A Dynamometer-based Wireless Pelvic Floor Muscle Force Monitoring

Batoul El-Sayegh[1,2], Chantal Dumoulin [2,3], Mohamed Ali[1,4], Hussein Assaf[1], and Mohamad Sawan[1,5]

***Abstract*— This paper covers the design and implementation of a proof of concept for a wireless system measuring pelvic floor muscle forces based on a dynamometer. The proposed device is the main component of a novel assessment tool intended for pelvic floor muscle rehabilitation in women suffering from urinary incontinence. The proposed system allows the physiotherapist to wirelessly monitor variation in pelvic floor muscle forces during assessment or training. Wireless communication is provided by a Bluetooth low energy transceiver and a corresponding interface designed for this purpose. Force measurements are sensed with strain gauge precision sensors operated in a Wheatstone bridge configuration. The designed module consumes 14 mW of power in operating mode. System design and experimental results are reported and discussed.**

***Clinical relevance*— This paper details the successful development of a wireless measurement system for the assessment and training of pelvic floor muscles in women with lower urinary tract dysfunctions (urinary incontinence and pelvic organ prolapse). The system can be used by both clinicians and patients.**

I. Introduction

The integrity of women's pelvic floor muscles (PFM) is of high importance for the maintenance of urogynecological health. PFM health can be evaluated by measuring PFM forces. Studies have shown that pelvic floor muscle training (PFMT) reduces the incidence of many conditions, such as pelvic organ prolapse and urinary incontinence (UI) [1], [2], [3], [4].

UI is a highly prevalent condition, especially among women: one out of three women suffer from UI [4], and up to 50 % of women over the age of 65 are affected [4]. The Canadian Urological Association estimated that 3.3 million Canadians suffer from UI in 2012 [4]. In addition to stress and social isolation, UI has a major impact on self-esteem and quality of life [4]. Furthermore, a significant financial burden is imposed on patients and healthcare organizations, with expenses estimated at 16.4 billion per year according to a US study [5].

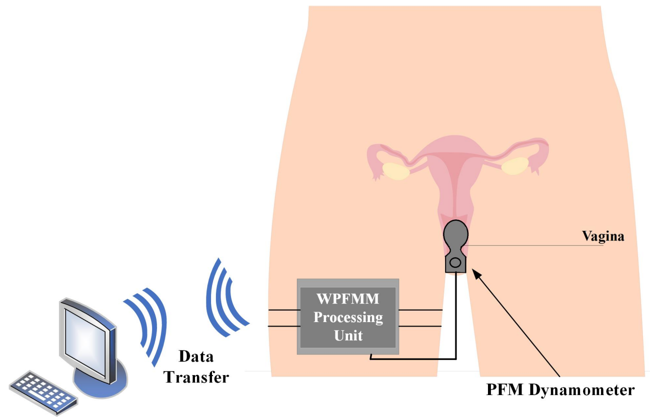

Fig. 1. Overview of the proposed wireless pelvic floor muscle measurement (WPFMM) system.

UI in women is caused by defects or dysfunctions of the PFM, which close the urethra and support the pelvic organs [1]. PFMT is the first line treatment for UI and has been shown to improve urethral closure and pelvic organ support, thereby preventing urinary leakage [3]. The International Continence Society (ICS) and the International Urogynecological Association (IUGA) recommend assessing PFM function prior to and during training to measure improvements and provide feedback to patients in order to offer the best training program for specific PFM dysfunctions [3].

To better understand the pathophysiology for the assessment and training of PFM, several measurement methods have been presented [6], [7], [8], [9]. Digital palpation is the most commonly used method in which the physiotherapist inserts his/her finger in the vagina of the patient to perform the assessment [6]. However, repeatability of measurements is low as this method is subjective and based on physiotherapist experience [7]. On the other hand, the PFM dynamometer is a reliable and direct measurement method of PFM forces [7], [10], [11]. The PFM dynamometer consists of strain gauges mounted on a speculum, which measure the PFM resting and contractile forces. These measurements are then sent to a processing unit for processing and display. Research and development of PFM dynamometer have produced a number of prototypes in the past 20 years. The Montreal Dynamometer proposed by Dumoulin et al [8] is one of the several PFM dynamometer prototypes used in research. However, all these prototypes are connected via wires to processing units [8], [12], [13].

Wire-based monitoring systems may function adequately,

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[1]Batoul El-Sayegh, Mohamed Ali, Hussein Assaf and Mohamad Sawan are with Polystim Neurotech. Lab., Department of Electrical Engineering, Polytechnique Montreal, QC H3T 1J4, Canada batoul.el-sayegh@polymtl.ca

[2]Batoul El-Sayegh, and Chantal Dumoulin are in the Canadian research chair of urogynecological health and aging laboratory, Institut Universtaire de Geriatrie de Montreal, Canada

[3]Chantal Dumoulin is with the School of Rehabilitation, Faculty of Medicine, Universite de Montreal, Montreal, Canada

[4]Mohamed Ali is with the department of Microelectronics, Electronics Research Institute, Cairo 12622, Egypt

[5]Mohamad Sawan is with the School of Engineering, Westlake University, and with Westlake Institute for Advanced Study, Hangzhou, Zhejiang, China, 310024, sawan@westlake.edu.cn

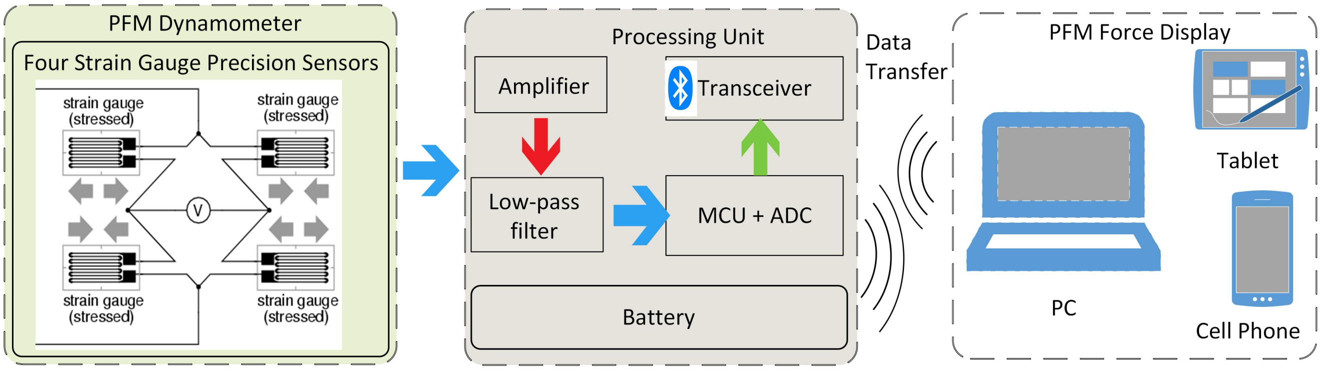


Fig. 2. Components of the proposed wireless pelvic floor muscle measuring (WPFMM) system.

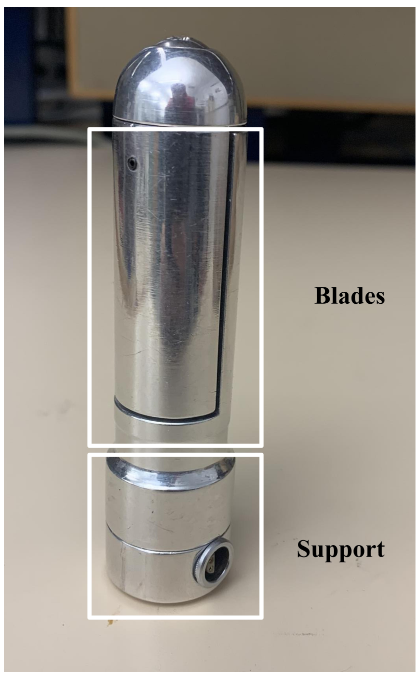


Fig. 3. PFM Dynamometer parts.

however, the wires are a major cause of discomfort to both the physiotherapist and the patient during assessment and training sessions. Patients are also limited to lying in the supine position due to the wires, when standing would be more appropriate for UI-related assessments. To overcome this limitation, a wireless pelvic floor muscle measuring (WPFMM) prototype is proposed in this paper. This system aims to provide high-quality assessments and enhance the efficiency of PFMT in women. Section II of this paper presents the proposed WPFMM prototype followed by a detailed description of the system's components. In Section III, the experimental results are shown. Finally, the conclusion is given in Section IV.

II. Wireless Pelvic Floor Muscle Measuring Prototype

PFM force/pressure can be measured to evaluate PFM function. Both clinically and in research, measurement of the active/maximal PFM forces are obtained digitally or by an instrument measuring the forces exerted by the PFM in the inclined vagina in an antero-posterior direction (ventral-cephalic contraction pattern). Figure 1 presents an overview of the proposed WPFMM system, where a dynamometer in direct contact with the PFM is used to measure PFM force using strain gauges. A processing unit with wireless communication capabilities was used to process and transmit PFM measurements to the user interface. The processing unit is portable and can even potentially be worn on a woman's waist or in an integrated pocket in underwear.

A. System Building Blocks

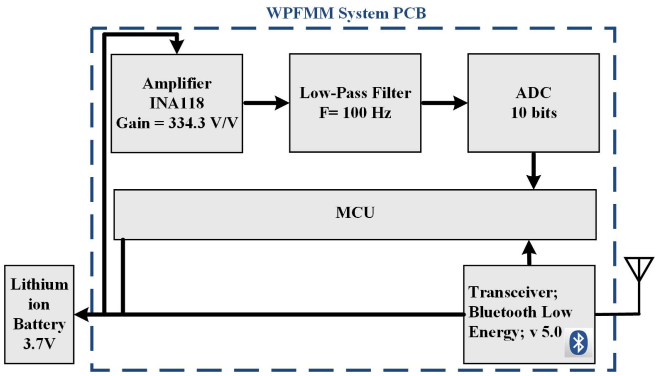
Figure 2 presents the block diagram of the proposed WPFMM system intended to collect force variation and send it to a local base station (computer including RF receiver/smart phone). In the following, we provide a detailed description of the various components used to construct the proposed system.

1) Dynamometer: A force transducer system can be constructed by attaching strain gauges to a cantilever. The free end of the cantilever moves as a result of the vertical load (force/pressure). When the cantilever is bent, the electrical resistance strain gauges mounted on the cantilever are strained and a resistance change can be monitored.

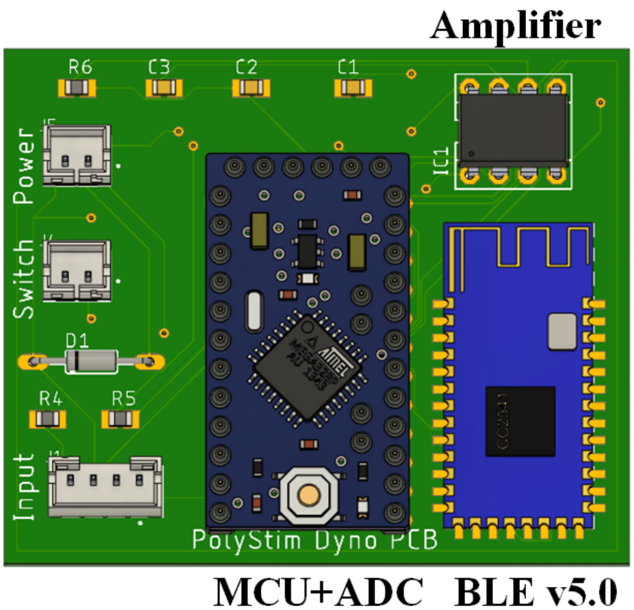
The resistance change unbalances the full Wheatstone bridge circuit. A non-zero output voltage is resulted and can be measured. Through calibration, a force-voltage equation is obtained, and the output voltage of the Wheatstone bridge circuit is calibrated into its corresponding force value.

In the proposed WPFMM system, the principle of a cantilever beam is used. Where two pairs of strain gauges (4 precision strain gauge sensors (EA-13-125PC-350)) are glued on the top and bottom surfaces of the inner based part of the PFM dynamometer. The strain gauges are mounted in a full Wheatstone bridge using differential arrangement. The differential arrangement assures that the force is independently measured of the exact site of application of the force [9].

The employed PFM dynamometer prototype is shown in Fig. 3. The dynamometer is made of two parts; support and blades, and is covered with a condom for hygiene purposes.



(a)



(b)

Fig. 4. Processing unit for the proposed WPFMM system (a) Block diagram, and (b) Designed PCB.

2) *Processing Unit:* Figure 4(a) presents the block diagram of the utilized processing unit in the proposed WPFMM system with the corresponding specifications. It is composed of an instrumentation amplifier, a low pass filter, a microcontroller (MCU) with analogue-to-digital converter (ADC) module, and a bluetooth low energy module (v5.0). The printed circuit board of the processing unit is shown in Fig. 4(b).

3) *Graphical User Interface:* The computer user interface as well as the signal processing are both developed in "Arduino IDE". The computer interface developed allows the user to visualize real-time variations of the PFM force measurements. It is also possible to control system characteristics, such as the sampling rate. In addition, smart phones and tablets could be used to display the measured force signal through the free access DSD TECH Bluetooth mobile application, developed by DSD TECH company, for both IOS and Andriod systems.

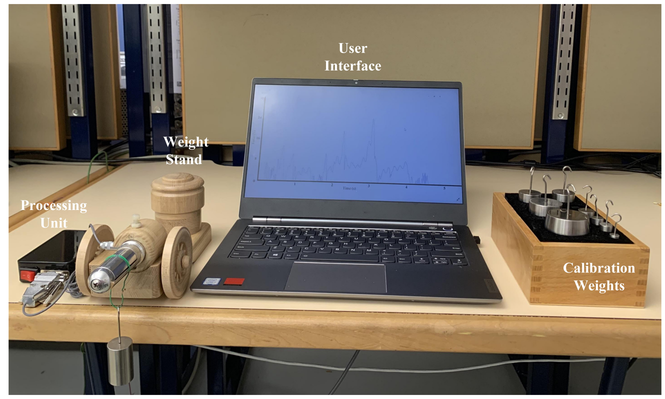


Fig. 5. Wireless pelvic floor muscle measurement system experimental setup.

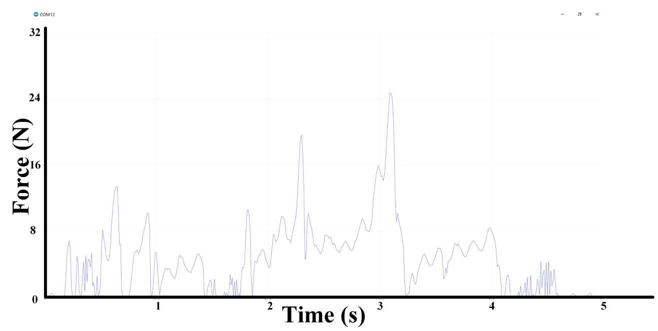


Fig. 6. Real-time PFM force data measure via laptop.

III. Experimental Results

The proposed WPFMM hardware has been realized and tested using the test bench shown in Fig. 5. Firstly, each building block of the system is validated separately for proper functioning and characteristics fulfillment. Then, the complete system is constructed and validated with Arduino IDE interface developed for results visualization.

The dynamometer was firstly calibrated to obtain the calibration factor that coverts from voltage (V) to force (N).Previously known calibrated weights have been applied to the PFM dynamometer at 3.5 cm, and the resulting voltages as a function of force have been recorded. Using the obtained calibration factor, real-time PFM force curves are plotted on computer via Arduino IDE as shown in Fig. 6. Also, real-time PFM force data are monitored via DSD TECH Bluetooth mobile application as shown in Fig. 7.

In operating mode, the presented device consumes around 14 mW from 3.3 V supply. Figure 8 shows the power consumption distribution across the different system blocks. Using a 3.7 V/1200 mA Li-Ion battery, and at a rate of 100 measurements per second, for one hour per day (2 sessions of 30 minutes training), 60 days of measurement can be achieved without the need for battery charging. In addition, a communication range of 100 m is achieved. Despite the possible loss due to human skin, the communication range is high enough to be used at home with a computer, phone, or tablet in a room area.

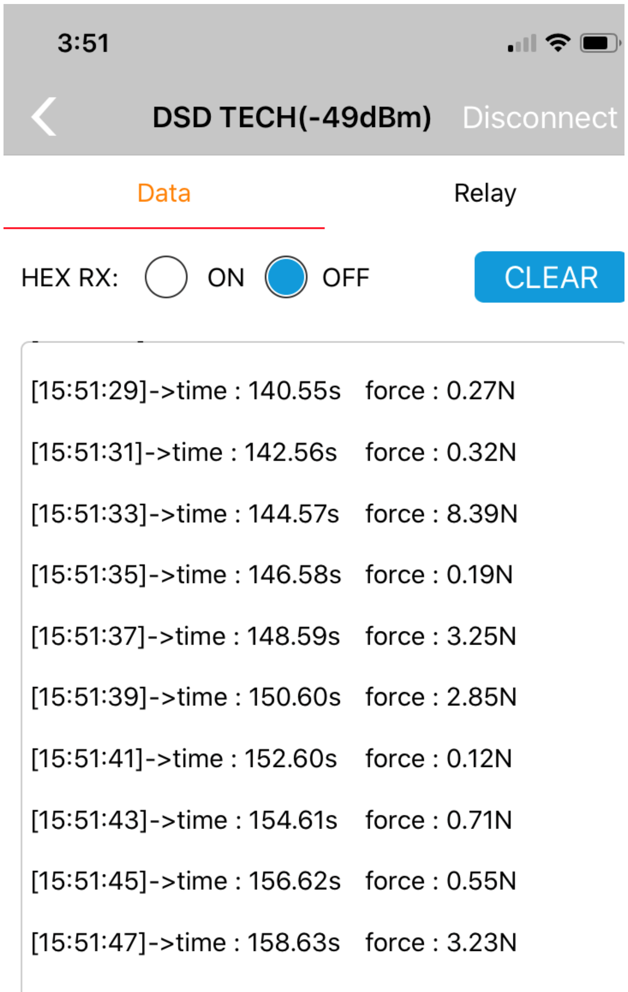


Fig. 7. Real-time PFM force data via smart phone.

IV. Conclusion

This paper presents the proof-of-concept of a portable and wireless PFM assessment system for the evaluation and training of women with PFM dysfunctions. To the best of our knowledge, it is the first research based WPFMM system. The WPFMM system allows patients to reproduce natural PFM function with more portability and flexibility. Also, it allows to measure PFM forces in the standing position, which is the naturally occurring position of urinary incontinence. The system is planned to be used at the Canadian research chair of urogynecological health and aging laboratory, CRIUGM (Centre de recherche de l'Institut universitaire de gériatrie de Montreal) for assessment and training of older women with UI. The full integration of the WPFMM system into the PFM dynamometer probe is under progress.

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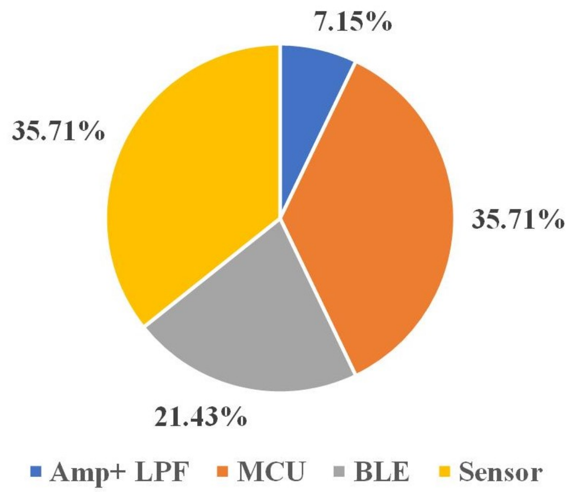

Fig. 8. Power consumption percentages of the different blocks of the WPFMM system.

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