Abstract— Under different neurogenic conditions patients may suffer from lack of Bladder fullness sensation which drastically affects patient’s quality of life and may even lead to serious kidney damage. To help the patients to void voluntarily and resolve the problem of enuresis several methods were proposed. This paper aims in designing a Non-invasive NIRS wearable sensor for bladder fullness sensation and alerting them about the bladder fullness. The urinary continence subject was studied by designing a wearable belt of NIR sensor. The belt is worn over the patients body. The measurement was first made in vitro using using phantom solution, which simulates the bladder fullness. The Differences in the detected output signal for before(full) and after(empty) voiding in patients was estimated.

Index Terms—Wearable sensor, Bladder Dysfunction, Biomedical cognizance, Near infrared spectroscopy

I. INTRODUCTION

The main role of the bladder is for the collection and expulsion of urine. At birth the bladder stores and discharges urine in a rhythmic manner which is independent of central cortical control. During the first five years of life this pattern comes under voluntary regulation, particularly during a period of adult supervision and during biofeedback known as training.[1] Similar methods are used in the treatment of incontinence. The majority of the normal bladder cycle is spent storing urine at increasing volumes with a continuously low intravesical pressure which gradually results in central awareness. Normal adult bladder function is characterised by quiescence of the parasympathetic efferent pathways and absence of involuntary bladder contractions during the filling phase. In addition, the pressure in the bladder remains low during filling because of the almost infinite compliance of the bladder until capacity is increased. This is largely achieved by the arrangement of detrusor muscle[7] fibres, reflex inhibitory pathways and the absence of connective tissue restriction, particularly by collagen. To have control over urination, the bladder muscles and other parts of urinary tract, the nerves controlling the urinary system, the ability to feel and respond to the urge to urinate. Biomedical applications of near-infrared spectroscopy (NIRS) utilize non-invasive optical technology to monitor alterations in tissue oxygenation and hemodynamics in real time via changes in concentration of the chromophore oxygenated and deoxygenated hemoglobin. Transcutaneous monitoring over the bladder as it fills and empties provides unique physiologic information, as hemodynamic variations in the organ’s microcirculation and alterations in oxygen supply, demand and consumption in the detrusor muscle can be inferred. Such information, which is not available by other means, enhances investigation of patients with bladder dysfunction, offers new insights into the disease and hence potentially impact choice of pharmaceutical agents. Problem voiding is common, but the principal diagnostic test is invasive, and gives limited diagnostic information and therapeutic information (pressure/flow). Continuous wave NIRS[2] instruments are used for bladder monitoring. Initially NIR light was laser-generated; now miniaturized self-contained devices using light emitting diodes, spatial configuration of emitters to detector, and wireless capacity enhance research scope and clinical monitoring potential. NIRS bladder chromophore patterns during filling and voiding differ in health and disease. Such data are physiologic because NIRS only detects changes during events in the voiding cycle, pathologic changes mirror NIRS-derived effects of physiologic events (hypoxia/ischemia/fatigue) observed in other tissues (muscle/brain/spinal cord), and animal data and independent
research corroborate the principal findings. In vivo biomedical applications of NIRS have been employed for more than 30 years, and using near infrared (NIR) light in the 700–1000 nm wavelength range enable changes in the concentration of hemoglobin in the microcirculation of tissue to be measured in real time. NIR light has unique properties in terms of penetration through the skin and into tissue, and also as photons are absorbed differently at individual wavelengths by naturally occurring compounds with light affinity in tissue called chromophores.

Behnam Molavi et al [1] have designed and developed a compact wireless optical sensor prototype for continuous noninvasive monitoring of the bladder in patients who are unable to sense when their bladder is full. The aim of the study was to determine when the bladder is empty or contains a small volume of urine and when it becomes full, by using the absorption properties of water at a wavelength of 950 nm. In this paper 950nm IR Led and OPT101 detector is used. Joshua N et al [2] they modeled bladder system which accurately emulates various phases of filling and voiding of the human bladder. The model of the bladder consists of air filled latex balloon immersed in a container attached with the sensor unit. Andrew Macnab et al, NIRS is used to monitor the changes in [O2Hb], [HHb], and blood volume [Hb] reflecting hemodynamic and oxygenation related volume [Hb] reflecting hemodynamic and oxygenation related changes in the bladder during voiding. NIRS is a non invasive parameters for evaluation of voiding dysfunction with wireless technology. Regine Choe et al prepared Liquid phantoms which serve as the gold standard to test the instrument and the algorithm using a combination of absorbers and scatters with known spectra. The phantom solution contain intralipid mixture of egg yolk phospholipids glycerin, soybean oil and NaOH has been added to adjust the pH so that the final product pH range is 8.

II. BLADDER VOLUME DETECTION USING NIRS

Transcutaneous NIRS[5] through the skin of the abdomen over the bladder provides unique functional information from the detrusor muscle in the anterior wall of the bladder as the organ fills and empties. The changes in chromophore concentration derived provide insights into the physiology of hemodynamic variations in the organ’s microcirculation and alterations in oxygen supply, when changes occurring in the detrusor muscle are compared to NIRS data from other tissues where specific physiologic events have been studied. An inexpensive, wireless and easy to use device as a noninvasive method for monitoring the point in time when the bladder becomes full, with lower computational requirements and complexity compared to ultrasonic continuous measurement systems is designed. This method employs the properties of NIR light absorption of human tissue and water to measure changes in water content in the field beneath a NIRS [6] device. Because the bladder rises out of the pelvis below the anterior abdominal wall as urine accumulates within the organ, this device can detect when a bladder capacity previously defined by ultrasound is reached. When the bladder rises into the NIRS light field as it fills, the water in the urine it contains results in high light absorption that generates an abrupt decrease in the light intensity sensed returning to the NIRS device.

This event can be set to activate an alarm; potentially benefiting patients with any of the problems related to an inability to sense when their bladder is full. The major absorbing chromophore of physiologic interest in NIRS wavelength window are Hbo2 and HHb. Water which is the main compound in urine (95%), also has an absorption peak at 975nm and this peak can be used to detect urine content in the bladder and differentiate between an empty bladder, one with low volume, and a full bladder. In NIRS, light in the NIRS window is used to interrogate the tissue. A light source (emitter optode) is placed on the skin surface, with a detector (receiver optode) placed a few centimeters away. Changes in the light attenuation due to absorption of the transmitted light by chromophores in the tissue (HbO2, HHb and water) are detected by the receiver optode.

In this method, it uses variance form to measure concentration changes in the tissue. The active depth of penetration in this method is approximately half the separation distance (SD).

Self-contained wireless NIRS devices have been utilized for a wide range of studies involving brain, muscle, and the bladder. Such devices have the advantages of imposing no motion restriction, which means subjects can engage in active physical pursuits, and suitability for longer term monitoring in ambulant patients. Wireless NIRS devices often use Light Emitting Diodes (LEDs) as the light source. Even though LED based NIRS systems have a broader spectrum compared to laser-based NIRS devices, they have the benefits of being small, low weight, inexpensive, compact and self-contained and can be applied directly on the skin surface without need for the fiber-optic cables required for laser systems.

The hypothesis for our NIRS-based method for monitoring the level of urine in the bladder and detecting bladder filling to capacity was that with an LED light source using a wave length close to the absorption peak of water at 975 nm, a self-contained NIRS device placed on the lower abdominal skin would detect water (urine) when the bladder enlarged into the NIRS light field. Although ultrasound sound data indicates that as the bladder fills naturally, the dome of the organ rises within the abdominal cavity bringing the bladder and the urine it contains into the NIRS light field. The water contained in the bladder then absorbs light, causing a decrease in detected light intensity.

In this method, it is the urine in the bladder (rather than the anterior wall of the bladder) which is indicated by a Boolean integrated with a comparator in LabVIEW (when the
bladder is full/empty). The level of bladder fullness that corresponds to the urine capacity that needs to be detected will depend upon the patient's symptoms and his/her underlying medical condition. The NIRS device is then positioned on the lower abdominal skin so that it indicates when the bladder is full corresponds to the capacity required for that patient.

A. Electronics

The hardware consists of a NIRS device[7,8], that is worn by the subject on the abdominal skin. The block diagram of the sensor is shown in Fig. 1. The sensor is made using commercially available components on a printed circuit board and is enclosed in a custom made 3-dimensionally (3D) printed enclosure. The source LED and the detector are mounted using standard surface mounting technology. The source and detector are mounted on the front side of the enclosure and are wired to the LabVIEW interface. All the signal controls, sampling and processing are performed by LabVIEW components. The source LED is a 950 nm LED 55 nm spectral half width, 16 mw nominal power driven by a driver. Even though the absorption peak of water is at 975 nm, the 950 nm source output is still highly absorbed by water as the spectral bandwidth of the source covers 975 nm wavelength.

The light detector is a 5.22mm monolithic photodiode integrated with a transimpedance amplifier (TIA)(OPT101)[4]. The responsivity of the detector is 0.45A/W at 950 nm and the transimpedance amplifier is set to provide a gain of $6 \times 10^6$ V/A and a bandwidth of 2.5 KHz. The amplifier’s output is filtered and sampled. The filtered output wave is continuously monitored to set the threshold level (comparator value) for which an boolean is set.

The sensor is powered with 5v and interfaced with National Instruments DAQ Acquisition system (NI USB 6009). The observed data can be stored in the PC using write to measurement file tool in LabVIEW 2014 for further analysis. The sensor is encapsulated in a custom made 3D printed enclosure. An extruded feature that houses source and detector provides higher coupling with the tissue and also reduces the ambient light interference.

B. Firmware

The firmware controls the source LED current, data sampling process, logs data and communicates with a PC for command reception or data transmission. To limit the total tissue exposure and minimize the possibility of tissue thermal overheating, the power has to be kept within a safe range. An average power limit of 2 mW can be considered safe and has been used as the limit for similar NIRS devices.

The LED’s positive terminal is connected to a 5V Supply given from the DAQ Assist device (USB 6009) interfaced with the PC. The LED draws a maximum of 73mA from the 5V Power Supply by connecting a resistor of resistance 68ohm to the positive terminal of the source led. The detector’s output signal is initially sampled at 5kS/s and continuous samples are recorded. These recorded samples are then stored in write to measurement file for further analysis.

To prevent potential interference from ambient lighting, background light level is sampled such as sampling rate allows use of butterworth topology with bandpass filter whose cutoff frequency ranges between 100hz and 2450hz.

III. INVITRO EVALUATION

The long-term stability of the sensor was evaluated by...
continuous recording of data from a phantom using the sensor for 30 minutes after a warm up period of 1 minute. The aqueous phantom was prepared. The phantom scattering and attenuation parameters are chosen to be close to those of abdominal tissue (in particular, abdominal fat with attenuation coefficient). The phantom was made with 20% intra-lipid mixed with ink to obtain desired optical parameters. The difference between the initial and final reading normalized to the initial signal value was recorded as the drift. The device shows 1.5% drift over the period of 30 minutes. To verify the capability of the sensor in detecting bladder level changes in vitro, a simple setup as shown below was employed. The setup was made to simulate the bladder, urine and the abdominal tissue during bladder filling and voiding. A latex balloon was submerged in a phantom prepared as described in the previous section in such a way that the balloon neck is attached to the top of the container. The balloon can be filled with water from the top using a syringe. The distance of balloon from the side-walls was 1.5 cm when full and 6 cm when empty. The sensor was placed on the side-wall of the cylindrical container and secured with medical adhesive tape. The sensor detected output signal from the phantom setup was interfaced using DAQ (data acquisition system) and voltage differences was observed.

Fig 4: Steps in in vitro evaluation

Fig 5: Schematic diagram of the in vitro setup for simulating bladder filling

IV. INTERPRETATION OF DATA DETECTION FROM THE SETUP USING LAB VIEW

The recorded data is taken from LabVIEW data using read from measurement block as shown in fig 4. Then, the output of the block is connected to the statistical data block for signal analysis. The signal is analysed using different parameters such as variance, standard deviation, RMS and maximum in order to set the threshold level. The spectral measurement block performs FFT-based spectral measurements, such as the averaged magnitude spectrum, power spectrum, and phase spectrum on a signal. The averaged magnitude spectrum of the peak is displayed by creating a graphical indicator. Then the RMS value of the magnitude spectrum is given as the input signal to the amplitude and level measurement block where the positive peak signal from the recorded data is observed. And also the histogram of the data is graphically indicated by a waveform. The following table illustrates the potential differences for empty and full bladder taken for ten different subjects.

Fig 6: Analysis of the signal detected from the sensors after filtration

V. RESULTS AND DISCUSSION

The belt is worn by the subject. The signal is acquired using the detector OPT101 from the NIR Sensor. The reading is acquired through arduino under in vitro evaluation and for in vivo evaluation, the signal is acquired from the subjects before and after voiding using DAQ acquisition. Taking the variance for the in vitro setup, the values of variance deviates for filled and empty balloon. The acquired signal through DAQ under in vivo evaluation is analysed using LabVIEW. The statistical parameters are extracted from the voltage signal recorded from the subjects. These values were tabulated and were found that the parameters Variance, Standard Deviation, Maximum and Positive peak had a deviation in the recorded signal subject to conditions before and after voiding. All the parameters had an increased value after voiding. When the bladder gets filled, the value decreases subsequently.
Fig 8 and 9 shows the status of the recorded voltage before and after voiding. The graphical indicator clearly depicts the difference voltage between bladder fullness and empty. Boolean indicator shows the status of voiding which is an output that gives the correctness of measurement. It clearly indicates that the signal is more

<table>
<thead>
<tr>
<th>Subject</th>
<th>Condition</th>
<th>Maximum voltage (mV)</th>
<th>Variance in measurement</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BEFORE</td>
<td>0.0004</td>
<td>0.02</td>
<td>0.06</td>
</tr>
<tr>
<td>2</td>
<td>AFTER</td>
<td>0.002</td>
<td>0.04</td>
<td>0.12</td>
</tr>
<tr>
<td>3</td>
<td>BEFORE</td>
<td>0.0009</td>
<td>0.03</td>
<td>0.08</td>
</tr>
<tr>
<td>4</td>
<td>AFTER</td>
<td>0.002</td>
<td>0.05</td>
<td>0.01</td>
</tr>
<tr>
<td>5</td>
<td>BEFORE</td>
<td>0.0012</td>
<td>0.036</td>
<td>0.08</td>
</tr>
<tr>
<td>6</td>
<td>AFTER</td>
<td>0.003</td>
<td>0.056</td>
<td>0.13</td>
</tr>
<tr>
<td>7</td>
<td>BEFORE</td>
<td>0.004</td>
<td>0.04</td>
<td>0.11</td>
</tr>
<tr>
<td>8</td>
<td>AFTER</td>
<td>0.002</td>
<td>0.05</td>
<td>0.17</td>
</tr>
<tr>
<td>9</td>
<td>BEFORE</td>
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<td>0.01</td>
</tr>
<tr>
<td>10</td>
<td>AFTER</td>
<td>0.002</td>
<td>0.05</td>
<td>0.13</td>
</tr>
</tbody>
</table>

VI. CONCLUSION

The method proposes a compact NIRS device for continuous non-invasive monitoring of the bladder in patients who are unable to sense when their bladder is full. This is a significant clinical problem in individuals with abnormal (neurogenic) bladder function, such as patients affected by stroke and/or spinal cord injury, elderly patients with incontinence, and children with persistent enuresis. The device is capable of differentiating between when the bladder is empty or contains a small volume of urine and when it becomes full, by using the absorption properties of water at a wavelength of 950. As a future work, with such a device used as a sensor with an alarm, it is hence feasible to warn the subject when the volume of urine in his/her bladder reaches a pre-determined threshold of the bladder capacity. This would potentially enable patients at risk for urinary retention to protect themselves from renal damage, elderly subjects prone to incontinence to retain the ability to void voluntarily, and children with problematic enuresis to become conditioned to when they need to wake to void. In later development phases, the capacity value can be defined for individual patients, and the fullness and position of the bladder beneath the abdominal skin such that this volume corresponds to can be assessed by ultrasound.

REFERENCES


