses with electrical actuators.

The vital part of this system is the artificial sphincter made of EAP that is always in a closed state. When electrical actuation is given, it should open the urethra and when it is withdrawn, it should get back to the original state. If a polymer is selected, it should be modeled as an electromechanical actuator that is capable of displacing the maximum amount of urine on minimum voltage.

The artificial sphincter should be designed carefully keeping in mind that one cm band would be enough to compress the urethra to cause sufficient occlusion.

Another way of designing the EAP actuator is using a gel [10] or fluid type of material. We have to make a fluid containing water tight cuff with battery or energy harvesting methods etc can be used as energy source. EAP clip can be solid or malleable type of material. Another proposed design type is considering like a small 2-3mm cuff depending upon the tensile strength or elasticity of the solid type of material. Then we should go for a spiral form or folding hand type like a hair clip. The main challenge is developing a well design of EAP polymer material into convenient form just in our case gel polymer, cuff or clip based material. With advances in material science and polymer engineering developing an artificial sphincter using EAP polymer is possible.

C. The Challenges of Designing In Body Communications

One of the important features we are resolving in the artificial sphincter design is the wireless communication which emerged as a vital part in implantable medical devices. MICS band (401-405 MHz) is the standard frequency band used for in body wireless communication. Some devices use 2.4 GHz and PAN communication in the body area networks. Wireless monitoring allows patients to keep free from medical environments, decreasing health care costs etc. The main challenge is the power consumption and cost of small devices. However one of the important considerations is the effect of path loss due to wireless transfer through blood, fat and skin etc which hinders the wireless communications. Basically we considered this effect in our design.

IV. ARCHITECTURE DESIGN

In order to implement artificial sphincter it is necessary to design precise device with the help of wireless communication. The following fig 2 shows the overall architecture of wireless artificial urinary sphincter system based on EAP polymer. This architecture depicts the improvement from the current artificial sphincter devices.

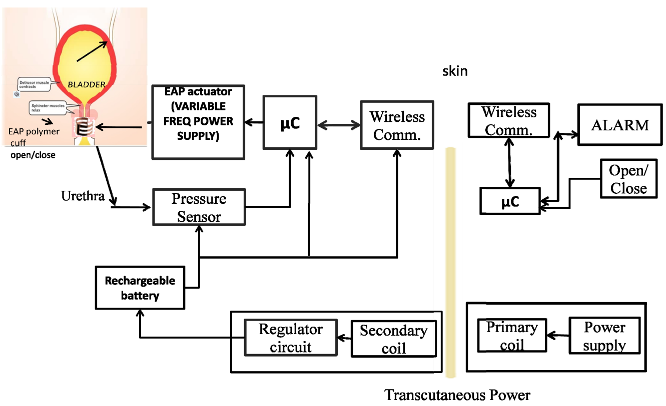

Fig 2: Architecture of Real time Wireless Artificial Urinary Sphincter System

The wireless based sphincter system consists of embedded module design for both inside and outside human body. Overall system architecture showed in fig 2 consists of two sections one part is kept inside the body along with EAP clip and pressure sensor. The other part will be kept outside having one control circuitry. The device must use silica gel for sealing in order to make the module bio-compatible. In order to make the system more efficient, careful circuit module design for inside and outside part is important. The circuit outside consist of microcontroller, wireless communication circuit and transcutaneous power transfer and alarm circuit. The in body system consists of power receiving circuit and pressure sensor circuit with secondary coil of transcutaneous power.

The working principle of this system is described as follows. The pressure of urinary bladder will be continuously monitored and sent to control circuit outside the body. When the pressure goes above a threshold, the system will generate audio-visual indication to the patient or caregiver. The patient can open and close the EAP based sphincter by pressing the buttons. The important modules in this design are described in the below section.

I. Transcutaneous Power

One of the important circuit configurations is the use of transcutaneous power transfer. It is necessary to give power to inside the circuitry modules [17]. It consists of transmitter and receiver with coils for wireless power supply and charging. Artificial heart and other device like artificial eye widely use inductive based coil due to small size and coil makes suitable for wireless applications. The primary coil is located outside the body and secondary coil is located inside the body, closely attached to skin. As coil produces electro-magnetic field within the transmitter circuit that will directly power the device or charge the battery. Other wireless methods like solar and ultrasound can also be considered.

II. Wireless Communication Module

One of the important parts in this design that keeps apart from other sphincter design is wireless communication device. For in body wireless communication, minimum current consumption with low interference and safety of device is necessary. Communication should be integrated between sender and receiver, if any frequency change occurs. Fig 3 shows basic wireless module.

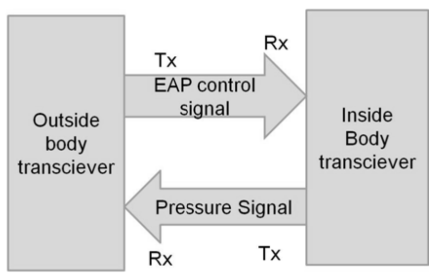

Fig 3: Wireless Communication module [17]

V. Material Selection for Sphincter Control

EAP materials are suitable for development of an artificial sphincter for the treatment of urinary incontinence. Fig 4 shows the general EAP bending upon voltage biasing.

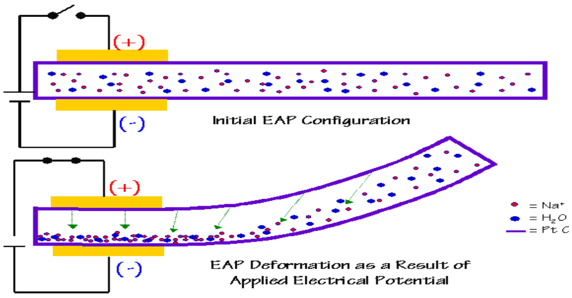

Fig 4: General EAP Polymer bending

Based on their activation mechanism, EAP materials are divided into Ionic and electronic EAP. Electronic EAP requires high actuation voltage that makes it non biocompatible. On the other hand, ionic EAP materials require only less voltage as low as 1-2 volts. From Cohen et al., [6] the most common types of ionic EAPS are Ionic Polymer Metallic Composite (IPMC), Ionic Polymer Gels (IPG), Conductive Polymers (CP), Carbon Nanotubes (CNT), and Electro Rheological Fluids (ERF). EAP materials that produce high actuation displacement and force are opening new avenues to bioengineering in terms of medical devices for diagnosis, treatment and assistive devices for disabled [7]. We are trying to develop an artificial urinary sphincter based on EAP circumscribed above urethra which extends from bladder to outside urinary bladder. As discussed above there are different types of polymer are available. Most of the polymers available are designed in the lab only. There are only a few polymers like Electro Rheological polymer, IPMC, Conducting Polymers (Poly-Propyl (PPy), Polyaniline), PVDF etc. available in the market. The important criteria for selecting a suitable polymer are that applying minimum voltage to get maximum displacement. Considering above discussed features if we get millimeter displacement of EAP clip will be enough for urine flow. Another characteristic of this polymers are as thickness increases with increase in resonant frequency, the maximum displacement will decreases [11].

1. *IPMC Polymer*

IPMC proposed in Panwar et al., [16] is the most common type of ionic polymer widely employed in space and artificial muscles applications. Figure 2 illustrates the displacement characteristics on voltage actuation of IPMC polymer having thickness of 0.18mm, 0.2mm, and 0.8mm respectively. It is clear that displacement varies with respect to voltage.

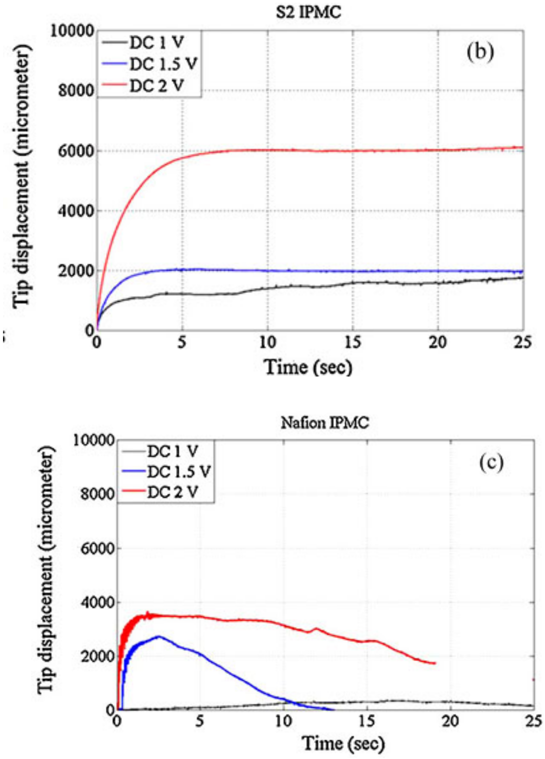

Fig 5: Displacement v/s voltage characteristics of S1 IPMC, S2 IPMC and Nafion IPMC polymers [16]

2. *Conducting Polymers*

Conducting polymers are one of the promising materials nowadays used in making artificial muscles for various applications.

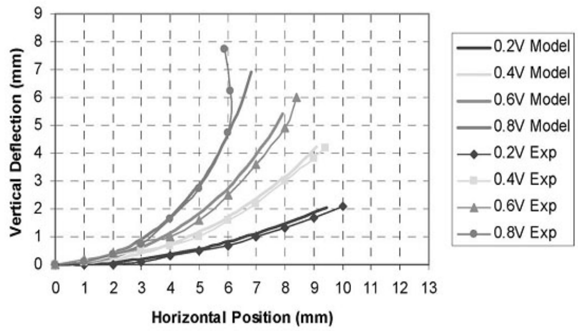

Fig 6: Bending of experimental and theoretical curve of PPy actuator [15]

3. *EAPap Actuator*

Fig 7 illustrates the displacement of EAPap actuators, which has direct relation to voltage and material characteristics. The maximum displacement occurs at resonance frequency on applying voltage.

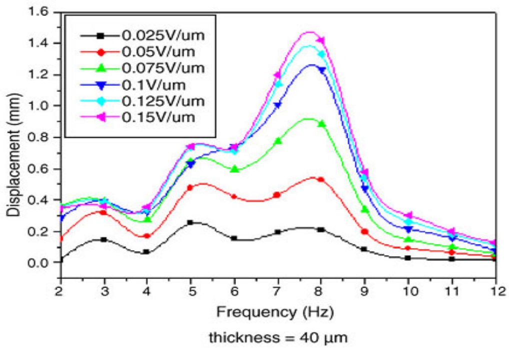

Fig 7: Thickness v/s displacement upon voltage applied. [16]

In order to implement and modeling of urinary bladder system two remote PC‘s are considered. Implementation consists of three sections as follows control and sensor part and wireless communication using micaz mote. One of the PC as shown in fig. 7 act as sensor circuit for pressure monitoring and other PC act as control circuit modeled as watch. We used Proteus Professional 7.0 Software Tool for doing simulations and real time in both the PC’s. The circuit diagram for the both control circuit and sensor circuit are shown in fig. 8 and fig 9. For wireless communication, micaz motes are used which is connected to each PC.

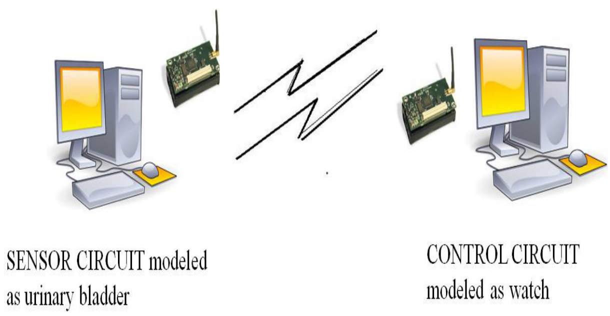

Fig 7: Urinary bladder pressure monitoring PC implementation

Proteus Professional is one of the best electrical simulation tools with inbuilt electrical components that can be used in virtual environment. In order to model urinary bladder we used MPX4115 pressure sensor, in which pressure values can be varied. Serial communication is provided between the PC and Universal Asynchronous Receiver and Transmitter (UART).

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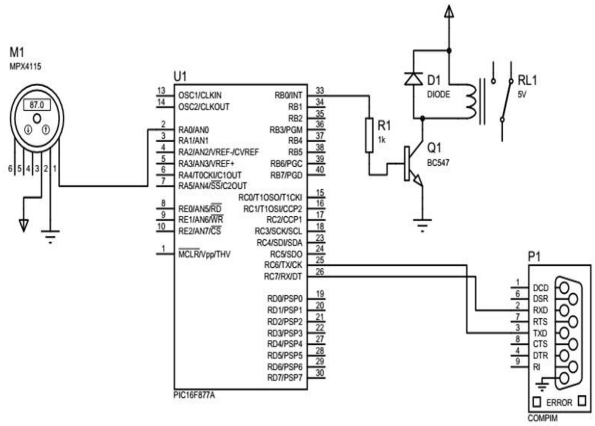

Figure 3: Sensor Circuit for Bladder pressure monitoring

The working principle is described as follows. In the control part like in a watch, a patient can open and close the urethra by pressing the ‘open’ and ‘close’ buttons. The serial command goes through the virtual terminal port to UART via Micaz mote to the other PC which is modeled as sensor part for urinary bladder pressure monitoring.

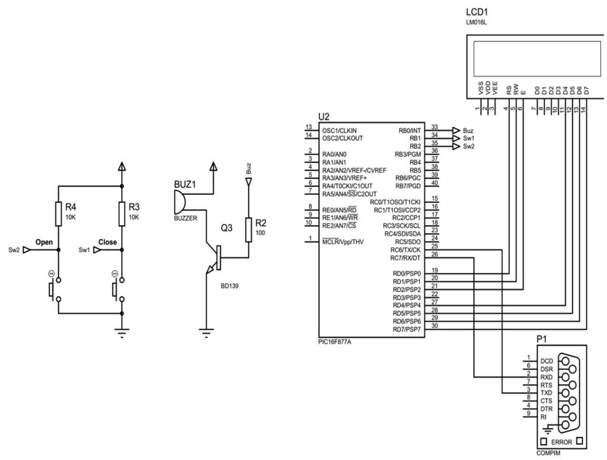

Fig .9: Control circuit for pressure monitoring with alarm

Correspondingly relay get opened or closed, which is modeled as opening and closing of urethra. LCD will display the corresponding commands. It is programmed like, when pressure values exceed more than threshold it starts to produce alarm. This is done because the patient will know the level of urinary bladder whether it is full or not. Wireless communication ensures the remote control of entire system. Thus above implementation shows a wireless based modeling of urinary bladder control and sensor system.

Using Proteus simulation software, we animated the entire system to make it good feel about urinary bladder control and artificial sphincter system. Fig.10 and Fig.11 depicts entire simulation for the control and sensor circuits.

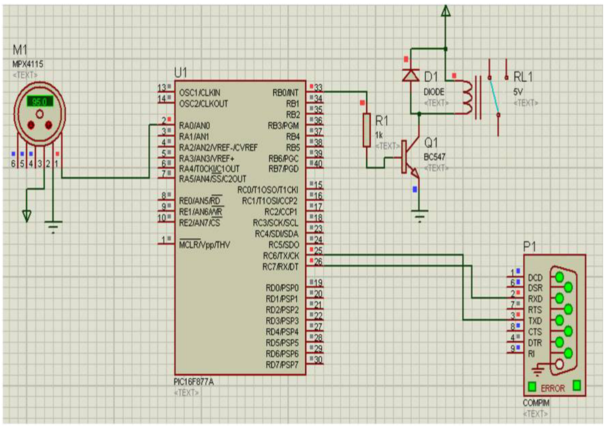

Fig 10: Simulation of Sensor module for Pressure monitoring

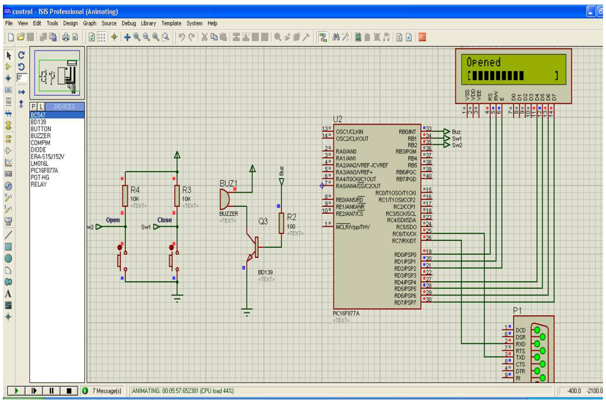

Fig 11: Simulation for Control Module with alarm

The simulation in virtual environment is a first level implementation of the wireless artificial sphincter implementation remotely.

VI.CONCLUSION AND FUTURE WORKS

This research work aims to develop a novel sphincter system that helps the patients with urinary incontinence. The challenges in developing this system has been explored and analyzed. Using those results an innovative design for a real-time artificial sphincter control system has proposed. The development of complete system involves design of several subsections such as design of EAP actuator, in body wireless power transfer and wireless communication, real time pressure monitoring of urinary bladder etc. We have performed electrical modeling of entire system and the results shows that system will work in the required real time configurations. As our future works we will develop this proposed real time wireless artificial urinary sphincter system and evaluate with respects to parameters like accurate time response for opening and closing of urethra, in body wireless communications and durability of device with urethra corrosion resistant.

ACKNOWLEDGEMENT

We would like to express our immense gratitude to our beloved Chancellor Shri. (Dr.) Mata Amritanandamayi Devi for providing good motivation and inspiration for doing our research work.

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