POLYTECHNIQUE MONTRÉAL
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A Portable Platform for Women Pelvic Floor Muscles Function Monitoring and Assessment

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A Portable Platform for Women Pelvic Floor Muscles Function Monitoring and Assessment

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DEDICATION

To whom I own my life,
To whom I consider my blessings,
To my parents, my husband, and my siblings,
and lastly, to whom I would have not been here today,
to myself...

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RÉSUMÉ

L'incontinence urinaire (UI) est une problématique de santé très prévalente, caractérisée par la perte involontaire d'urine. Elle touche une grande partie de la population, en particulier les femmes âgées. Entre 30 et 50% des femmes sont touchées par cette condition. L'incontinence urinaire réduit considérablement la qualité de vie et l'estime de soi des patients, tout en imposant un fardeau financier à la fois aux patients et aux organismes de soins de santé. Le traitement de première ligne de l'IU est l'entraînement des muscles du plancher pelvien (PFMT), qui consiste à contracter correctement les muscles du plancher pelvien (MPP). Pour optimiser les effets de cet entraînement, il est recommandé d'évaluer la fonction des MPP avant et pendant le processus d'entraînement.

De nombreuses méthodes de mesure ont été mises au point pour évaluer et rééduquer les MPP. Cependant, seuls les dynamomètres permettent une prise de mesure directe, fidèle et objective. Malgré la disponibilité des dynamomètres dans la recherche et l'industrie, il n'existe pas de système complet qui à la fois, mesure la fonction des MPP et évalue la performance lors de l'entraînement de manière portable. Les prototypes de recherche existants ont tendance à être encombrants, non portables et à ne pas fournir de rétroaction sur les performances des contraction des MPP, ce qui les rend sous-optimaux pour l'usage en clinique. Les prototypes commerciaux, quant à eux, sont limités et ne font pas l'objet de recherches suffisantes sur leur fonctionnalité et leur efficacité. Présentement, il n'existe pas de dynamomètre des MPP en provenance de la recherche ou de l'industrie possédant un système portable capable de mesurer la fonction MPP et de détecter les contractions correctes des MPP.

L'objectif de cette thèse est de concevoir et de construire un système de mesure de la force des MPP et d'évaluation de la qualité des performances à partir d'un nouveau dynamomètre portable. Notre hypothèse propose qu'un nouveau prototype de dynamomètre des MPP, conçu en fonction des besoins des utilisatrices et équipé d'un système autonome d'évaluation de la qualité des MPP, permettra d'évaluer la force des MPP dans des positions fonctionnelles, telles que la position debout, améliorant ainsi l'efficacité de l'évaluation de la fonction des MPP ainsi que de la rééducation pour les femmes souffrant de troubles urinaires.

Dans un premier temps, afin de définir les défis techniques et d'évaluer les options de conception, nous avons construit un prototype de système de mesure de la force des MPP à partir d'un dynamomètre existant. Au cours de cette phase, nous avons conçu une unité de traitement des données légère et effectué des tests avec le dynamomètre existant des MPP.

Le prototype consomme environ 14 mW à partir d'une alimentation de 3,3 V et atteint une portée de communication sans fil de 100 m. Les données de force des MPP en temps réel peuvent être obtenues et contrôlées sans fil à l'aide d'applications mobiles et d'ordinateurs portables.

Notre deuxième version du prototype représente une nouvelle conception. À la suite d'un examen approfondi de la littérature et des recommandations de quatre physiothérapeutes experts, nous avons conçu, imprimé en 3D, assemblé et testé un dynamomètre des MPP auprès de dix femmes afin d'en évaluer la facilité d'utilisation et l'acceptabilité. La sonde du dynamomètre est conçue de manière unique pour assurer sa stabilisation dans la cavité vaginale. La rétroaction de l'étude d'usabilité a été utilisé pour optimiser la conception de la sonde, ce qui a permis d'obtenir deux tailles de sonde pour s'adapter aux différentes dimensions de l'hiatus vaginal des femmes. Par la suite, un système de mesure de la force des MPP a été mis en œuvre sur la base de la sonde intra-cavitaire conçue et soumis à des tests de linéarité, de répétabilité, d'hystérésis, de bruit et d'effet de chaleur, ainsi que de consommation d'énergie. Les résultats ont démontré une linéarité et une répétabilité élevées, une hystérésis, un effet de bruit et un effet de chaleur minimaux sur les mesures du système. Il est important de noter que la facilité d'utilisation du prototype a été validée avec succès en position debout, ce qui supporte sa fonctionnalité.

Dans la dernière étape, nous avons conçu un nouveau système d'évaluation de la qualité des contractions des MPP, incorporant un détecteur de contractions des MPP et un classificateur de performance des contractions maximales des MPP. Le détecteur de contractions détermine d'abord si une contraction MPP s'est produite, puis le classificateur de performances évalue la qualité de ces contractions sur la base de diverses caractéristiques, qui sont combinées en une note globale. Les deux algorithmes utilisent des techniques d'intelligence artificielle (IA). Le détecteur est basé sur un réseau neuronal convolutionnel (CNN), tandis que le classificateur de performance utilise un extracteur de caractéristiques personnalisé suivi d'un classificateur de forêt aléatoire pour prédire l'évaluation de la force selon l'échelle d'Oxford modifiée lors de la contraction maximale. Les algorithmes d'IA ont été entraînés et évalués à l'aide d'ensembles de données provenant de la dynamométrie vaginale, parfois combinés à des évaluations digitales, intra-cavitaire réalisées par des physiothérapeutes experts. Le détecteur de contractions des MPP a été entraîné sur un ensemble de données, puis testé sur deux ensembles de données mesurés avec différents dynamomètres de notre base de données, atteignant une précision de 97% sur le premier ensemble de données et une précision de 100% sur le second. En outre, le classificateur de performance des contractions maximales des MPP a atteint une précision de 96,53% avec une marge de $\pm$ 1 classe dans notre base de données.

Dans cette thèse, nous avons construit avec succès un dispositif portable pour mesurer les forces des MPP et évaluer de manière autonome la qualité des contractions des MPP sur la base d'un nouveau dynamomètre vaginal destiné à l'évaluation et à l'entraînement de la MPP chez les femmes souffrant de trouble urinaire. Les prototypes mis en œuvre ont répondu à nos spécifications. Les résultats expérimentaux ont confirmé la fonctionnalité du dynamomètre, soulignant le potentiel de notre système pour améliorer l'entraînement et la rééducation des MPP, et pour permettre aux femmes de surveiller et d'améliorer leurs performances de la PFMT d'une manière portable et pratique.

ABSTRACT

Urinary incontinence (UI) is a highly prevalent condition, characterized by the involuntary loss of urine. It affects a large portion of the population, particularly older women. Approximately 30-50% of women are affected by this condition. UI significantly reduces the patient's quality of life and self-esteem while also imposing financial burdens on both patients and healthcare organizations. The first line of treatment for UI is pelvic floor muscle training (PFMT), which involves performing correct pelvic floor muscle (PFM) contractions. To optimize the benefits of training, it is recommended to assess the PFM function before and during the training process.

Multiple measurement methods have been developed for assessing and training the PFMs. However, only dynamometers provide a direct, reliable, and objective assessment tool. Despite the availability of dynamometers in research and industry, there is a lack of a comprehensive system that measures PFM function and evaluates training performance in a portable manner. Existing research prototypes tend to be bulky, non-portable, and lack feedback on PFM contraction performance, making them suboptimal for clinical applications. Commercial prototypes, on the other hand, are limited and lack sufficient research on their functionality and efficacy. Currently, there is no PFM dynamometer in research or industry that offers a portable system capable of accurately measuring the PFM function and detecting PFM contractions.

Our objective in this thesis is to design and build a portable force-measuring and performance-monitoring quality assessment system based on a novel dynamometer. Our hypothesis proposes that a novel PFM dynamometer prototype, designed based on user needs, and equipped with an autonomous PFM quality assessment system, will enable the evaluation of PFM strength in functional positions, such as the standing position, thereby improving the efficiency of the PFM function assessment and training for women with urinary dysfunctions.

As a first step and to define technical challenges and evaluate design options, we built a proof-of-concept prototype of a PFM force-measuring system based on an existing dynamometer. In this phase, we designed a lightweight processing unit and conducted tests with the PFM dynamometer. The prototype consumes approximately 14 mW from a 3.3 V supply and achieves a wireless communication range of 100 m. Real-time PFM force data can be wirelessly obtained and monitored using both mobile applications and laptop computers.

Our second version of the PFM prototype represents a novel design. Following an intensive literature review and recommendations from four expert physiotherapists, we designed, 3D

printed, assembled, and tested a PFM dynamometer on ten women to evaluate its usability and acceptability. The PFM probe is designed uniquely to ensure stabilization within the vaginal cavity. Feedback from the usability study was utilized to optimize the PFM probe design, resulting in two probe sizes to accommodate varying vaginal hiatus dimensions. Subsequently, a force measuring system was implemented based on the designed PFM probe and subjected to tests for linearity, repeatability, hysteresis, noise and heat effect, and power consumption. The results demonstrated high linearity and repeatability, minimal hysteresis, noise effect, and heat effect on the system measurements. Importantly, the usability of the prototype was successfully validated in the standing position, further cementing its effectiveness.

In the final step, we designed a novel PFM contraction quality assessment system, incorporating a PFM contraction detector and a maximal PFM contraction performance classifier. The contraction detector initially determines if a PFM contraction has occurred, and then the performance classifier assesses the quality of these contractions based on various features, which are combined into an overall rating. Both algorithms utilize artificial intelligence (AI) techniques. The detector is based on a convolutional neural network (CNN), while the performance classifier employs a custom feature extractor followed by a random forest classifier to predict the strength rating according to the modified Oxford scale for maximum pelvic floor muscle contraction graphs. The AI algorithms were trained and evaluated using datasets from vaginal dynamometry, sometimes combined with digital assessments from expert physiotherapists from our database. The contraction detector was trained on one dataset and then tested on two datasets measured with different dynamometers from our database, achieving 97% accuracy on the first dataset and 100% accuracy on the second. Additionally, the PFM strength classifier attained an accuracy of 96.53% within a ± 1 class margin.

In this thesis, we successfully built a portable device to measure the PFM forces and autonomously evaluate the quality of the PFM contractions based on a novel vaginal dynamometer intended for the assessment and training of PFM in women with urinary dysfunction. The implemented prototypes met our specifications. Experimental results have confirmed the dynamometer's functionality, highlighting the potential of our system to enhance PFM training and rehabilitation, and to enable women to monitor and improve their PFMT performance in a portable and convenient way.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF SYMBOLS AND ACRONYMS

ADC	Analogue to Digital Converter
AI	Artificial Intelligence
AUC	Area Under the Curve
CNN	Convolutional Neural Network
CRIUGM	Centre de recherche de l'Institut universitaire de gériatrie de Montréal
EMG	Electromyography
IAP	Intra-abdominal Pressure
ICS	International Continence Society
IUGA	International Urogynecological Association
LR	Logistic Regression
MOS	Modified Oxford Scale
MRI	Magnetic Resonance Imaging
MVC	Maximum Voluntary Contraction
Mcu	Microcontroller
PFM	Pelvic Floor Muscle
PFMT	Pelvic Floor Muscle Training
POP	Pelvic Organ Prolapse
PVD	Provoked Vestibulodynia
RFC	Random Forest Classifier
ROC	Receiver Operating Characteristic
UI	Urinary Incontinence
WPFMM	Wireless Pelvic Floor Muscle Measuring system
XGB	Extreme Gradient Boosting

CHAPTER 1 INTRODUCTION

1.1 Motivation

1.1.1 Overview of the Urinary System

In any functional system, waste production is an inherent aspect that requires effective management. Within the human body, waste accumulation can disrupt normal physiological processes and compromise overall well-being. Consequently, the implementation of a robust waste control system becomes imperative to eliminate waste products and prevent any potential toxicity. In this context, the urinary system functions as one of the body's waste management systems.

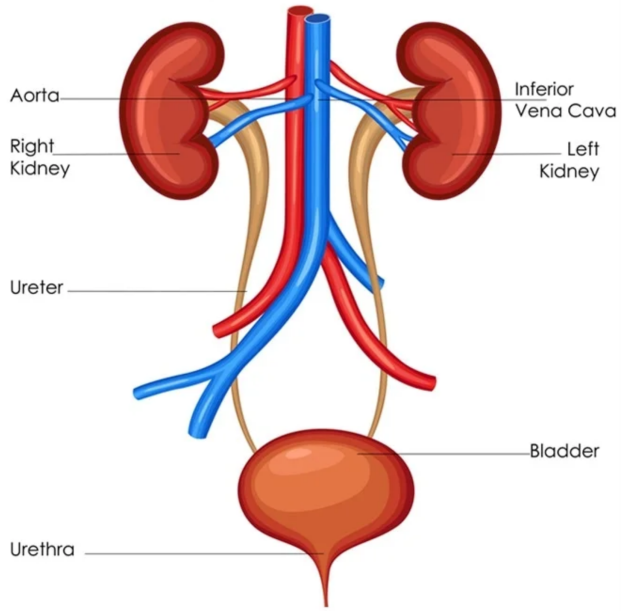

Figure 1.1 The urinary system and its main organs [1].

The urinary system, shown in Figure 1.1, is made up of kidneys, ureters, bladder, and urethra. The urinary system is a complex and highly integrated system that works together to maintain the proper balance of electrolytes and fluids in the body. The process starts with the kidneys, which filter waste from the blood and produce urine. The urine flows from the kidneys into the ureters, which are narrow tubes that connect the kidneys to the bladder. The bladder stores the urine until it is eliminated from the body during urination. When the bladder is full, signals are sent to the brain, which triggers the need to urinate. If it is

an appropriate time to urinate, the pelvic floor muscle (PFM) relaxes, allowing urine to pass through the urethra, a tube that connects the bladder to the outside of the body. Conversely, if it is not an appropriate time, the PFM will contract to prevent urination, ensuring that urine is retained in the bladder until it can be released appropriately.

A well-functioning urinary system is fundamental for body sustainability and, ultimately, survival. Its ability to eliminate waste efficiently and maintain fluid and electrolyte balance is vital for optimal health. However, disruptions or dysfunctions within the urinary system can lead to conditions such as urinary incontinence (UI).

1.1.2 Definition and Types of Urinary Incontinence

UI is defined by the International Continence Society (ICS) and International Urogynecological Association (IUGA), as the complaint of involuntary loss of urine. UI is a highly prevalent condition, estimated to affect nearly 420 million people (300 million women and 120 million men) worldwide [2], and around 10% of the Canadian population [3]. The prevalence of UI increases with age, affecting 30% to 60% of patients over 65 years old, and up to 55% of older community-dwelling women [3, 4].

There exist several types of UI, from which are the following three major types: [5, 6]:

1. Stress UI (SUI): Complaint of involuntary loss of urine on physical exertion or effort including sporting activities, or on coughing or sneezing. SUI is the most common type of UI, accounting for almost 50% of UI patients [3, 7].

2. Urgency UI: Complaint of involuntary loss of urine accompanied by urgency.

3. Mixed UI: Complaints of both urgency and stress urinary incontinence.

In addition to the more prevalent forms of urinary incontinence, there are less common categories. These include total incontinence, which is typically associated with ectopic ureter or urinary tract fistula. Functional incontinence, on the other hand, is linked to psychiatric or mobility disorders. There are also uncategorized cases, as well as overflow incontinence, incontinence resulting from radiotherapy [3].

1.1.3 Causes and Contributing Factors for Urinary Incontinence

UI can have various causes, including medical conditions such as urinary tract infections, bladder stones, tumors, and medications with potential side effects. Women are particularly susceptible to developing urinary incontinence during pregnancy, after childbirth, or due to

hormonal changes associated with menopause. Risk factors for UI encompass age, obesity, smoking, gender, pregnancy and childbirth, menopause, and psychological or neurological disorders [6, 8].

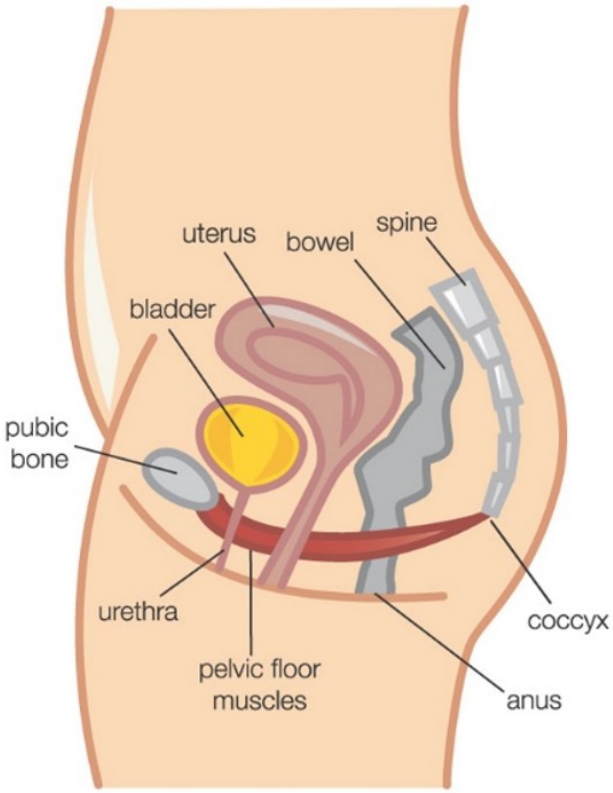

Figure 1.2 Pelvic floor muscle location [9].

Continence is multi-factorial but relies mainly on the urethral closure and detrusor control function. PFM integrity is of high importance in maintaining urogynecological health [10]. The PFMs consist of passive (ligaments, fascia) and active (muscles) that form a supportive hammock-like structure at the base of the pelvis (Figure 1.2) [11]. These muscles are responsible for supporting the pelvic organs (bladder, uterus, rectum) and closing the urethra [5].

UI in women is linked to dysfunctions and defects in the PFMs. When there is an increase in intra-abdominal pressure, a weak PFM will not be able to support and close the urethra, and thus a leakage will occur.

1.1.4 Consequences of Urinary Incontinence

UI significantly affects the quality of life of individuals influenced by this condition. It often leads to social embarrassment, as individuals may feel self-conscious or ashamed about

experiencing urine leakage in public or social situations. This can result in social isolation, decreased participation in social activities, and a negative impact on overall well-being [12–14].

Furthermore, the financial burden associated with managing UI is substantial and creates challenges for healthcare organizations. According to a study conducted on a US population, the expenses related to UI was estimated to be 16.4 billion dollars annually [15, 16]. In another study focusing on a UK population, it was suggested that the UK National Health Service incurs healthcare costs of 117 million pounds per year [7].

1.1.5 Available Treatments

UI can be treated by different methods, depending on its type and severity. Some treatment methods are as follow:

- Behavioral therapy such as scheduled voiding, fluid restriction when appropriate, and bladder training [3].
- Medication: Several medications are available for the treatment of UI, mainly Urgency UI.
- Electro-stimulation: Temporary insertion of electrodes into the rectum or vagina is performed to stimulate and enhance the strength of PFMs.
- Surgery: Surgery is considered if the non-invasive treatments didnot work. The surgical choice depends on the severity of incontinence and patient expectations [3].

The first line of treatment for UI, particularly SUI, is pelvic floor muscle training (PFMT), which is a form of PFM rehabilitation [5]. PFMT is a set of exercises, targeting the PFM, aimed to improve PFM strength, power, relaxation, endurance, or a combination of these parameters. PFMT involves contracting the PFM in a constriction and inward (ventrocephalad) movement of the pelvic openings [17]. Research has demonstrated the effectiveness of PFMT in enhancing UI overall, and SUI specifically [18, 19].

ICS and IUGA recommend assessing the PFM function prior to and during PFMT to teach effective PFM contraction and measure improvement, thereby giving the best training program for specific PFM dysfunctions [5]. A valid and reliable PFM assessment tool is needed to better understand UI pathophysiology in women, and better assess the effect of PFMT.

1.2 Pelvic Floor Muscles Function Measurement Methods

A key element in the management of UI in women is the proper evaluation of PFMs. Various direct and indirect measurement methods have been developed to evaluate and train the PFMs [20–23]. A direct assessment method assesses the PFM function by measuring forces produced during PFM rest and contraction. This assessment of PFM forces evaluates the ability of PFMs to contract and relax actively. One of the most common direct assessment methods is the following:

- Digital palpation: The physiotherapist inserts her/his fingers in the vagina of the patient to assess active forces during maximal PFM contraction and passive forces at rest. However, the repeatability of digital palpation is limited as it is a subjective measurement of PFM function [20, 21, 23] and relies on the evaluator's competency.

Further, indirect assessment tools evaluate PFM function by measuring parameters such as pressure rather than directly assessing the force. Some of the most commonly indirect assessment methods include:

- Perineometry is a technique used to assess PFM function by measuring the pressure generated by the muscles in the perineal area. It employs a perineometer, which is a small device equipped with a pressure sensor. Moreover, the measurements' validity can be influenced by artifacts such as intra-abdominal pressure [21–23].
- Electromyography (EMG) is used to measure the electrical activity generated by the PFMs. To detect and record the electrical signals produced during muscle contractions, small electrodes are placed on the skin near the PFMs. EMG provides information about the timing, strength, and coordination of muscle contractions. It can help evaluate muscle activation patterns, identify muscle weakness or dysfunction, and monitor changes in muscle activity during various tasks or exercises. The main limitation of EMG is the potential for measurement bias in PFM readings caused by interference from nearby muscles [21, 23].
- Imaging techniques (magnetic resonance imaging (MRI) and ultrasound) where the quantification is based on the internal pelvic structure displacement such as the bladder neck and the anorectal angle during contraction. The weakness of these methods is that contraction does not always correlate with the contractile force produced by the PFM. In addition to being expensive, these techniques are user-dependent, and their outcomes are affected by the evaluator's training and experience [21–23].

Based on the presented information, there is a need for a direct and reliable measurement method. Recently, PFM dynamometry has been introduced as a direct and reliable PFM function assessment method [5, 24, 25].

1.3 Pelvic Floor Muscles Dynamometry

Over the past 15 years, dynamometry has emerged as a promising approach for obtaining reliable and direct measurements of PFM function in women [5, 24, 25]. IUGA and the ICS joint report on the terminology for female pelvic floor dysfunction define PFM dynamometry as “an instrument measuring PFM contractile and resting forces using strain gauges mounted on a speculum, which is inserted into the vagina" [5]. Dynamometry measures PFM forces in Newton units (N = 1 kg × m/s2) [5].

Over the past two decades, research and development efforts have resulted in the creation of several PFM dynamometer prototypes, serving both research and commercial purposes. Various designs have been proposed in terms of the shape and the size, the direction of measurement (i.e., antero-posterior, latero-lateral or multidirectional) and the device specifications (e.g., the configuration of strain gauges) [26]. An example of a research PFM dynamometer is presented in Figure 1.3.

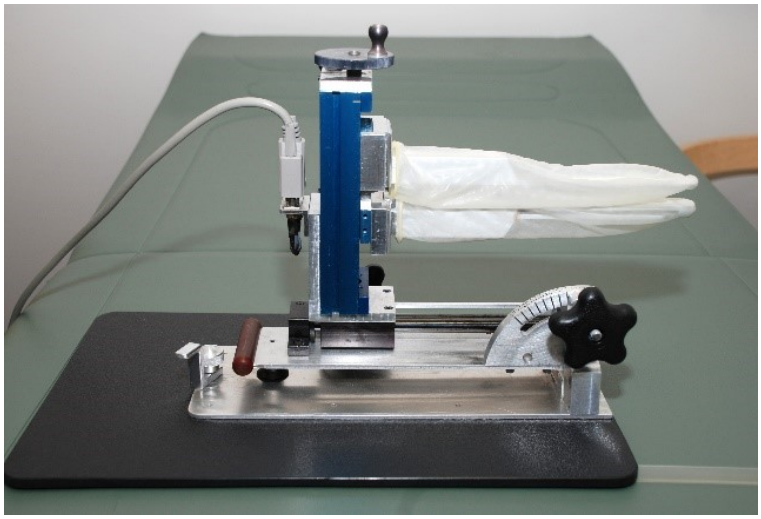

Figure 1.3 PFM dynamometer used at Centre de recherche de l’Institut universitaire de gé riatrie de Montréal (CRIUGM) developed by Prof Dumoulin’s team [27].

A PFM dynamometer could be either handheld (the user holds the device using their hand) or a fixed-to-base device (the user inserts the PFM dynamometer into the vagina), implemented with force sensors that are capable of measuring the force exerted by the PFMs.

Upon performing a PFM contraction, the force exerted by the PFM muscles is transmitted to the force sensors in the dynamometer. These sensors convert the applied force into an electrical signal, which is then processed and displayed as a quantitative measurement of the force generated by the PFM using a calibration process.

PFM dynamometer force measurements are analyzed to evaluate the passive force, active force (strength), coordination, rapidity of contraction and endurance of PFM. This information is helpful in assessing PFM function, diagnosing pelvic floor dysfunction, monitoring progress during rehabilitation (PFMT), and measuring the efficacy of interventions meant to enhance PFM function.

1.4 Research Objectives

Given the importance of assessing and monitoring PFM function in women with UI, the main objective of this thesis is to build an electronic device that is wearable, portable and wirelessly operable which includes a biofeedback real-time measurement interface for the assessment and monitoring of PFM function in women.

The specific objectives of the thesis tasks are:

Aim 1: Build a proof-of-concept prototype for a force measuring system based on a dynamometer that: 1) Can be integrated with an existing PFM dynamometer 2) Must be as small and lightweight as possible to facilitate its implementation into PFMT session; 3) Integrates a minimal number of components to minimize power consumption, lower failure risks, and reduce production costs.

Article 1 discusses the design and test results of a proof-of-concept prototype for a force-measuring system based on an existing dynamometer.

- **Article 1**: B. El-Sayegh, C. Dumoulin, M. Ali, H. Assaf and M. Sawan, “A Dynamometer-based Wireless Pelvic Floor Muscle Force Monitoring," 2020 42nd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC), Montreal, QC, Canada, 2020, pp. 6127-6130, doi: 10.1109/EMBC44109.2020.9176660.

This work was also presented in CRIUGM Scientific days (Montreal, April 2021).

Aim 2: Design and build an electronic device that is wearable, portable and wirelessly operable which includes a biofeedback real-time measurement interface based on a novel dynamometer.

Article 2 presents a novel portable PFM dynamometer system designed to provide real-time measurements in a wearable and portable format, based on a newly designed vaginal probe.

- **Article 2**: B. El-Sayegh, C. Dumoulin, M. Ali, H. Assaf, J. De Jong, M. Sawan, and F. Leduc-Primeau, “Portable Dynamometer-Based Measurement of Pelvic Floor Muscle Force," in IEEE Journal of Translational Engineering in Health and Medicine, vol. 11, pp. 44-53, 2023, doi: 10.1109/JTEHM.2022.3223258.

Aim 3: Propose a PFM contraction quality assessment system that differentiates between PFM contraction and non-contractions and autonomously quantifies the quality of maximal PFM contraction across different features.

Article 3 introduces a quality assessment system for PFM contractions, incorporating a PFM detector and a maximal PFM contraction performance classifier to evaluate and enhance contraction quality. In this study, quality refers to the performance evaluation of PFM contractions based on specific measurable features analyzed by the system.

- **Article 3**: B. El-Sayegh, C. Dumoulin, F. Leduc-Primeau, and M. Sawan, “Improving Pelvic Floor Muscle Training with AI: A Novel Quality Assessment System for Pelvic Floor Dysfunction," submitted to MDPI Sensors journal.

1.5 Thesis Organization

This PhD thesis consists of seven chapters. The first chapter, Chapter 1, provides an overview of the motivation for the research. It presents the main and specific objectives and establishes the organization of the thesis to ensure consistency between the papers and the research objectives.

Chapter 2 includes a comprehensive literature review of existing PFM dynamometers, used to monitor the PFM functions, available in both research and industry. A review article, is referenced and reproduced in Chapter 2.

Chapter 3, Chapter 4 and Chapter 5 are the subject of publications that directly address our main objectives in this thesis. These chapters delve into the details of our work and results.

Chapter 6 provides a comprehensive discussion of our contributions. Finally, Chapter 7 provides a summary of our achievements in this project. It also provides recommendations for enhancing the current design, and proposes potential directions for future research.

CHAPTER 2 LITERATURE REVIEW: THE STATE OF PELVIC FLOOR MUSCLE DYNAMOMETRY: A SCOPING REVIEW

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This chapter presents a comprehensive scoping literature review with the objective of identifying and discussing the advantages and limitations of various PFM dynamometers available in research and industry. This work was published in Neurology and Urodynamics Journal as a regular paper in December 2022. The following chapter presents a reproduction of the published paper with minor adjustments.

2.1 Introduction

The International Continence Society and International Urogynecological Association recommend pelvic floor muscle training (PFMT) as a first-line treatment for women with urinary incontinence (UI) [10, 28]. To better understand UI pathophysiology in women, and better assess the effect of PFMT, a valid and reliable pelvic floor muscle (PFM) force measurement tool is needed. In the last century, the design and implementation of the PFM dynamometer has emerged as an important method that directly measures PFM force [29, 30].

Research on the development of the PFM dynamometer has led to various prototypes in both research and commercial fields. However, to this day, there is no current gold standard, nor a consensus approach for the PFM dynamometer's design and measurement protocol. Therefore, the aim of this critical review is to discuss the advantages and limitations of available

PFM dynamometers, in both research and commercial fields, through the comparison of their main characteristics. This review also evaluates the extent of variation between different dynamometers in terms of description, functioning, psychometric properties and measurement protocols, and the potential effect on reported measurements [17].

2.2 Search Methods

2.2.1 Search methods for identification of studies

We searched relevant records from Web of Science, MEDLINE, Pub Med, Compendex, and the Derwent Innovations Index from inception up to December 2020. In addition to peer-reviewed papers, conference proceedings, patents and user's manuals were considered when no other source of information was available on specifications of the device design. Only peer-reviewed papers and conference proceedings were considered regarding information on psychometric properties of the instrument. There were no language restrictions, and the search terms were used until no further records were identified. References of these records were checked for additional relevant records. Additional details on the search methods and terms used are provided in Tables 2.1, 2.2, and 2.3.

Table 2.1 Search Strategy use in Web of Science

#	**Search Strategy**	**Result**
1	(Dynamomet* AND muscle* strength* AND pelvic* AND urinary incontinence)	37
2	(Dynamomet* AND muscle* strength* AND pelvic*)	106
3	((Dynamomet* OR perineomet* OR instrumented speculum) AND (Muscle* OR strength* measurement*) AND (Pelvic* OR vagina OR levator ani))	284
4	((Dynamomet* OR perineomet* OR instrumented speculum) AND (Muscle* OR strength* measurement*) AND (Pelvic* OR vagina OR levator ani) AND (urinary incontinence OR urodynamics*))	163
5	((Dynamomet* OR perineomet* OR instrumented speculum OR probe) AND (Muscle* OR strength* measurement* OR endurance OR force) AND (Pelvic* OR vagina OR elevator ani OR pelvis OR pelvic diaphragm) AND (urinary incontinence OR urodynamics* OR stress* OR diagnosis*))	269

Table 2.2 Search Strategy use in MEDLINE

#	**Search Strategy**	**Result**
1	(Dynamomet* AND muscle* strength* AND pelvic* AND urinary incontinence)	37
2	(Dynamomet* AND muscle* strength* AND pelvic*)	11
3	((Dynamomet* OR perineomet* OR instrumented speculum) AND (Muscle* OR strength* measurement*) AND (Pelvic* OR vagina OR levator ani))	249
4	((Dynamomet* OR perineomet* OR instrumented speculum) AND (Muscle* OR strength* measurement*) AND (Pelvic* OR vagina OR levator ani) AND (urinary incontinence OR urodynamics*))	117
5	((Dynamomet* OR perineomet* OR instrumented speculum OR probe) AND (Muscle* OR strength* measurement* OR endurance OR force) AND (Pelvic* OR vagina OR elevator ani OR pelvis OR pelvic diaphragm) AND (urinary incontinence OR urodynamics* OR stress* OR diagnosis*))	208

Table 2.3 Search Strategy use in PubMed

#	**Search Strategy**	**Result**
1	(Dynamomet* AND muscle* strength* AND pelvic* AND urinary incontinence)	19
2	(Dynamomet* AND muscle* strength* AND pelvic*)	90
3	((Dynamomet* OR perineomet* OR instrumented speculum) AND (Muscle* OR strength* measurement*) AND (Pelvic* OR vagina OR levator ani))	166
4	((Dynamomet* OR perineomet* OR instrumented speculum) AND (Muscle* OR strength* measurement*) AND (Pelvic* OR vagina OR levator ani) AND (urinary incontinence OR urodynamics*))	40
5	((Dynamomet* OR perineomet* OR instrumented speculum OR probe) AND (Muscle* OR strength* measurement* OR endurance OR force) AND (Pelvic* OR vagina OR elevator ani OR pelvis OR pelvic diaphragm) AND (urinary incontinence OR urodynamics* OR stress* OR diagnosis*))	251

Further hand search was performed using the author names (in Compendex and Derwent Innovations Index), the peer-reviewed papers, the conference proceedings, the patents, and the user's manuals for commercial dynamometers. A total of 24 additional references were found from the hand search.

2.2.2 Selection of Studies

Records were included in the review if they described the development or application of assessment tools specifically designed to measure PFM force objectively and directly in women at either rest, on contraction or both, intravaginally, by means of force sensors such as strain gauges. Two review authors (CD and BS) independently screened the list of titles and abstracts generated by our search using Covidence software [31] and further independently assessed full-text articles of potentially relevant records to determine inclusion. Any differences of opinion were resolved by a third party (LPC). Abstracts were included when full-text copies were not available.

2.2.3 Data Extraction and Management

Data extraction was undertaken independently by two review authors (BS and LPC) and cross-checked by CD. Any differences of opinion related to data extraction were resolved through discussion. Where study data were possibly collected but not reported, or data were reported in a form that could not be used in the formal comparisons, we sought further clarification from the authors. When the data was found, it was added to the extraction sheet.

Extracted data comprised the dynamometer's description (material, structure, base), functioning (direction of measurement, aperture), and psychometric properties (reliability, construct validity and known group validity [including UI vs control, provoked vestibulodynia (PVD) vs control, and pelvic organ prolapse (POP) vs control]). Details of the measurement protocol were also extracted, namely pre-assessment procedures (bladder filling condition, confirmation of correct PFM contraction) and assessment procedures (dynamometer insertion depth and orientation, body position, task assessed, number of trials and any instruction or encouragement provided).

2.3 Findings

2.3.1 Total Number of Records in the Study

A total of 2,087 abstracts, patents and user manuals were retrieved in Covidence, together with 24 additional records identified through other sources. After duplicate records were removed, the titles and abstracts of the remaining 503 records were screened. In total, 109 records were found to be possibly relevant and retrieved in full for detailed evaluation of eligibility. Eight records were excluded, either because they do not correspond to our

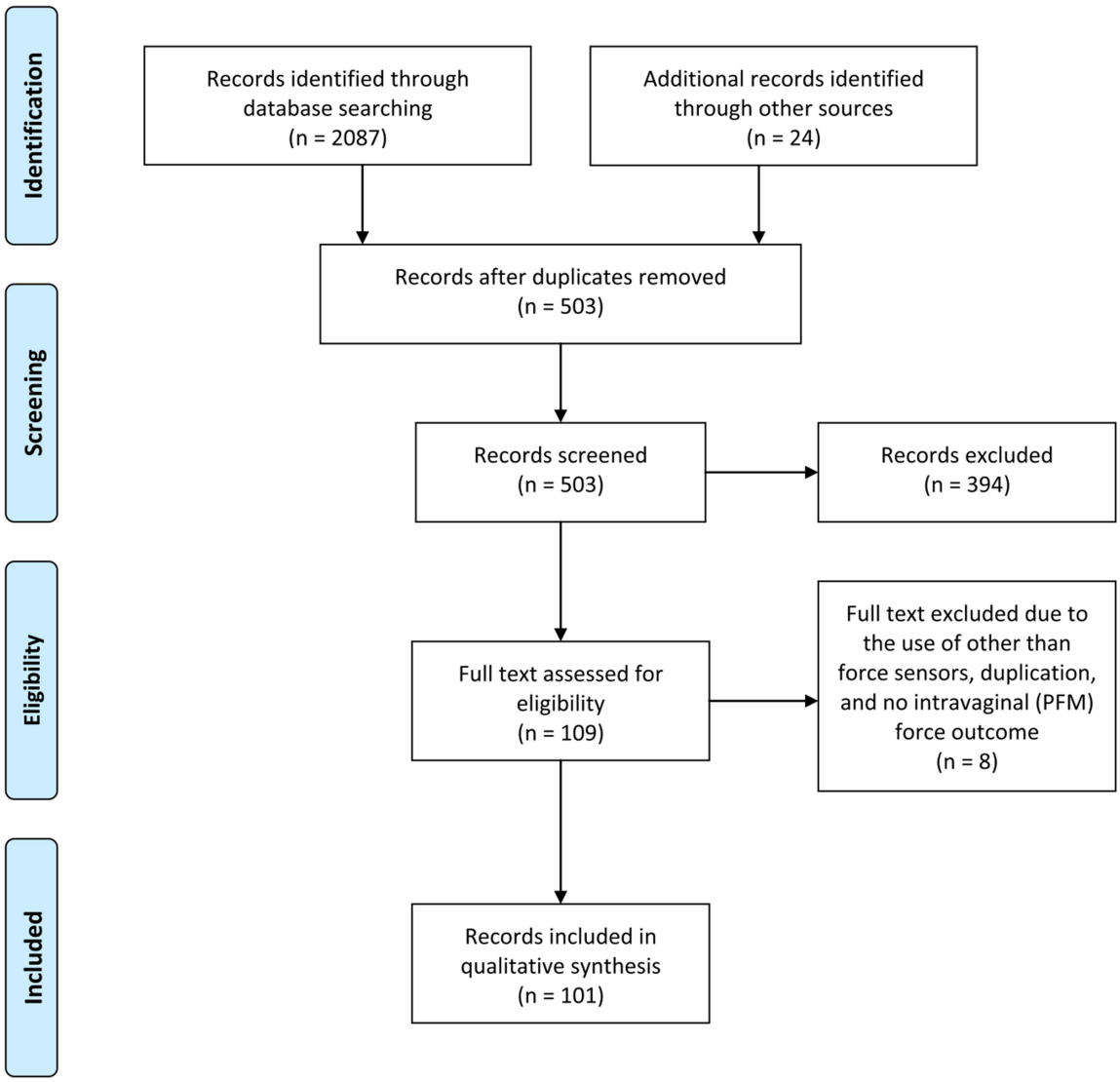

Figure 2.1 Search strategy for pelvic floor muscle dynamometers.

definition of PFM dynamometers (n = 5), were duplicate abstracts (n = 1) or did not include new intravaginal PFM force outcomes (n = 2), as detailed in Table 2.4. One hundred and one records were included in this review (Figure 2.1).

2.3.2 Device Categorization, Clinical and Personal

From the 101 records included, 23 PFM dynamometers from 15 research groups were identified. PFM dynamometers were grouped into two categories: clinical PFM dynamometers (n = 20, from 12 research groups) [27, 40–58], meant for research settings, and personal PFM

Table 2.4 Characteristics of Excluded Studies

Study	**Reason for Exclusion**
Bohorquez 2020 [32]	Presented an intravaginal probe that that displays the shape and motion of the vagina during PFMT using micro-electro-mechanical systems accelerometer system. Not considered a dynamometer since it does not measure force directly.
Ferreira 2006 [33]	Presented an intravaginal probe that measures force using a fiber Bragg grating sensor system. Not considered a dynamometer since it does not measure force directly.
Sanches 2009 [34]	Presented an intravaginal probe that measures force using a pressure sensor system. Not considered a dynamometer since it does not include a force sensor.
Jean-Michel 2010 [35]	Presented a Colpexin sphere that measures force using a force gage. Not included since it measures PFM resting and contractile forces against resistance only.
Santiesteban 1988 [36]	Presented a manometer (although referred to as dynamometer). Not considered a dynamometer since it does not include a force sensor.
Morin 2010 [37]	Duplicate of an abstract in another journal.
Bo 2007 [38]	Editorial Comment for Dumoulin 2003 dynamometer. Did not have intravaginal PFM force outcome.
Hasegawa 2011 [39]	Secondary outcomes from Constantinou 2007 (simulation study). No new data presented.

dynamometers (n = 3, from three groups), which were commercially available and intended for patient use [59–61].

Table 2.5 shows a comparison of the major characteristics, advantages, and limitations of the personal PFM dynamometers.

2.3.3 Clinical Dynamometers

Dynamometers were made of a wide range of materials. Specifically, nine dynamometers were made of aluminum [27,40,41,49,52–55,57], one was made of plastic externally and steel internally [50], two were made of stainless-steel [42,51], one was made of metal [56], three out of plastic [46–48], two out of polylactic acid [44,45], one was made of acrylonitrile butadiene styrene and polycarbonate [43] and one was of unknown material (not reported) [58]. Of interest, the material used for the research PFM dynamometers appears to have shifted over time from aluminum and stainless-steel to 3D-printed plastic (polylactic acid, acrylonitrile butadiene styrene and polycarbonate), which allows for more possibilities in device design.

There were differences in the structure of the intra-vaginal dynamometers with one type being

Table 2.5 Personal pelvic floor muscle (PFM) dynamometers key features

Device name		**Elvie, 2013 [59]**	**PeriCoach, 2014 [60]**	**Emy, 2018 [61]**
Geometry	weight width length	25 g 3.5 cm 8 cm	50 g 3 cm 12 cm	55 g 3.4 cm 10.5 cm
Base		Stays in place	Stays in place	Stays in place
Cover Material		Medical-grade silicone	Silicone	Medical-grade silicone
Price US $		199 $	221 $	235 $
Psychometric Evaluation	Reliability	Yes [59]	No	No
	Construct validity	Yes [59]	No	No
	Known group method	No	No	No
Advantages		• Size: two sizes are available through an extra cover • Wireless • Position of use: supine and standing	• Gyroscope and accelerometer used for improved accuracy • Wireless • Position of use: supine and standing	• Customized mobile application • Wireless • Position of use: supine and standing

more prominent. Fifteen dynamometers were "speculum shaped" [40–46] and made of two branches, four were cylindrical-shaped probes [48–51], and one had four-leaf spring branches attached to a cylinder [47]. Interestingly, while most speculum-shaped dynamometers opened their branches in parallel to each other, seven opened in an angle [42, 43, 46, 53, 55–57],which causes a higher opening pressure applied to deeper vaginal tissues. This in return, can cause discomfort and thereby limit the measurement of PFM force at different muscle lengths.

Dynamometers varied in their force sensor number and arrangement. Most used multiple sensors (n = 11) [27, 40–42, 45, 47–49, 52, 54, 58] while some used one force sensor only (n = 9) [43, 44, 46, 50, 51, 53, 55–57]. Furthermore, only two reports mentioned the use of differential arrangement of strain gauges [27, 41], which is important to ensure the force is measured independently of its exact site of application on the dynamometer branch [62]. This can have a significant impact on the repeatability of measurement if the dynamometer is not

systematically inserted to the same depth in the vagina as force is dependent of lever arm when only one sensor is used [63].

Dynamometers varied in their base design, and a higher number of dynamometers were meant to be handheld by the evaluator (n = 13) [40,41,43–45,47,48,50,51,53,55,57,58]. Others were either fixed to a base (n = 5) [27, 42, 52, 54, 56] or meant to stay in place inside the vaginal canal without falling out (n = 2) [46, 49]. Noticeably, dynamometer designs are shifting over time from handheld and fixed to a base to a "stay in place" model, which facilitate assessment of PFM contractility and tone in different body positions (e.g., standing position). Of note, further studies are needed to assess the psychometric properties of these instruments.

In the case of speculum shaped devices, dynamometers differed in their diameter or aperture range. Some dynamometers had a fixed diameter, ranging from 22-35 mm (22 mm [50]/ 23 mm [49]/ 25 mm [41]/ 33 mm [51]/ 35 mm [48]). Other dynamometers had adjustable apertures varying between 10-69 mm (19-54 mm [27]/ 15-50 mm [52]/ 10-45 mm [54]/ 30-50 mm [58]/ 23-70 mm [47]/ 20-76 mm [53]/ 25-50 mm [55]/ 28-60 mm [57]/ 10-28 mm [42]/ 10-50 mm [44]/ 15-55 mm [45]/ 24-69 mm [46]). In three dynamometers, the aperture range/device diameter was unclear [40, 43, 56].

Dynamometers also varied in their direction of measurement. Because they were not fixed to a base, 14 dynamometers could potentially measure PFM force in different directions [40–46, 49–51, 53, 55, 57, 58]. Four dynamometers measured in one direction only [27, 52, 54, 56], as they were fixed to a base, and two measured in four directions simultaneously [47, 48]. Of note, there was one dynamometer that was fixed to a base and could be used in variable directions [42]. This is due to its support system, which allows adjustments of the dynamometer in both anteroposterior and laterolateral directions. Interestingly, although hand-held and "stay in place" dynamometers could be potentially used in different directions, all [40, 41, 43–49, 51, 53, 55, 57, 58] except one report found [50] restricted measurements to one direction only, which was based on the intended objectives of the research group. The anteroposterior direction was often used to measure the active/maximal PFM forces with regard to UI and pelvic organ prolapse [27]. In contrast, the laterolateral measurements were most commonly used to evaluate the passive (tone) /elastic properties of the vaginal tissues during pregnancy [57].

Reliability studies were conducted for 13 dynamometers in 18 reports [41–44,50–52,55,57,58, 64–71]. Most presented intra-rater reliability either within-visit (n = 9) [43, 44, 57, 64, 65, 67–69, 71] or between-visits (n = 13) [41, 42, 44, 50–52, 55, 58, 64–66, 70, 71]. Only five reports in four dynamometers (two handheld, and one "stay in place") presented inter-rater reliability [43, 50, 51, 69, 70]. Maximal force during PFM maximal voluntary contraction was the most

studied parameter (n = 14) [40, 42, 43, 49, 50, 54, 63, 65–68, 70–72]. Overall results suggested moderate to strong repeatability of measurements, supporting dynamometers as a reliable instrument to assess PFM function. For handheld dynamometers, where measurements are more likely to be influenced by the examiner, inter-rater reliability can be especially relevant. Of note, there were 10 handheld dynamometers with no reports on their inter-rater reliability and thus further investigation is needed [40, 41, 44, 45, 47, 48, 53, 55, 57, 58].

Convergent validity studies were conducted for six dynamometers in 12 reports [41, 43, 67, 69, 70, 73–79]. Most reports compared dynamometry measures of PFM contraction with digital assessment scores of PFM strength [41, 43, 67, 69, 70, 77–79]. Furthermore, PFM passive and contractile properties were compared between dynamometry and EMG [70], intravaginal manometry [70] and PFM morphometry on magnetic resonance images (MRI) [75]. The association between dynamometry and aforementioned methods varied between moderate to very strong, except for PFM contraction on dynamometry vs EMG [70], which could be expected as the relationship between muscle force and electrical activity is not linear [17].

Overall, construct validity studies support pelvic floor dynamometry as a valid measurement of PFM passive and contractile properties. Of interest, only four studies evaluated the effect of intra-abdominal (IAP) pressure on PFM dynamometer measurements and concluded that it was negligible for the design of their PFM dynamometers either at rest or during PFM contraction [41, 73, 74, 76]. Other research groups have yet to quantify the effect of intra-abdominal pressure variations on their PFM dynamometer measurements.

Known group validity studies were conducted in 15 reports for seven dynamometers only [52, 63, 66, 72, 79–89]. Most studies compared stress urinary incontinence (SUI) vs controls [52, 66, 77–79, 82, 84, 86, 88–90]. Other comparisons included POP vs control [80, 81] and PVD vs control [63, 87]. All reports found significant differences in PFM passive and contractile properties between the compared groups except for one study comparing SUI vs control, where no significant difference was found at rest or for PFM contractions [82]. Interestingly, in this study, correct PFM contraction was not verified by vaginal palpation prior to the assessment, and it is possible that not all women were able to perform a correct PFM contraction on verbal command. Overall, the ability of most dynamometers to differentiate aspects of PFM function between known groups (SUI vs controls, POP vs controls, and PVD vs controls) confirm further aspects of their validity.

Regarding the assessment protocol, 75 reports described measurements of PFM function in women using 11 of the clinical dynamometers identified. The protocol described between reports varied considerably. Important pre-assessment procedures, such as standard bladder filling condition and correct PFM contraction confirmation were described by only 27% (n

= 20) and 33% (n = 25) of the reports, respectively. In 11% (n = 8) of the reports, PFM contraction was verified visually during the assessment or, in one case, using a micro-tip dual sensor placed in the bladder to monitor pressure as a surrogate for intra-abdominal pressure [73]. Regarding the assessment procedure, one report [73] only included PFM assessment with the women in the standing position, while the positions of choice for all other 73 reports were supine, semi-recumbent or half-sitting. There was a wide variation in the vaginal aperture used between and within research groups, ranging from 10 mm to the maximal tolerated by the women (20-40 mm), depending on the task being assessed or the population studied, as shown in Table 2.6. Of note, in 41% (n= 31) of the reports, the device diameter or precise aperture used during data acquisition was not reported, incomplete or unclear (i.e., reports of the opening angle or distance between branches without specifying the branch thickness). Depth of insertion varied from 3.5 to 8 cm and was mentioned by only 27% (n = 20) of the reports. Most reports assessed PFM force at rest and during maximal PFM contraction. Other tasks assessed included passive pelvic floor properties on stretch-release cycles (17%, n = 13); sustained or rapid PFM contractions (17%, n = 13); submaximal PFM contractions (3%, n = 2); and cough or straining (11%, n = 8). Variation was also observed in the PFM contraction hold time (from 4 to 90 seconds, when reported), number of trials acquired for each task (from 1 to 5), rest time between trials (from 10 seconds to 2 minutes) and instruction/encouragement given to participants during the assessment.

2.3.4 Personal Dynamometers

None of the personal dynamometers were of speculum type; all were cylindrical shaped. However, there was a difference in the structure between them: the length varied from 8 to 12 cm, the width ranged from 3 to 3.5 cm, and the weight ranged from 25 to 55 g. One dynamometer had two size options (Elvie), and the change in size could be achieved by adding a sleeve. Although the sleeve appears to be very thin from publicity, no information could be found regarding the precise size increment achievable with the sleeve. None of the personal dynamometers were fixed to bases or required holding. They were all meant to stay inside the vaginal canal without support. However, the feasibility of the dynamometers to stay in place at least in the standing position is expected to be directly affected by the weight of the device. Interestingly, although all three dynamometers potentially allowed measurements in variable positions (such as supine and standing), only one report on the psychometric properties of one dynamometer (Elvie) was found to support this assumption. In this report, the participants' ability to perform a correct (ventral cephalic) PFM contraction in both supine and standing was confirmed by using an accelerometer, which measures the angular rotation of the device in situ [59].

Table 2.6 Maximal Aperture Tolerated

Study	**Maximal vaginal aperture (mm)**	**Population**
Benoit-Piau 2018 [91]	21.4 ± 8.3	Women with vulvodynia
Bernard 2017 [92]	32.3±5.3	Women with hysterectomy without UI
	23.4±6.0	Women with hysterectomy and radiotherapy for endometrial cancer
Cacciari 2021 [93]	Individual treatment, Group treatment	Older women with UI
	36.3 ± 8.3, 37.5 ± 8.1	Baseline
	24 ± 4, 36.4 ± 7.6	Post treatment
	24 ± 4, 36.5 ± 7.6	1-y follow-up
Chamochumbi 2012 [86]	21 ± 3	Women that were continent
	24 ± 4	Women with SUI
Cyr 2017 [94]	38.9 ± 10.5	Women with complete avulsion
	35.4 ± 9.8	Women with no avulsion
Fontaine 2018 [95]	20.4 ± 7.7	Women with primary vestibulodynia
	21.9 ± 8.6	Women with secondary vestibulodynia
Mercier 2016 (case report) [96]	Baseline, Post Tx	Women with vulvovaginal atrophy and UI
	20.5, 25.1	
Morin 2008a (reliability study) [52]	25.4 ± 3.0 to 27.1 ± 3.91	Post-menopausal women with SUI
Morin 2008b [90]	Not reported	Postmenopausal women with and without UI
Morin 2010 [37]	33.5 ± 7.3	Women that were continent
Morin 2017 [63]	21.3 ± 3.7	Women that were continent vestibulodynia
	28.7 ± 4.6	Healthy women (controls)

Regarding the material, all personal dynamometers were made of medical grade silicone. Of interest, this is a biocompatible material that is commonly used as a cover for medical devices based on FDA guidelines [97–99].

Psychometric studies were limited to only one peer-reviewed report, in which reliability and

construct validity were assessed for the Elvie dynamometer [59]. The results suggested strong between-visit reliability and very strong within-visit reliability for dynamometer measurements of PFM force at rest (baseline) and during PFM maximum contraction (relative peak and peak force) in both standing and supine positions. As for construct validity, the association was weak between other PFM function assessment tools (Elvie vs EMG, Elvie vs Berube's dynamometer, Elvie vs digital palpation using the modified Oxford scale) [59]. No known group validity reports were found. Overall, additional studies are needed to assess validity, and reliability of these instruments.

2.4 Discussion

To the best of our knowledge this is the first review paper to discuss the characteristics, advantages, and limitations regarding existing clinical and personal PFM dynamometers, as well as particularities of each assessment protocol reported. This review consisted of a comprehensive search conducted by two independent researchers and cross checked by a third party. The search comprised a broad inclusion criterion, acknowledging for all possible information found in different published materials with no language restriction. A total of 20 clinical dynamometers and three personal dynamometers were identified.

2.4.1 Clinical Dynamometers

Design and psychometric evaluation

The variabilities found between the shape (including its length and diameter), structure (if fixed or not to a base) and direction of measurement, across PFM dynamometers, make it complex to compare or combine measurements done with different instruments, which emphasizes the need for a standardization. Details on limitations and recommendations for dynamometer design are summarized in Box 1 and 2.

Assessment Protocol

The wide variation found on assessment protocol reports across studies highlights the need for standardization of important procedures that could reduce bias and improve repeatability of data acquisition. In addition, there is a critical need for experts in the field to meet and establish guidelines for PFM dynamometers' design, assessment protocol and measurements. Details on limitation and recommendations are summarized in Box 1 and 2.

2.4.2 Personal Dynamometers

Findings to date present limited information on personal PFM dynamometers. First, for only one personal dynamometer, studies of construct validity, reliability, and ability to distinguish correct (ventral cephalic) PFM contraction were conducted [59]. More research is needed to confirm reliability and validity of measurements taken with these instruments in different populations and conditions. Of note, two out of three of the commercial dynamometers had a fixed diameter, and therefore cannot be adapted to different vaginal sizes, which may limit its use by a specific population [60, 61]. Further, more work is needed (ie: assessing the

Box 1 Clinical PFM dynamometers design advantages and disadvantages & reported psychometric properties

Fixed base or wearable

A fixed base limits the position of use of the dynamometer to supine and restricts most of the time the direction of measurement to one direction. Handheld dynamometer allows measurements in functional positions such as standing; however, repeatability of measures may be lower as they will be dependent on user experience. Because UI and POP symptoms usually occur in the standing position rather than in supine, it may be relevant to measure intravaginal forces in this position. Of note, in this review only one study reported on the psychometric properties (construct validity) specific to the standing position. Stay in place dynamometers are potentially more comfortable and allow measures in different position, but they could move affecting validity of measurement. Presently there are no studies to support their psychometric properties to assess PFM contractility or tone.

Adjustable aperture/fixed diameter

Dynamometers with adjustable aperture can accommodate different assessment purposes and populations, unlike dynamometers with fixed diameters. For example a dynamometers with adjustable aperture has been used to evaluate the PFM function in women with provoked vestibulodynia in static conditions at different vaginal apertures and during repeated dynamic cyclic stretching [63]. Further, as for any other muscle group, PFM force is dependent on muscle length [27]. Dumoulin 2003 [65], reported on the PFM length tension curve, showing higher force related to higher aperture or muscle length. Additionally, Morin 2008 [52], found that PFM forces measured at a lower dynamometric opening are less repeatable. Therefore, the variability found between diameters

and apertures across instruments make it complex to compare or combine measurements done with different instruments.

Direction of measurement

Dynamometers vary in their capacity to measure PFM forces in different directions. Some of them measure at a fixed direction (e.g., fixed base devices that can only measure force in the anteroposterior or laterolateral direction). Others at variable directions (e.g., hand-held or stay in place devices that can potentially be used in any direction). Few measure at multiple directions simultaneously (e.g., devices with multiple force sensors) [47, 48]. Of note, 93% of the dynamometers potentially able to measure PFM force in variable directions present data in one direction only (anteroposterior or laterolateral) [40, 41, 43, 44, 46, 49–51, 53, 55, 57, 58]. The heterogeneity in the direction of measurements also makes the comparison between different studies difficult.

Differential arrangement PFM measurements will vary according to the site of force application on the dynamometer in relation to the force sensor location. Since the precise location of the PFM resultant force can vary between subjects and is difficult to determine, it constitutes an important source of error within a unit or between units, unless the depth of introduction is standardized. By using differential arrangement the force is measured independent of its exact site of application, reducing possible measurement bias [62]. Of note, only 5 dynamometer (2 research groups) had utilized differential sensor arrangement in their design.

Psychometric evaluation

As only few research groups conducted and published psychometric assessments of their measuring instrument, additional research is needed on the validity and reliability of clinical PFM dynamometers. Further, as part of validity assessment, it is important to evaluate the influence of intra-abdominal pressure on PFM measurements. Morin et al. 2006, evaluated the effect of intra-abdominal pressure (IAP) on PFM strength measurement with an intra-rectal balloon [76]. For Dumoulin 2003* dynamometer [27], the influence of the IAP on PFM strength measurements was found to be small during PFM voluntary contraction and Valsalva (6.8-14.2%). Further, Ashton-Miller 2014* estimated the intra-abdominal pressure via intra-vesical catheter and proved that IAP was also not correlated with their dynamometer measurements [41]. Many research groups have yet to quantify the capacity of their clinical PFM dynamometers to distinguish PFM

contractions from other artifacts (e.g., deep abdominal pressure).

* Unless clearly defined by the authors, each dynamometer was named after the first author of the first related publication identified.

Box 2 Recommendations for PFM dynamometer design & assessment protocol

Recommendations for new dynamometers

Key design features should favor: (1) Adjustable aperture or diameter, allowing for measurements in different populations. (2) Differential arrangement for strain gauges sensors, reducing assessment bias related to force sensor location. (3) Wearable devices, that are properly validated for assessments in different body positions as they allow more versatility (e.g., supine and standing position). Use of fixed dynamometers in supine position are to be favored in the meantime as they present highest level of evidence.

Psychometric evaluation recommendations for all existing and new dynamometers

Key psychometric evaluation should include: (1) Validity (known group, construct) and reliability (test-retest, inter evaluator) of PFM contractility and tone assessed in clinically important positions such as supine and standing. (2) Assessment of intra-abdominal pressure effect on the PFM dynamometer measurements. (3) Ability to confirm correct (ventral cephalic) PFM contraction. This may be more important for personal dynameters as they are intended for patient use presumably without the need for contraction confirmation by a clinician.

Assessment protocol recommendations for all existing and new dynamometers*

Recommended pre-assessment procedures:(1) Ask the woman to empty their bladder. (2) Explain the measuring instrument's objective and procedures. (3) After the woman has undressed, ask her to adopt a supine position, hips and knees flexed and supported, feet flat on a treatment table or ask the patient to take a standing position. (4) Prior to the insertion of the dynamometer's probe/speculum, give detailed instructions about contracting the PFM using anatomical models, drawings. (5) Assure the woman is able follow the assessment protocol by checking their ability to perform correct PFM contraction and relaxation, preferably using vaginal palpation. (6) Gently insert the dynamometer into the vaginal cavity to a deep enough to reach the PFM. Note the angle of dynamometer on insertion as well as the insertion depth and orientation (anteroposterior or transverse) to ensure repeating the same testing situation from one measurement to the next. (7) In case of dynamometers with adjustable apertures, choose a proper aperture (counting the branch thickness) that is both most reliable and specific to the studied population. Further, make sure to use the same aperture when comparing measurements within or between patients. (8) Allow enough time for the woman to adjust to

the sensation of the probe/speculum inside her vagina; time that can be used for practicing the required maneuver before recording a task (e.g., PFM maximal contraction) and to check for any discomfort.

Recommended assessment procedures: (1) Record and report on data with the woman at rest, which can be used as reference for other tasks. (2) For a PFM maximal contraction, ask the woman to breathe out and then to squeeze and lift the PFM as if to prevent the escape of flatus and urine or any other standardize prompt. Make sure to standardize the PFM contraction hold duration. (3) Assess at least 3 trials of each task, so a mean can be taken. (4) Allow at least 1-min for the woman to rest between tasks. (5) Give standardize feedback while taking active measurements tasks such as strength, endurance and coordination or encourage relaxation during passive force measurements. (6) Note all PFM contraction instruction and encouragements provided, as well as access to any other feedback during the assessment. (7) After each evaluation session, proceed to high level disinfection/sterilization of the dynamometer as per institution standards."

*Based on the most commonly reported procedures and on the recommendations established by the International Continence Society (ICS) report on the terminology for pelvic floor muscle assessment [26].

impact of intra-abdominal force on PFM) for personal dynamometers to be recommended for patients as a valid/reliable measure of PFM force. Overall, in face of all variability observed on PFM dynamometer design, psychometric evaluation, and assessment procedures across reports, standardization is needed to enable comparison and consistency between studies. Standardized design and detailed assessment procedures could guide clinicians and researchers by not only increasing the precision of measurements but also by enabling the generalizability of results across studies using similar equipment. For existing dynamometers, we suggest key assessment protocol recommendations (Box 2). As for new dynamometers, key recommendations were based on the existing evidence, aiming to limit as much as possible biases. For example, a PFM dynamometer should accommodate different vaginal cavity sizes if intended to be used by different populations. It should also allow measurement at a vaginal opening where force produced is large enough to ensure sensitivity of measurements and measurement change. Additionally, differential arrangement for the sensors is preferable to avoid lever arm influence. Further, it may be of interest that the unit is wearable to allow measurement in functional positions (such as standing), although more studies are needed to confirm its feasibility and validity. Assessments in the upright posture, for example, would

capture the natural action of the muscle in a position that it must function daily, and at the same time requires greater tone in the PFM [75].

2.5 Conclusion

This review presents details on 23 available PFM dynamometers in both research and industry including discussion of the characteristics, advantages, and limitations of each instrument. There is considerable heterogeneity in existing PFM dynamometers design, and methods of assessing the PFM function. These variations made comparison between studies difficult preventing the understanding of overall PFM function, dysfunction, and the effect of different intervention on PFM function.

There is a crucial need to document existing dynamometer design and PFM force assessment protocol, accounting for direction of force measurement and structure and shape of the PFM dynamometers (including diameter and depth of insertion). Additionally, this review recommends establishing design and assessment protocol standards for new dynamometers to ensure the reproducibility of PFM measurements and allow the establishment of normalized data as it has been done for other muscle groups.

CHAPTER 3 ARTICLE 1: A DYNAMOMETER-BASED WIRELESS PELVIC FLOOR MUSCLE FORCE MONITORING

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This chapter presents the first objective of the thesis, which is to design and test a proof-of-concept prototype for a force measuring system based on an existing PFM dynamometer. This work was published at the 42nd annual international conference of the IEEE Engineering in Medicine and Biology Society (EMBC), 2020.

3.1 Abstract

In attempts to improve the quality of life of women, continuous projects are sought between rehabilitation intervention and engineering. The knowledge of Urinary dysfunctions' pathophysiology sheds the way for smart rehabilitation technology. Using the knowledge of Pelvic Floor Muscle physiology, assessment, and training methods are developed to reduce lower urinary tract symptoms such as urinary incontinence. Therefore, this paper covers the design and implementation of the proof-of-concept of a wireless pelvic floor muscle force measurement system based on a dynamometer as a first step toward providing a fully integrated solution. The proposed device allows the physiotherapist to wirelessly monitor variation in pelvic floor muscle force during assessment and/or training. Wireless communication is performed through a Bluetooth low energy transceiver v5.0, with a corresponding interface on

both computer and smartphone. Force measurements are made with strain gauge precision sensors operated in a full Wheatstone bridge configuration. The device operates at a 3.3 V supply and achieves a power consumption of 14 mA in operating mode. System design and experimental results are reported and discussed.

3.2 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) [12, 28, 100, 101].

UI is a highly prevalent condition, especially among women: one out of three women suffer from UI [12], and up to 50% of women over the age of 65 are affected [12]. The Canadian Urological Association estimated that 3.3 million Canadians suffer from UI in 2012 [12]. In addition to stress and social isolation, UI has a major impact on self-esteem and quality of life [12]. 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 [15].

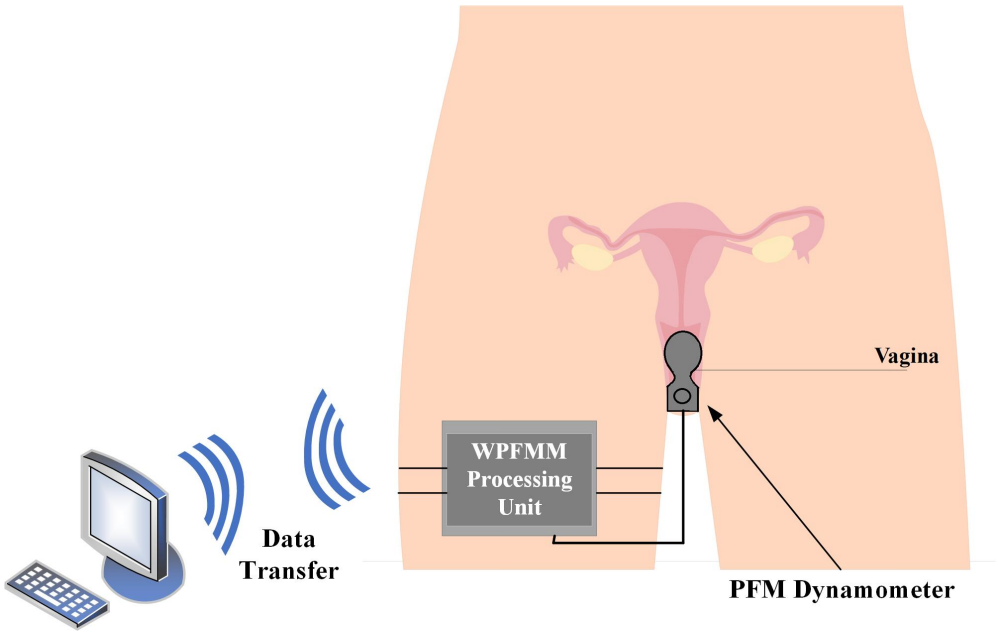

Figure 3.1 Overview of the proposed wireless pelvic floor muscle measurement (WPFMM) system.

UI in women is caused by defects or dysfunctions of the PFM, which close the urethra and support the pelvic organs [100]. PFMT is the first-line treatment for UI and has been shown

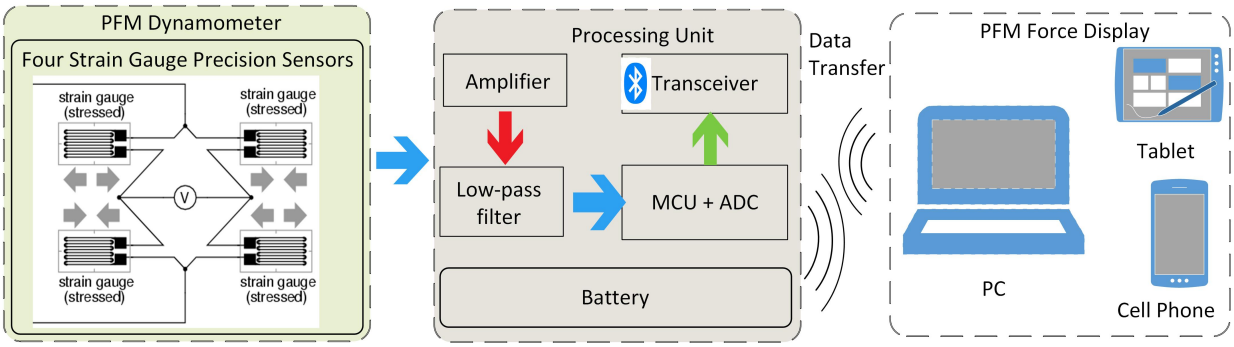

Figure 3.2 Components of the proposed wireless pelvic floor muscle measuring (WPFMM) system.

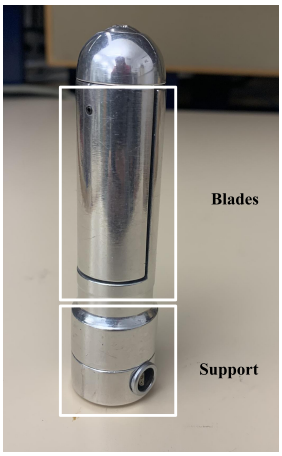

Figure 3.3 PFM Dynamometer parts.

to improve urethral closure and pelvic organ support, thereby preventing urinary leakage [28]. 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 [28].

To better understand the pathophysiology for the assessment and training of PFM, several measurement methods have been presented [20, 23, 27, 102]. 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 [20]. However, the repeatability of measurements is low as this method is subjective and based on physiotherapist experience [23]. On the other hand, the PFM dynamometer is a reliable and direct measurement method of PFM forces [23,103,104]. 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 dynamometers have produced a number of prototypes in the past 20 years. The Montreal Dynamometer proposed by Dumoulin et al [27] is one of the several PFM dynamometer prototypes used in research. However, all these prototypes are connected via wires to processing units [27,41,57].

Wire-based monitoring systems may function adequately, 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.

3.3 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 3.1 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.

3.3.1 System Building Blocks

Figure 3.2 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/smartphone). In the following, we provide a detailed description of the various components used to construct the proposed system.

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

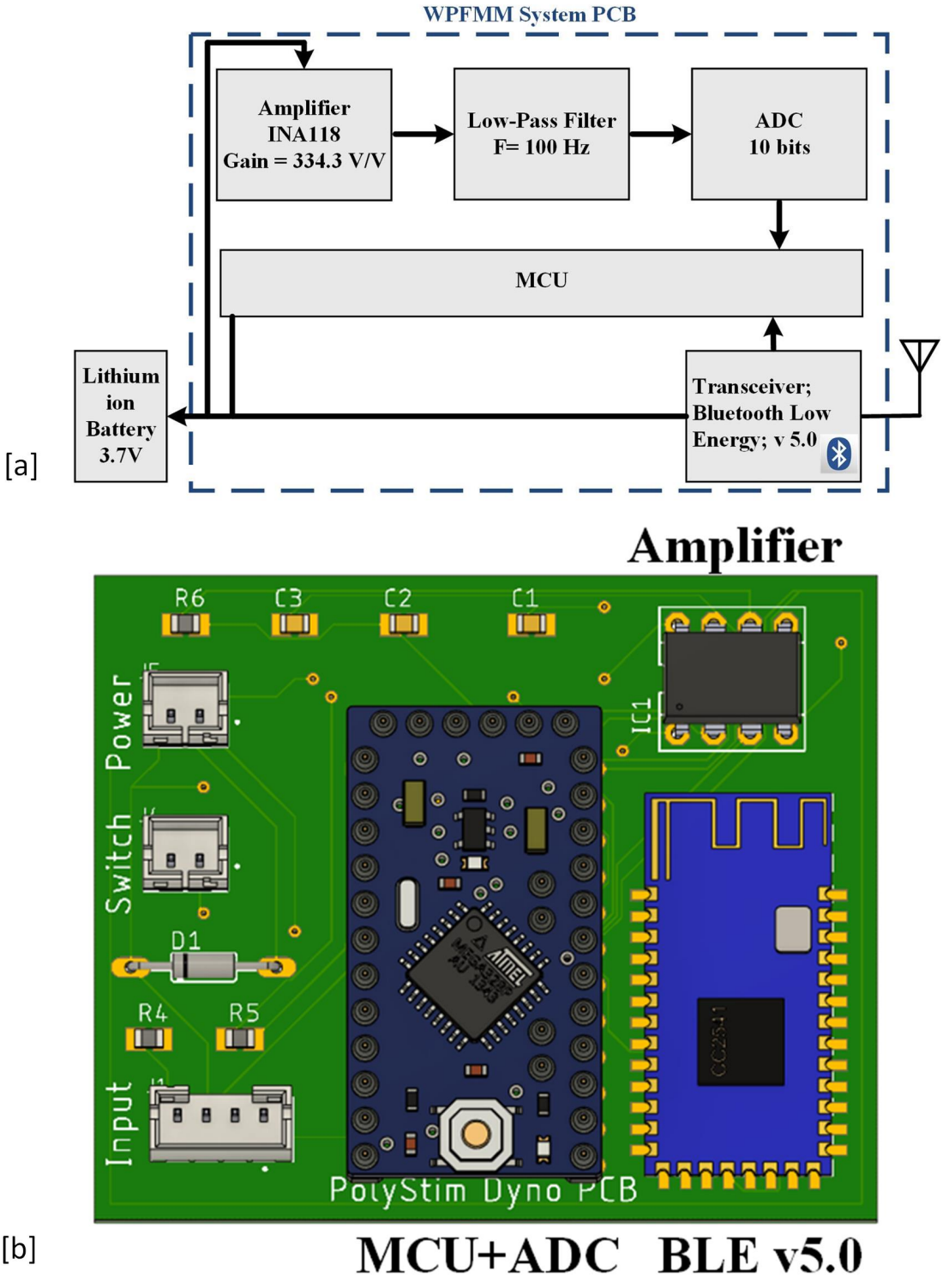

Figure 3.4 Processing unit for the proposed WPFMM system (a) Block diagram, and (b) Designed PCB.

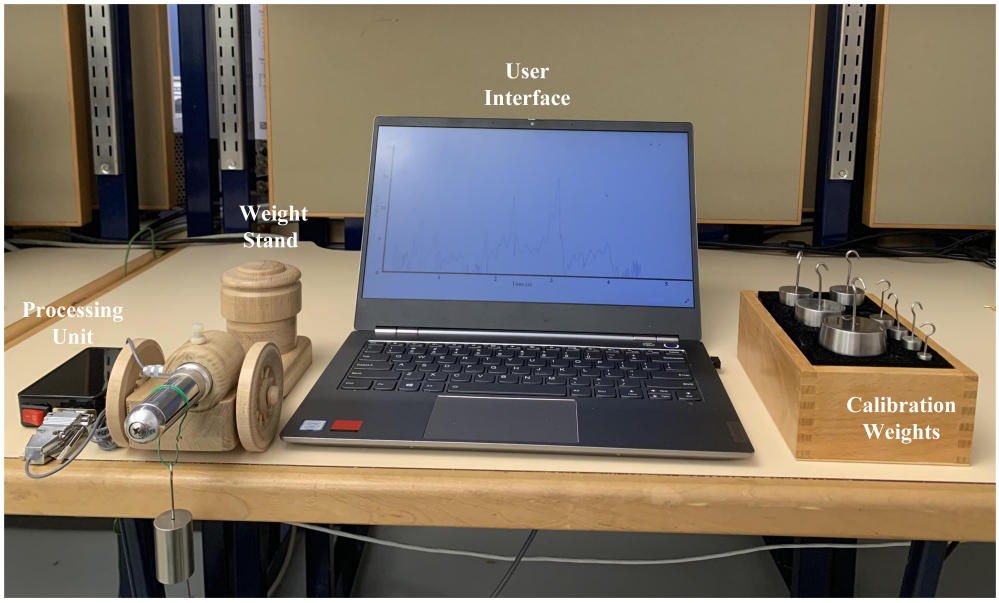

Figure 3.5 Wireless pelvic floor muscle measurement system experimental setup.

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 a differential arrangement. The differential arrangement assures that the force is independently measured of the exact site of application of the force [102].

The employed PFM dynamometer prototype is shown in Figure 3.3. The dynamometer is made of two parts; support and blades, and is covered with a condom for hygiene purposes [102].

Processing Unit

Figure 3.4(a) presents the block diagram of the utilized processing unit in the proposed WPFMM system with the corresponding specifications. It is composed of an instrumenta-

tion amplifier, a low pass filter, a microcontroller (MCU) with analog-to-digital converter (ADC) module, and a Bluetooth low energy module (v5.0). The printed circuit board of the processing unit is shown in Figure 3.4(b).

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, smartphones 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.

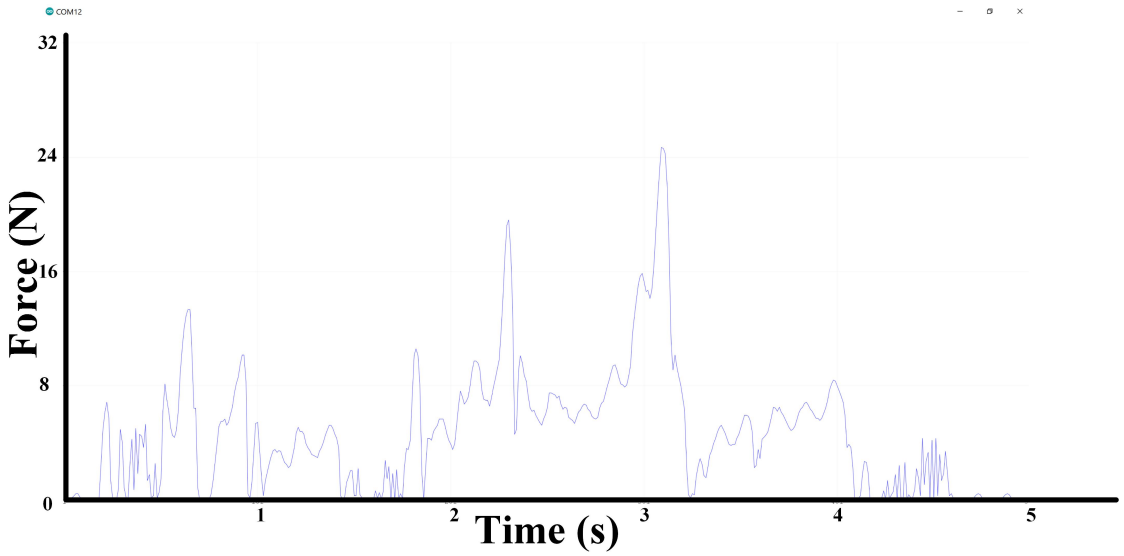

Figure 3.6 Real-time PFM force data measure via laptop.

3.4 Experimental Results

The proposed WPFMM hardware has been realized and tested using the test bench shown in Figure 3.5. 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 an Arduino IDE interface developed for results visualization.

The dynamometer was first calibrated to obtain the calibration factor that converts from the 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 a computer via Arduino IDE as shown in Figure 3.6. Also, real-time PFM force data are monitored via DSD TECH Bluetooth mobile application as shown in Figure 3.7.

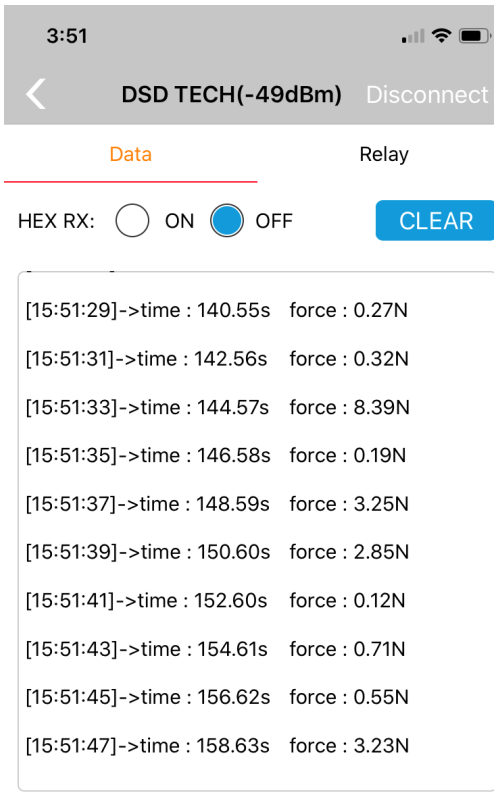

Figure 3.7 Real-time PFM force data via smartphone.

In operating mode, the presented device consumes around 14 mW from a 3.3 V supply. Figure 3.8 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.

3.5 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

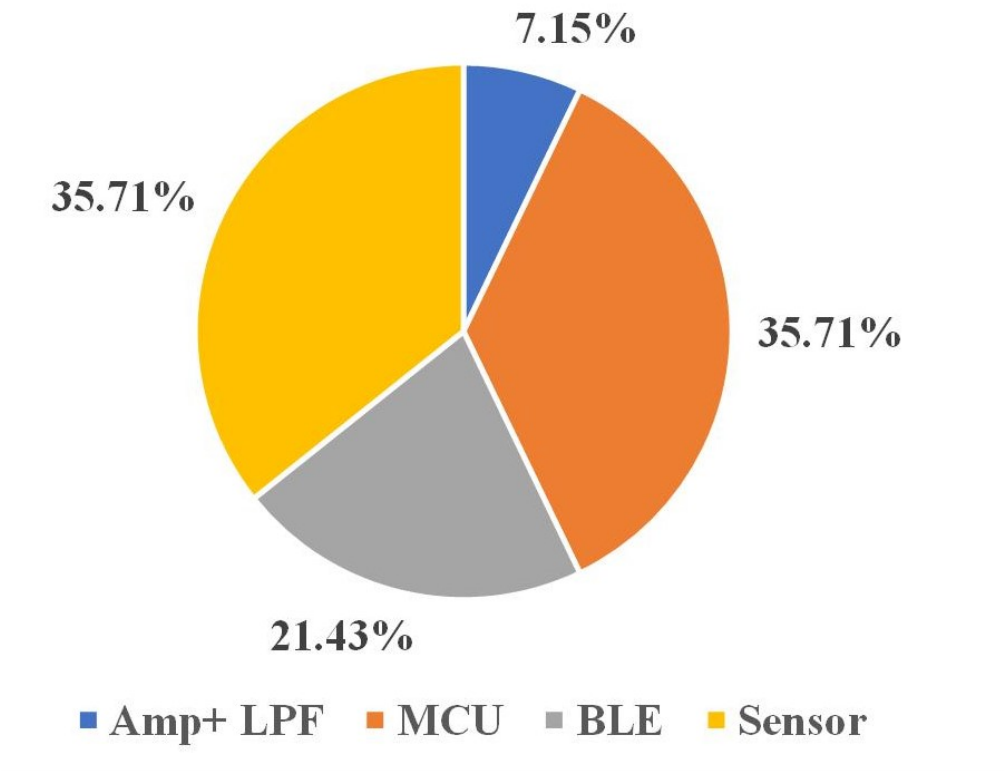

Figure 3.8 Power consumption percentages of the different blocks of the WPFMM system.

to reproduce natural PFM functions 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 in progress.

CHAPTER 4 ARTICLE 2: PORTABLE DYNAMOMETER-BASED MEASUREMENT OF PELVIC FLOOR MUSCLE FORCE

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This chapter presents the second objective of the thesis, namely the design, and implementation of a novel portable force measuring system consisting of a newly designed probe and processing unit. The system is tested and validated for functionality and usability. This manuscript was published in the IEEE Journal of Translational Engineering in Health and Medicine as a regular paper in November 2022.

4.1 Abstract

Objective: In attempts to improve the quality of life of women, continuous projects are sought between rehabilitation intervention and engineering. Using the knowledge of the pelvic floor muscle (PFM) physiology, assessment and training methods are developed to reduce lower urinary tract symptoms such as urinary incontinence. Therefore, this paper covers the design and implementation of a portable vaginal dynamometer.

Methods: A PFM probe is designed, 3D printed, assembled, and tested in ten women to assess its acceptability and usability. The feedback from the usability study is used to optimize the PFM probe design. A vaginal dynamometer is developed based on the designed

PFM probe, then tested for linearity, repeatability, hysteresis, noise and heat effect, and power consumption. The variability between the different produced PFM probe prototypes is evaluated.

Results: Force measurements are made using a load cell. Wireless communication is performed through a Bluetooth low energy transceiver v5.0, with a corresponding interface on both computer and smartphone. The device operates at a 3.3 V supply and achieves a power consumption of 49.5 mW in operating mode. Two PFM probe sizes are designed to accommodate different vaginal hiatus sizes, based on usability study feedback. The proposed system allows the physiotherapist to wirelessly monitor variation in pelvic floor muscle force during assessment and/or training.

Discussion/Conclusion: The testing results showed that the newly designed system has the potential to measure the PFM function in functional conditions such as the standing position.

4.2 Introduction

Involuntary loss of urine (urinary incontinence) is a highly prevalent condition especially among women. Approximately, one in three women suffers from this condition [3]. In 2012, the Canadian Urological Association estimated that 3.3 million Canadians suffer from urinary incontinence. In addition to stress and social isolation, urinary incontinence affects patient's self-esteem and quality of life [12]. Furthermore, a financial burden of high significance is imposed on patients and healthcare organizations. The expenses are estimated to be 16.4 billion dollars annually according to a study made on a US population [15]. Urinary incontinence in women is linked to defects and/or dysfunctions in the pelvic floor muscle (PFM), which is responsible for supporting the bladder neck and closing the urethra. The assessment of PFM forces evaluates the capacity of PFM to contract and relax actively. The first line treatment for urinary incontinence is PFM rehabilitation [28]. This treatment has been shown to improve pelvic organ support, and urethral closure, and thus preventing urinary leakage. It has been recommended to assess the PFM function prior to and during PFM training to evaluate dysfunctions, measure the improvement, give the best training program for specific PFM dysfunction, and to measure improvements [28].

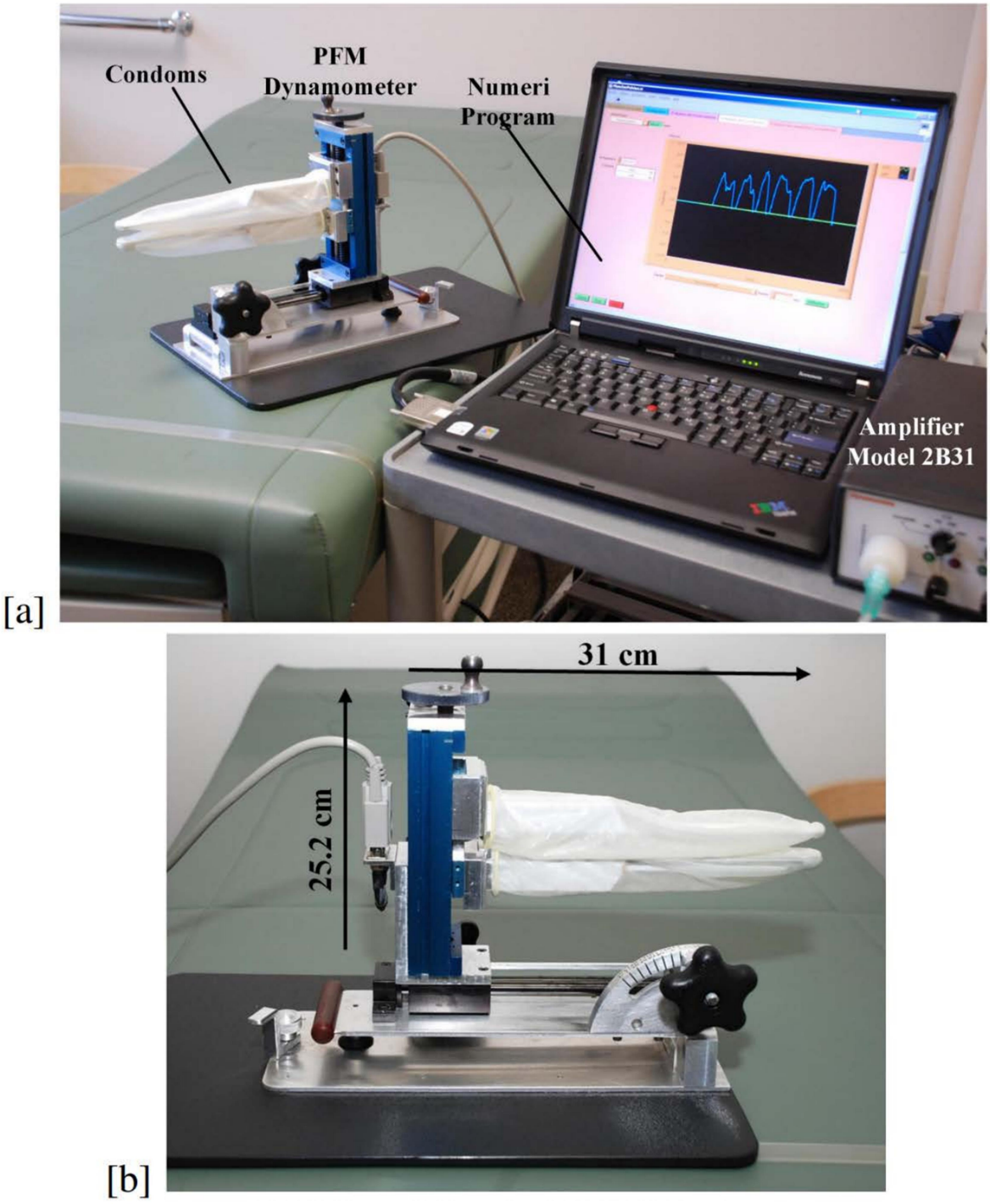


Figure 4.1 Example of a wired dynamometer-based measurement system: (a) Complete research system used at Centre de recherche de l'Institut universitaire de gériatrie de Montréal (CRIUGM), and (b) Experimental prototype.

Proper assessment of PFM is considered as a key element in the management of urinary incontinence in women. Several measurement methods have been developed to assess and train the PFM [20–23]. The most common assessment method is digital palpation, where the physiotherapist inserts his/her fingers in the vagina of the patient to palpate the PFM in order to feel passive forces at rest and active forces during maximal PFM contraction. However, repeatability is limited as it is a subjective measurement of PFM function [20] and dependent on the evaluator's competency. Perineometry, electromyography (EMG), and imaging techniques (ultrasound and magnetic resonance imaging (MRI)) are indirect force measurement methods [23]. The major drawback of EMG is the possible bias of the PFM measurements due to cross talk from the surrounding muscles. As for the perineometer (pressure measures), the validity of the measurements can be affected by artifacts such as intra-abdominal pressure.

Over the last 15 years, dynamometry has been proposed to achieve reliable and direct measurements [28, 104]. This device is inserted into the vagina, to assess the PFM function, through measuring the PFM resting and contractile forces using strain gauges (SG) mounted on a speculum. Then, a processing unit is used to process the force data. Finally, the data is displayed on a PC monitor. Several dynamometer prototypes, for research purposes, have been presented in the literature [23, 104]. However, in these approaches, the force signal is transferred to a user interface, for processing and display, through a wired connection between the user interface and the processing unit. The presence of a wire between the processing unit and the computer is problematic for both the patient and therapist in the evaluation and treatment environment. Moreover, and based on the system design, the wire could limit the measurement position to a supine position rather than a standing position in which UI is much more prevalent.

An example of a wired PFM real-time measurement system used in the Incontinence and Aging Laboratory at Centre de recherche de l'Institut universitaire de geriatrie de Montré al (CRIUGM) is depicted in Figure 4.1(a), where a dynamometer is used to measure the PFM force and transfer it to the amplifier model (Analog device model 2B31). Then, the amplified signal is delivered to a laptop computer for further processing and display. In addition to system complexity and requiring special training to be used, the employed dynamometer (developed by Dumoulin et al. [27] and improved by Morin et al. [52]) is bulky, and heavy, as shown in Figure 4.1(b). Although it is adequate for research, it is not optimal for clinical applications.

Recognizing the importance of a portable direct PFM force measurement tool in clinical research and rehabilitation intervention, our long-term objective is to build an electronic device

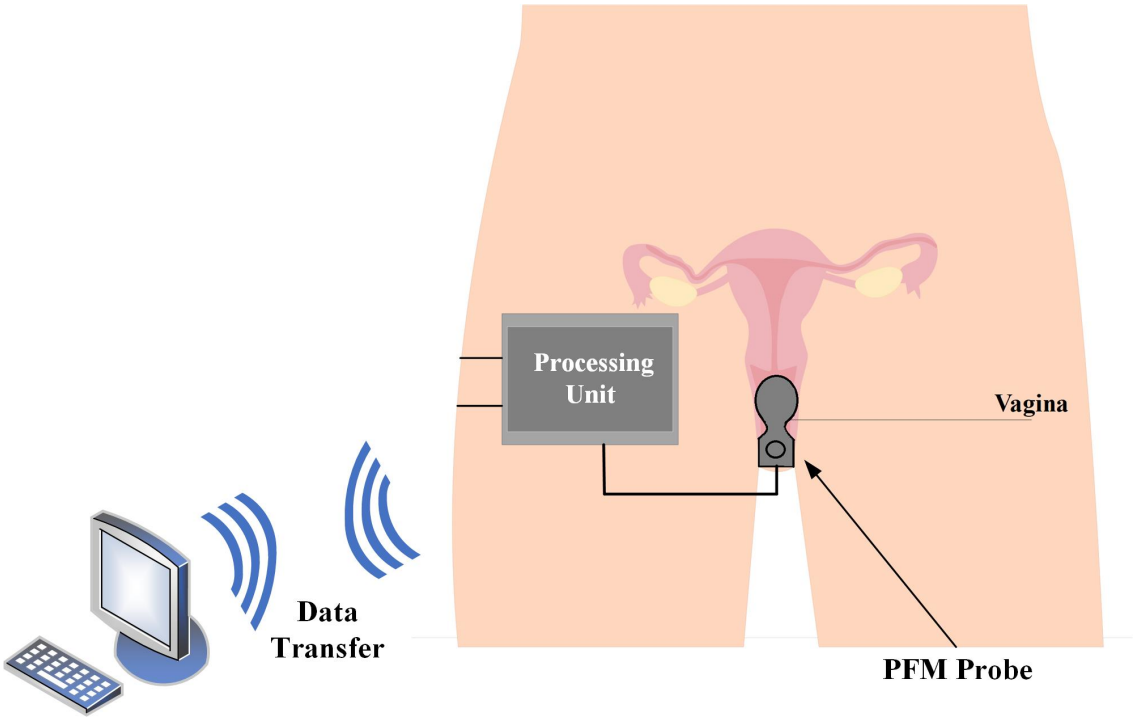


Figure 4.2 Overview of the proposed portable vaginal dynamometer.

that is wearable, and wirelessly operable which includes a biofeedback real-time measurement interface. In this system, the processing and the wireless transmission will be designed with a small, printed circuit board so that it can be included in the Dynamometer. Therefore, no wires will be coming out from the vagina.

A proof-of-concept prototype, for a system measuring pelvic floor muscle forces, based on a previous dynamometer, has been developed and tested in an earlier study [49]. Further, and as a first step towards achieving the projected system, a complete original portable vaginal dynamometer prototype is given in this paper. The vaginal dynamometer consists of a newly designed PFM probe, used to acquire the force signal, connected to a processing unit that has been constructed from discrete components. An overview of the proposed system is illustrated in Figure 4.2.

The proposed system is designed to be used in research and in rehabilitation settings. In research settings, the system is planned to be used in clinical research aiming to better understand the pelvic floor muscle function and dysfunction and to evaluate the effect of UI treatments on the pelvic floor muscles in functional positions such as standing position. In rehabilitation settings, the system will provide biological feedback during PFM training, while providing flexibility and portability for both the participant and the physiotherapist.

The presented system in this paper is a part of a developed geriatric rehabilitation exergame that uses wearable sensors (vaginal dynamometer and shoes step detection) and a web-based interface for the treatment of UI (AAL VITAAL project (www.aal-europe.eu/projects/vitaal/)). With a portable vaginal dynamometer, which allows women to move freely while exercising, older adults with mobility limitations, cognitive impairment, and urinary incontinence can train their strength, balance, and cognitive skills at once with such exergames.

The paper is organized as follows: the new PFM probe design is presented in Section II. Section III presents the architecture of the proposed system, where the function of the various building blocks is described. Then, the experimental results of the implemented system are presented in Section IV and discussed in Section V. Conclusion and future work are given in Section VI

4.3 Pelvic Floor Muscle Probe Design

Presently, there is no gold standard or universal reference for PFM measurement. Therefore, designing a reliable and valid assessment tool to both measure and train PFM is of high importance. We describe in this section, the literature review supporting the proposed PFM probe design in terms of the type of sensor used and the sensor's location, the direction of measurement, and finally the dimensions and shape.

4.3.1 PFM Probe Sensor Type

As the aim of the newly developed system is to directly measure the PFM resting and contractile forces, direct force sensors have been considered such as strain gauges (SG), load cells, and force-sensitive resistors (FSR). Among the force sensors, a load cell is implemented due to its flexibility in the design integration, and easy installation, allowing for rapid prototyping.

4.3.2 PFM Probe Sensor Location

Several works have investigated the force distribution in the pelvic floor under different pelvic floor muscle activities [105–107]. Such studies aimed at identifying the critical dimensional parameters for sensor measurements. For this reason, different studies have used different approaches to present the different dimensional parameters such as the location of force inside the vagina, vaginal length, vaginal width, and direction of measurement. These studies aimed at identifying the optimal strain gauge sensor's location on the PFM probe.

In 1992, a study described measuring vaginal pressure with a 1.5 cm balloon device. The

women performed three PFM contractions with a vaginal balloon placed in four different positions: 1) against the vaginal vault and in the posterior fornix, 2) in the proximal upper third of the vagina, 3) with the middle of the balloon 3.5 cm from the introitus vagina and 4) with half of the balloon outside the introitus vagina. The study found the highest pressures were recorded when the middle of the balloon was placed 3.5 cm from the vaginal introitus [105].

In 2005, a rapid pull-through technique utilizing a four channel water perfused catheter on a motor-driven puller was used in a study to create a pressure profile in the vaginal cavity for each woman. The profiles were measured with the women at rest and during a sustained contraction of the levator ani muscle. The individual subject's pressure profiles were averaged to create a composite profile at rest and during squeeze. The study made sure to cover the mid-portion of the vaginal canal for all participants (around 3.5 cm from the vaginal introitus). The study concluded that around 3.5 cm from the vaginal introitus is the most relevant region for pelvic floor muscle contraction, confirming previous results [106].

In 2017, a study used a novel instrumented probe for measuring 3D pressure distribution along the vaginal canal. The probe consisting of a hard plastic cylinder was covered by capacitive transducers placed in a 10 by 10 matrix configuration. The pressure distribution was constructed during two activities (maximum contraction and Valsalva maneuver). Through examining the 3D pressure with 100 sensors, the study showed that the maximal pressure values were located between 3 and 4 cm from the vaginal opening [107].

Therefore, since the pelvic floor muscular mass is located around 3.5 cm from the vaginal cavity opening, the SG sensors are arranged such that 3.5 cm from the vaginal introits is at the midpoint. This arrangement allows the sensors to record the optimal PFM measurements.

4.3.3 Direction of Measurement

The most challenging part of the design process is the highperformance requirements expected from the system in terms of repeatability, validity, and sensitivity of measurements. As a part of the validity of the system, there is a critical need to differentiate what is PFM contraction and what is not. This is because, when women are verbally taught how to contract their PFM, around 40% of women do an incorrect or a reverse contraction or a push which weakens their PFM rather than strengthens it [108]. Thus, it is very important to understand how to differentiate between correct and incorrect PFM.

Considering the functional anatomy of the PFM, a ventralcephalic contraction pattern is observed (compressing the vagina, urethra, and rectum against the pubic bone) during a

correct PFM contraction. Whereas upon an incorrect or reverse contraction of the PFM also called the Valsalva maneuver, a dorsal-caudal pattern is observed. Clinically, and in research measurements of the active/ maximal PFM forces are obtained by a digital or by an instrument measuring force exerted by the PFM in the anteroposterior direction in the inclined vagina (ventral-cephalic contraction pattern). These measurements are conducted with women with UI, and sexual dysfunctions and have been shown to produce larger pressures and force changes in anteroposterior than in latero-lateral [28, 48, 83, 109]. It is important to understand the movements of the PFM muscles to design the PFM probe. For example, the importance of identifying the direction of measurement of the PFM probe is that the configuration of the sensors is affected by the axis of measurement. Based on the presented information, it could be expected that our proposed vaginal dynamometer is focused on the anteroposterior assessment of the forces inside the vaginal cavity.

4.3.4 PFM Probe Dimensions and Shape

The dimensions and shape of the PFM probe are two critical parameters in the design process. The challenge in these two parameters arises from the quantitative interindividual differences in vaginal morphology which can be related to the presence or not of vulvar pain, sexual activity, vaginal delivery, aging, and menopause. Further, limitations in terms of the area are imposed from the PFM probe possible dimensions. Clinically, the major concerns when designing the dimensions and shape of the PDM probe are as follows:

1. What are the optimal probe dimensions that can fit different vaginal sizes and morphologies for different women's age groups? Considering that the vaginal length reduces with age [110].

2. How can the probe stay stable inside the vagina while exercising in both standing and supine positions?

Several limitations and suggested dimensions have been reported in the literature. Firstly, the muscular mass of the pelvic floor is located some 3.5 cm from the opening of the vaginal cavity [105]. Thus, the depth of the PFM probe, that is the portion entered into the vaginal cavity, is suggested to be more than 3.5 cm so that the force of the PFM is well captured [27, 105, 107]. Further, there should be some extra length to make sure the PFM probe stays stable inside the vagina. However, as a limitation and to consider young and elderly women the maximum depth is about 7 cm [110].

Therefore, a 6 cm depth allows the peri-vaginal portion of the pelvic floor to squeeze on the PFM probe while the PFM probe presses underneath the pubic bone to provide stability.

Secondly, an aperture range (opening of the dynamometer) between 3 to 4 cm has been proven to have good reliability for PFM assessment measurement and gave better results and more trustworthy measurements of PFM force [58, 107].

4.3.5 Proposed PFM Probe Design

Taking into account all the previously mentioned criteria, a complete PFM probe design is proposed. Threedimensional (3D) models of the PFM probe were designed according to the detailed requirements and limitations presented in terms of length and width (L = 6.5cm inside the vaginal cavity; D = 3.1 cm). Then the models were 3D printed using Polylactic acid and sanded to assure the maximum smoothness required for the mold painting step. Each time a model was printed, it was tested for usability by 2-3 women. After six enhancements the optimal prototype was reached. The design enhancements targeted enhancing the proportionality between the different probe parts and adding side elements for more stability inside the vaginal cavity. The different 3D-printed prototypes are shown in Figure 4.3(a).

Figure 4.3(b) shows the final PFM probe design. The proposed PFM probe is composed of three major parts: support, base, and external blade. The support can be analogized to the tail of the PFM probe. The support remains at the entrance of the vagina. The external blade is movable, fixed from one side to the PFM probe, and free from the other end. A load cell, utilizing the principle of a cantilever beam, is used as the base.

The SG mounted on the load cell utilizes a full Wheatstone bridge configuration using differential arrangement, as can be seen in Figure 4.3(b). This arrangement ensures that the PFM force is constant wherever the force is applied on the length of the dynamometer. The differential arrangement has been used previously by our team and in similar systems (Dynamometer for upper limb [62]/ Dynamometer for hip and knee [111]).

The PFM forces exerted on the PFM probe induce a strain on the external movable blade, causing the blade to move inwards. The strain is then transmitted to the load cell. The load cell measures the strain through a change in the load cells' electrical resistance. The resistance change, in turn, is measured as a voltage variation. Through the calibration process, a calibration factor is obtained. The output voltage values of the PFM probe are then converted into units of force using the calibration factor.

The PFM probe prototype shown in Figure 4.3(b) promotes stability inside the vaginal cavity through its unique design. The side elements situated on the left and right surfaces of the PFM probe are designed to prevent the PFM probe from turning. The PFM probe has been

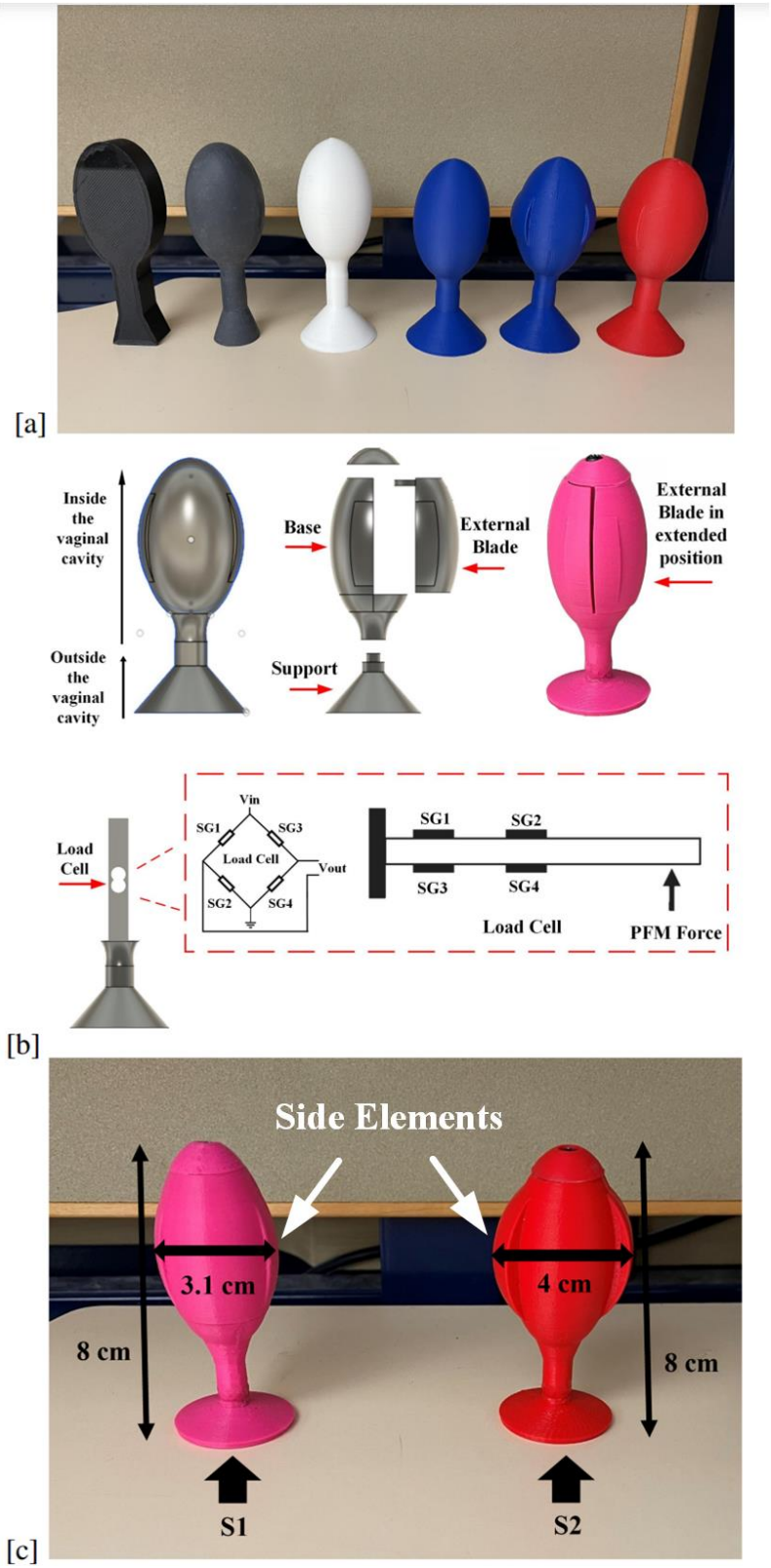


Figure 4.3 Proposed PFM probe design: (a) Different PFM probe 3D printed prototypes, (b) PFM probe CAD design, (c) PFM probe final design with the two sizes available (S1 S2).
* The PFM probe is connected to the processing unit.

primarily tested for comfortability by four of our expert physiotherapists.

4.3.6 PFM Probe Biocompatible Prototype

To ensure the biocompatibility of the PFM probe, medicalgrade silicone is used as an outer protective cover. The medical grade silicone grade is made up of a specific thickness of silicone mixture (Factor II A-103 Medical grade elastomer 1 lb kit). The silicone mixture consists of a base and a curing agent. The mix ratio is 10:1; every 10 grams base with a 1-gram curing agent. The thickness of the cover layer used depends on the stiffness needed for the specified application. Increasing the thickness of the cover layer increases the stiffness, thus making it less compliant. In our application, the thickness is chosen to be 1 mm, as a compromise between the stiffness and compliance needs of the system. After making the silicone mixture, the mixture is placed for around 15 minutes in a vacuum pump to remove air bubbles created upon mixing. Then using a paintbrush, the silicone mixture is applied and pressed on the PFM probe. Then the PFM probe is placed in a rotating oven to dry at a speed of 66 revolutions per minute.

4.3.7 Vaginal Dynamometer Usability Study

As pelvic floor muscle training (PFMT) is considered the first-line treatment of UI [3], a geriatric rehabilitation exergame that uses wearable sensors (vaginal dynamometer and shoes step detection) and a web-based interface is developed by an international research collaboration, from Belgium, Canada, Portugal, and Switzerland, for the treatment of UI [112]. Exergames are video game interactions that request the player to move to play the game and to be physically active [113].

A usability study including ten women (five from Switzerland and five from Canada) aged 65 and over with urinary incontinence was conducted to assess the acceptability, game experience, and usability of the developed exergame. During the study, the participants tried the vaginal dynamometer as a part of the exergame in a 30-minute session, in a standing position. More specifically, the vaginal dynamometer was considered as a PFM sensor and was used to advance the game. One of the targets of the exergame was pelvic floor muscle training. The usability of the vaginal dynamometer was assessed during the game using the think-aloud method [114] and after the exercise through a post-interview. The results of this usability study were used to identify problematic issues and make recommendations to optimize the vaginal dynamometer design.

During the think-aloud assessment and post-interview participants experienced mixed pos-

itive and negative impressions about the vaginal dynamometer. Although all participants liked the exergame and experienced 'joy', 'fun', or 'happiness' while playing the game (n = 10; 100%), three major issues were identified based on the participants' feedback. First, the PFM probe body and support were disassembled easily upon pulling out the PFM probe from the vagina. Secondly, some participants tended to pull the PFM probe from the connecting wire joining the PFM probe to the processing unit. This occurred at the end of the session when the participants were not sure how to remove the PFM probe. The pulling forces damaged the adhesion of the wire to the PFM probe. Lastly, some women experienced discomfort (40%; n = 4) or were not able to use it due to the dynamometer displacement (20%; n = 2) during the game as the PFM probe was too small for their vaginal cavity.

To overcome the problems, the PFM probe design was altered. The lock mechanism of the PFM probe was changed from push-fit to welding the two parts together after assembly. The welding of the support to the body increased the probe's stiffness and ensured the resistance of the support to different women pulling forces. Further, and as some women tended to pull the PFM probe out from the connecting wire, part of the connecting wire was partially embedded inside the PFM probe body and adhered with a strong glue that blocks any possible wire separation. Finally, two PFM probe sizes (S1 S2) were developed to overcome the discomfort caused by the dynamometer displacement. Both sized probes have the same length (L=8 cm), however, the diameter is different (Size1 (S1): D=3.1 cm and Size2 (S2): D=4 cm respectively). The two sizes allow to accommodate different vaginal hiatus sizes. Figure 4.3(c) shows the final PFM probe design, with the two sizes available, used in the proposed vaginal dynamometer.

4.4 Portable Vaginal Dynamometer Implementation

Figure 4.4 presents the block diagram of the proposed portable vaginal dynamometer intended to collect force variation and send it to a local base station (Laptop computer including RF receiver/ smartphone). The portable vaginal dynamometer is composed of three major building blocks: the PFM probe, the processing unit, and the graphical user interface (GUI). The PFM probe is connected through a wire to the processing unit. The processing unit, on the other hand, sends the data wirelessly to the GUI. The PFM probe voltage variations are inputted to the processing unit, where the programmable gain amplifier (PGA) amplifies the signal so that the signal amplitudes are adequate for digitization by the 24-Bit analog-to-digital converter (ADC). The Micro-Controller (MCU) then reads the digitized signal, calibrates it, and sends the calibrated signal to the Bluetooth module. Finally, the Bluetooth module transmits the processed data to the chosen GUI.

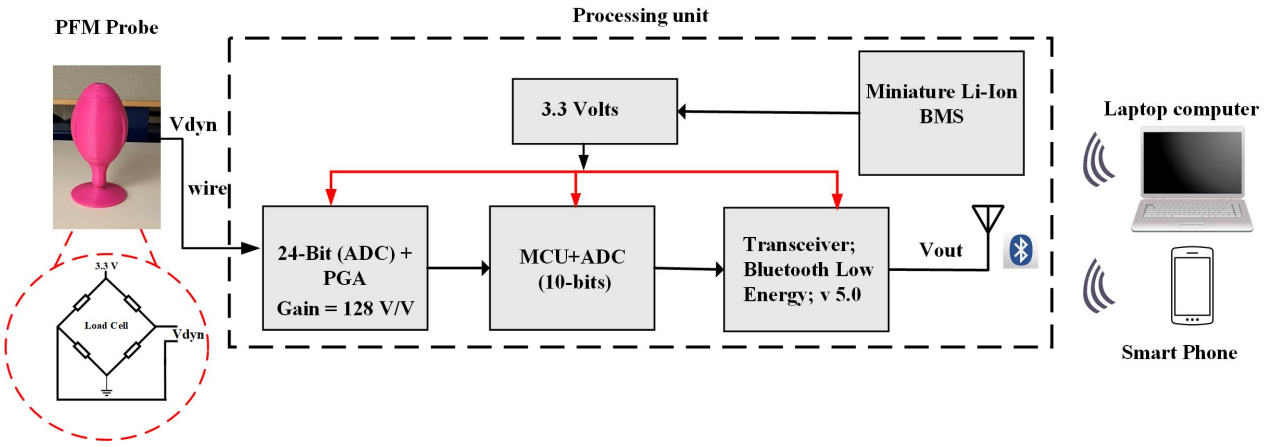


Figure 4.4 Block diagram of the proposed portable vaginal dynamometer intended to collect force variation and send it to a local base station for clinical application (Laptop computer including RF receiver/ Smartphone).

In the following subsections, the processing unit components along with their specifications are presented in detail

4.4.1 MCU

The Arduino Pro Mini 328- 3.3 V/8 MHz board, which comprising of both MCU and ADC, has been considered in our design due to its compact size (18 mm x 33 mm), lightweight ($\leq$ 2 g), thinness (0.8 mm thickness), low-power consumption, and low cost (8-9 USD dollars) compared with other off-the-shelf MCU boards. The board uses the ATmega328 microcontroller and provides fourteen digital inputs/outputs, eight analog inputs, and an 8-MHz crystal

4.4.2 24-Bit Precision Analogue to Digital Converter

The employed ADC (HX711) is a precision 24-Bit ADC module with two selectable differential input channels. It operates in a voltage range between 2.6 and 5.5 V and consumes a current of less than (1.5 µA) in operating mode, and less than (1 µA) in power down. An on-chip active low-noise PGA with selectable gain of 32, 64, and 128 is also utilized.

4.4.3 Bluetooth Model

CC2640R2F Bluetooth low energy (BLE) wireless MCU chip from Texas instrument implemented in DSD TECH HM-19 module has been used as a transceiver to send the digitized force signal to the Arduino interface (operated on a laptop computer) or/and Phone app for

both Android and IOS (DSDTECHBluetooth). The wireless communication protocol used is Bluetooth low energy version 5.0. HM-19 can be used as both master or slave and operates within a supply range of 1.9 V to 3.7 V. Also, it features an open communication range of up to 100 m, which is sufficient for our application. To minimize the power consumption, the HM-19 module operates in two power modes; active and sleep, which helps in decreasing the power consumption of the complete system.

4.4.4 Power Supply

Taking into account the power supply operation range of the MCU (3.3 V- 12 V), ADC (2.6 V-5.5 V), and BLE module (1.9 V-3.7 V), the need for a rechargeable battery to overcome the complexity of changing the battery in an international research project, a 3.7 V lithium-ion battery has been chosen. The battery height was the most critical constraint in our design, which controlled the size of the battery chosen. The length of the battery is 5.1 cm, the width is 3.4 cm, and the height is 0.6 cm. The flat design of the lithium-ion battery allows for overcoming any possible size limitations.

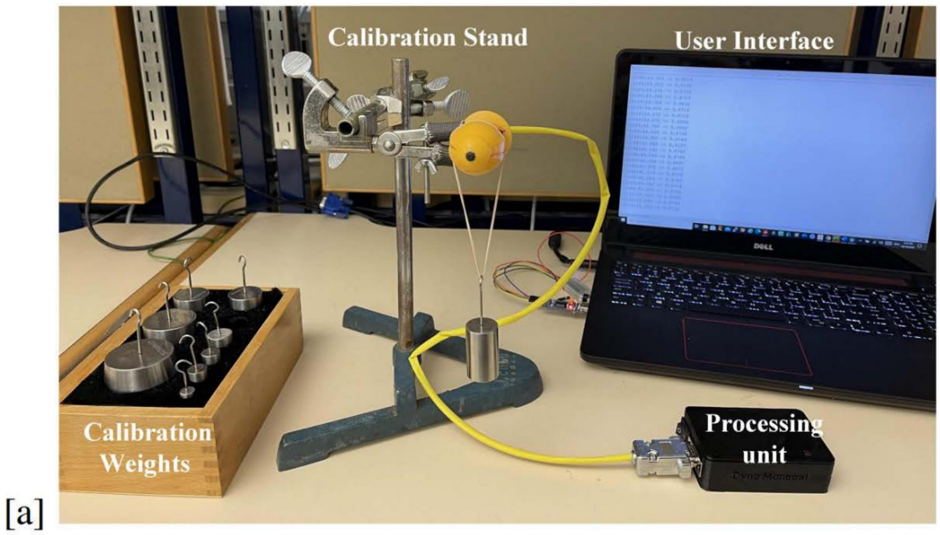
4.4.5 Power Management Design

As lithium-ion battery fluctuates between 4.2V (when the battery is fully charged), and 3.3V (when the battery is drained off), battery management is essential to monitor the voltage fluctuations of the battery and to allow for recharging the battery. MCP73831/2 linear charge management controller from Microchip implemented in Adafruit micro-lipo battery charger has been used, which features a 100 mA or 500 mA charge current.

Due to the lack of the specific size required, a box has been designed and 3D printed specifically for our application. The box takes into consideration the stability of the PCB and includes a case for the lithium-ion battery.

4.5 Experimental Results

The main interest of this portable vaginal dynamometer is its capability to assess and train the PFM in women with lower urinary tract dysfunction, in this case, UI, in the standing position, which is the naturally occurring position of UI. The vaginal dynamometer is supplied with a 3.3 V supply. The gain and sampling frequency are chosen to be 128 V/V, and 20 Hz respectively. Further, the ability to modify the sampling rate allows for fast and easy integration of the system data to other possible devices such as an exergame or mobile application. In addition, the system can be easily adjusted to accept other different force/pressure



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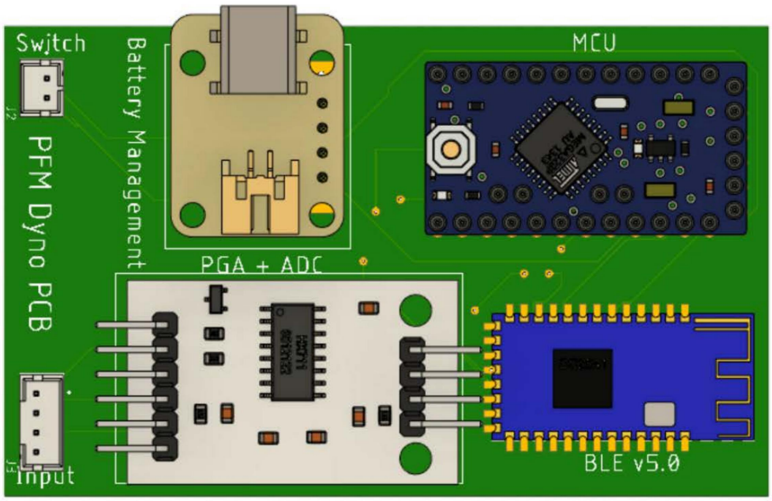


[b]

Figure 4.5 (a) Vaginal dynamometer test bench photograph, and (b) PCB design of the processing unit.

sensors. The properties of the system are detailed in Table 5.1.

The proposed vaginal dynamometer hardware has been realized and tested using the test bench shown in Figure 4.5(a). Firstly, each building block of the system is tested separately for proper functioning and characteristics fulfillment. Then, the complete system is validated with the Arduino IDE interface developed for results visualization.

The vaginal dynamometer was first calibrated to obtain the calibration factor that converts to force (N). Also, the system has been assessed for linearity, repeatability, hysteresis, accuracy, noise and heat effect, and power consumption.

Table 4.1 Measurement features for the vaginal dynamometer

Parameter	Measured Value
Power Supply	3.3 V
Power consumption	≤49.5 mW
Device weight	44.5g
PCB Dimensions	5.46 × 4.57 cm
Data Transmission	Bluetooth v5.0 BLE
Sampling (per second)	20 samples

4.5.1 Calibration

The vaginal dynamometer is calibrated before proceeding with plotting real-time force curves. Calibration is needed to obtain the conversion factor to force (N).

Previously known 8 calibrated weights (10g, 20g, 40g, 50g, 100g, 200g, 400g, and 500g) have been applied to the device at 3.5 cm on the PFM probe and the resulting output measurements as a function of force is shown in Figure 4.6. The weights have been chosen accordingly to present the possible expected output force range based on previous studies.

4.5.2 Linearity

The vaginal dynamometer exhibits a linear performance. Linear regression analysis is used in Figure 4.6 to compute the slope and intercept factors. The coefficient of determination is calculated and found to be R2 = 0.999, which corresponds to high linearity. The linear regression equation of the curve is computed to be:

$$Y = 10.4X - 0.01, \tag{4.1}$$

where Y represents the force (N) and X represents the system output readings. After the calibration is accomplished, the calibration factor is computed, and the real-time force curves are then drawn. Figure 4.7 shows a recording of pelvic floor maximal strength using the vaginal dynamometer for a participant during the study.

4.5.3 Repeatability

To evaluate the repeatability of the vaginal dynamometer, the loading technique used in calibration was repeated twice with the same 8 loads previously mentioned at a location of 3.5 cm on the PFM probe. In each trial, the linear regression equation was computed. Figure 4.8(a) shows the trials 1 and 2 plots obtained. Calculating the mean square error

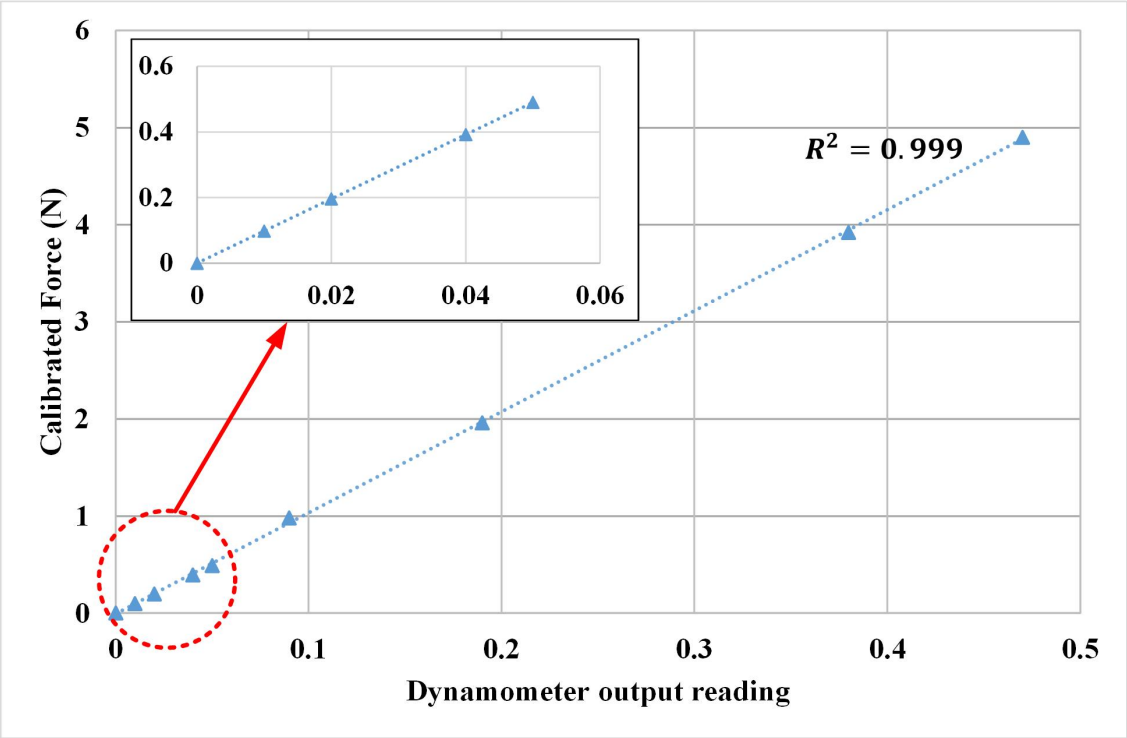


Figure 4.6 Vaginal dynamometer calibration graph.

(MSE) for both trial 1 (MSE = 0.003) and trial 2 (MSE = 0.003) with respect to the linear regression equation of trial 1 was similar. Since the linear regression equation obtained from trial 1 predicts well trial 2, the repeatability of the proposed system is validated.

4.5.4 Hystersis

The hysteresis of the vaginal dynamometer was measured through two load trials at 3.5 cm on the PFM probe. The first load trial is performed with increasing loads, whereas the second load trial is performed with decreasing loads. The same 8 loads (10g, 20g, 40g, 50g, 100g, 200g, 400g, and 500g) have been used in the two trials. A comparison between each load value is conducted. Figure 4.8(b) shows the hysteresis graphs between the loading and unloading trials. Calculating the mean square error for both the loading trial and the unloading trial with respect to the linear regression equation yielded MSE = 0.003 and MSE = 0.007 respectively. The MSE confirms that the difference between loading and unloading trials is almost negligible.

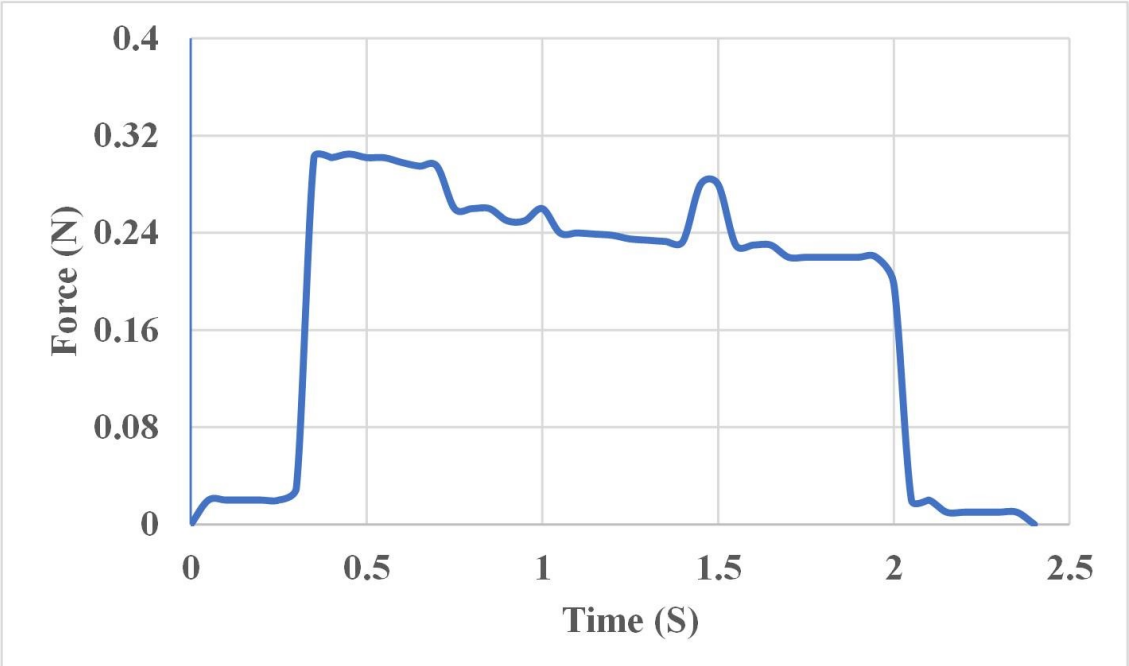


Figure 4.7 Real-time force variations as a function of time (s) displayed with Arduino IDE software.

4.5.5 Noise Effect on System Measurements

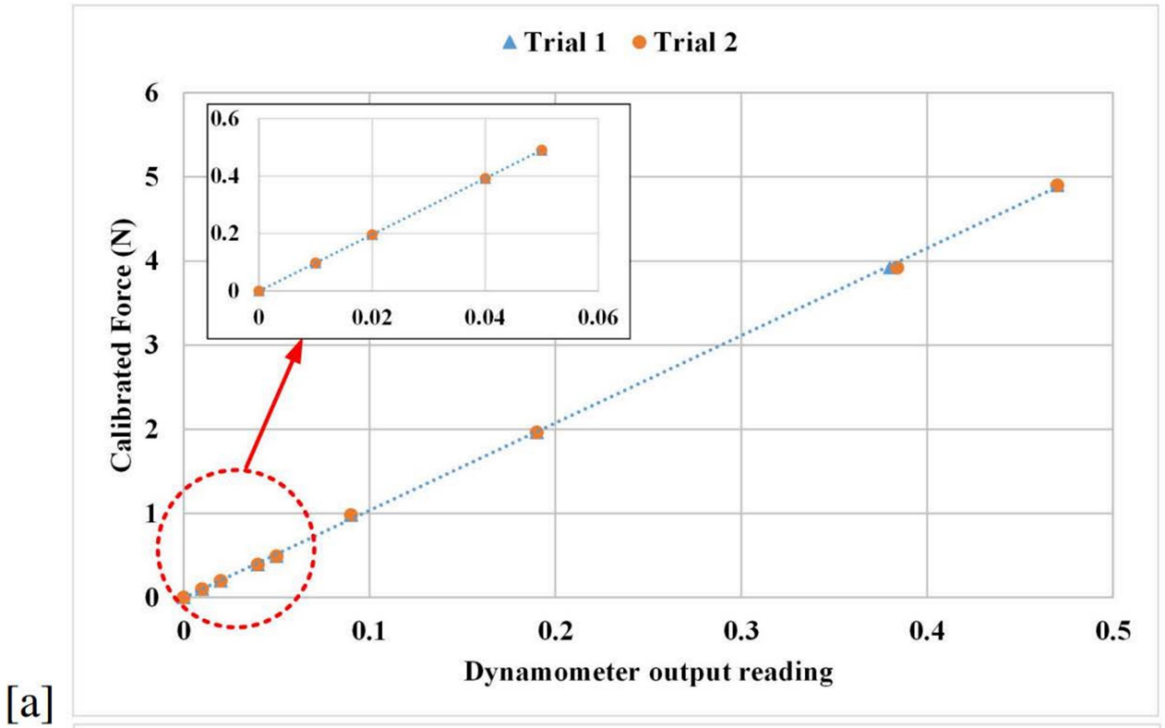
The noise effect on the vaginal dynamometer was measured through taking 100, 500, and 1000 recordings for each load consequently. A total of 8 loads (10g, 20g, 40g, 50g, 100g, 200g, 400g, and 500g) are used in this trial. The standard deviation and variance for each load value at 100, 500, and 1000 recording points are calculated and presented in Table 4.2.

4.5.6 Power Consumption

The power consumption of the vaginal dynamometer is evaluated. The system achieves a power consumption of 15mA/49.5mW in operating mode. Figure 4.9 shows the power consumption breakdown for the system.

4.5.7 Heat Effect on System Measurements

Finally, to evaluate the heat effect on the system, two load trials with the same 8 loads (10g, 20g, 40g, 50g, 100g, 200g, 400g, and 500g) are measured. The first load trial is performed directly after turning the system on (t=0), then the second load trial is performed after one hour from the initial trial (t = 1 hour) with the system being on for a complete hour duration. The thermal reliability of the system is calculated by running a Cronbach alpha test. The



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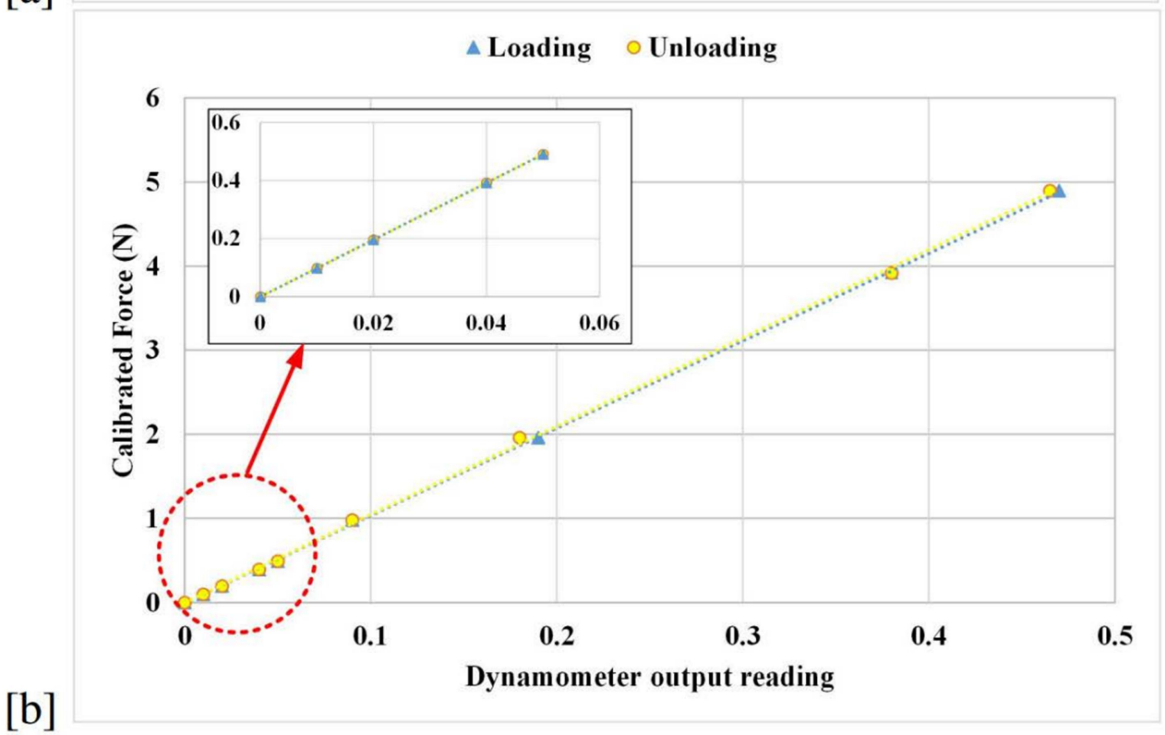

[b]

Figure 4.8 (a) Vaginal dynamometer repeatability graph, and (b) Vaginal dynamometer hysteresis graph.

Table 4.2 Noise effect on the system measurements in terms of standard deviation and variance values

Mass (g)			0	10	20	40	50	100	200	400	500
Force (N)			0	0.098	0.196	0.392	0.49	0.98	1.96	3.92	4.9
Noise effect on WPFMM system	100 points	STD Deviation	0	0.0007	0.0002	0.0004	0.0003	0.001	0.001	0.0023	0.0023
	500 points	STD Deviation	0	0.0006	0.0002	0.0004	0.0003	0.001	0.0009	0.0023	0.0023
	1000 points	STD Deviation	0	0.0007	0.0002	0.0004	0.0003	0.001	0.0009	0.0023	0.0023

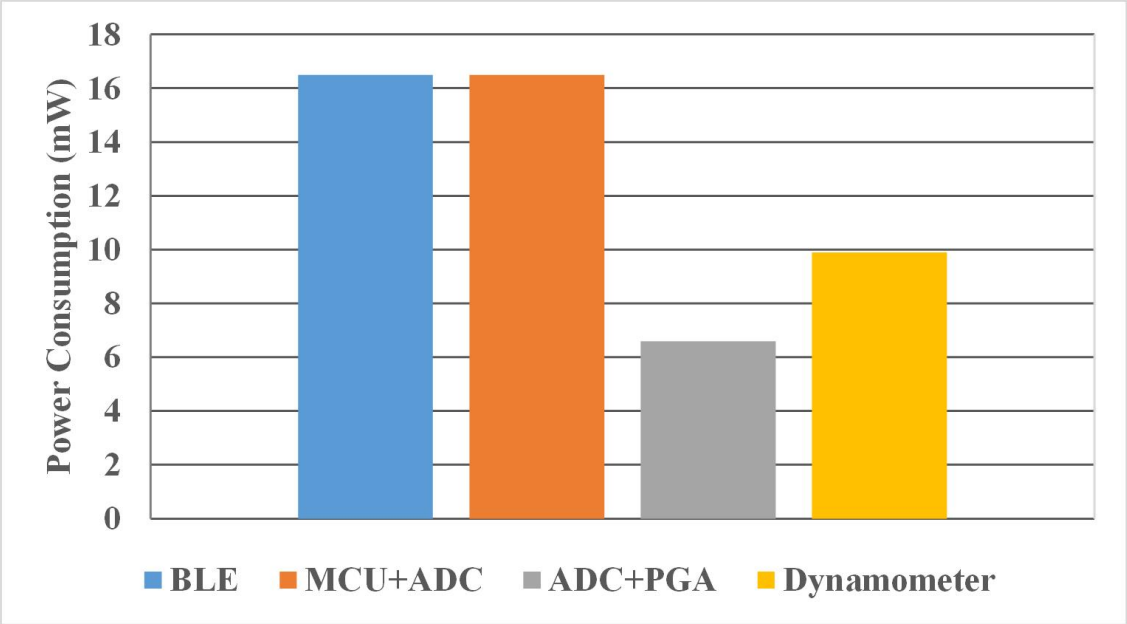

Figure 4.9 Vaginal dynamometer power distribution across different blocks.

resultant alpha value is 1, which indicates very good reliability. Thus, the effect of the heat on the system measurements is negligible.

4.5.8 Prototype Variations

Different prototypes of the proposed vaginal dynamometer were produced in preparation for a feasibility study. It was very imperative to study the variations between the different prototypes in terms of linearity, repeatability, and accuracy. The accuracy of each prototype was calculated through comparing the output force (N) of the vaginal dynamometer with the actual force applied (N) from the calibrated weights. Table 4.3 shows the parameters evaluated with the corresponding prototype.

Table 4.3 Final device bench testing using the entire system of prototypes

Test			linearity	Repeatability		Accuracy
			Coefficient of Determination	p-value	t-test	Average %
Dynamometer Prototype Outcome	Dynamometer Prototype	Red	0.995	p <0.05	Not significant	96.202
		Transparent	0.999	p <0.05	Not significant	96.33
		Yellow	0.999	p <0.05	Not significant	97.639
		Purple	0.997	p <0.05	Not significant	97.447
	Average		0.9975	difference between Trials 1 & 2 for all prototypes		96.9045
	Stand Dev.		0.001914854			0.74327048
	Variance		3.66667E-06			0.552451

4.6 Discussion

The proposed vaginal dynamometer utilizes an optimized PFM probe design based on a literature review, four expert physiotherapist evaluations, and a usability study with ten incontinent women. The PFM probe's diameter directly affects its usability. Dynamometers with adjustable apertures can accommodate different populations, unlike dynamometers with fixed diameters. For example, nulliparas or women with vaginal atrophy have smaller vaginal openings compared to parous women with levator ani defect. Thus, dynamometers with fixed diameters may not be proper for all women. With the two sizes available for the PFM probe, it is feasible to accommodate women with different hiatus sizes.

Noticeably, the PFM probe design is neither handheld nor fixed to a base, it is meant to stay in place which would presumably allow for more functional assessment conditions (e.g., standing position). Because UI and pelvic organ pro- lapse symptoms usually occur in the standing position rather than in the supine, it may be of interest that the unit is portable to allow measurements of intravaginal forces in functional positions (such as standing) but has yet to be evaluated in future studies.

The PFM probe is uniquely designed to allow for stabilization inside the vaginal cavity. The side elements of the PFM probe prevent the PFM probe from turning or falling down. Maintaining the PFM probe stability inside the vagina in both standing and supine position is a critical factor in increasing the patients' comfort during assessment and training sessions. It also insures the validity and repeatability of the measurements.

Another advantage of the device is its lightweight, especially since UI and other lower urinary tract symptoms are more prevalent in the elderly female population, where weight tolerance is a major concern. In addition, the agile methodology used in the production of

the vaginal dynamometers allowed for quick and easy iterations throughout the complete production process. Cleaning and sterilization of the newly designed vaginal dynamometer is one topic to further investigate. With the medical grade silicone material constraint in terms of sterilization, new cleaning and sterilization protocol is sought. Although the number of prototype units used for this study was limited, large-scale fabrication of the device would allow providing a personal device to each patient at a low cost.

Using a computer user interface and a companion app were both required in the design process. The computer user inter- face allowed the user to visualize the real-time variation of the PFM force measurements, control system characteristics such as the sampling rate, and create a database for the bench test data. Further, the free access DSD TECH Bluetooth mobile application, developed by DSD TECH, was important for the usability study. The physiotherapist used the DSD app as a reference for the vaginal dynamometer functionality. Both GUIs are advantageous in terms of being compatible with any operating system (Microsoft Windows, Linux, macOS/ iOS, and Android).

With a 3.7V/1200 mA Li-Ion battery, and a system power consumption of 49.5 mW at a sampling rate of 20 measurements per second, for 1 h per day (2 sessions of 30 minutes training), 80 days of measurement can be achieved with- out the need for charging the battery. Taking into account that the vaginal dynamometer is intended to be used for 20-30 minutes, once a day non-consecutively, the heat effect has been evaluated for one continuous hour of use and found to be non-significant. Thus, the possible effect of heat produced by the system components on measurements is non-significant as well.

A communication range of 100 m is achieved by the system in the air. Since wireless communication is between the processing unit and the GUI, the communication range is expected to be high enough to be used at home with a computer, phone, or tablet in the same room.

The vaginal dynamometer prototypes variability is assessed and proven to be non-significant. All the prototypes exhibited a highly linear behavior with a coefficient of determination varying between 0.995 to 0.999. As for repeatability, no significant difference was found between trials 1 and 2 for all vaginal dynamometers. Further, the system average accuracy error lies within 3.9% of the full scale. Taking into account the evaluation system of the PFM function, the error does not affect the correct categorization or classification of women's PFM strength and is thus non-significant. Therefore, all the vaginal dynamometer-produced prototypes can be randomly used with confidence in their proper functionality in future studies

Acknowledging the importance of evaluating the psychometric properties of the system, there is an ongoing feasibility study. The usability of the system is being re-tested as well, in the

feasibility study. Future studies are yet to evaluate the effect of intra-abdominal pressure on the system's measurements, and the feasibility of using the system within different clientele (such as pregnancy and obesity) or with different conditions such as pelvic organ prolapse.

4.7 Conclusion

This paper presented a fully functioning prototype of a portable vaginal dynamometer for the evaluation and training of women with PFM dysfunctions. The developed system allows patients to reproduce natural PFM function with more portability and flexibility. Also, it allows measuring PFM forces in the standing position, which is the naturally occur- ring position of UI. The system has been tested in a usability study and optimized based on the feedback of participating women. As a second step towards validating the system, the vaginal dynamometer is being used in an ongoing inter- national feasibility study, where it is combined with other sensors and a newly designed exergame for the treatment of geriatric UI. Furthermore, the next version of the proposed system is currently being designed to fully integrate all signal processing and wireless communication electronics into the PFM probe itself.

4.8 Acknowledgment

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CHAPTER 5 ARTICLE 3: IMPROVING PELVIC FLOOR MUSCLE TRAINING WITH AI: A NOVEL QUALITY ASSESSMENT SYSTEM FOR PELVIC FLOOR DYSFUNCTION

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This chapter addresses the last objective of the thesis, which is to develop a performance monitoring quality assessment system for PFM training. The quality assessment system detects PFM contraction through a CNN model and rates the contraction performance in terms of different features and an overall rating through an autonomous algorithm.

5.1 Abstract

The first line of treatment for urinary incontinence is pelvic floor muscle (PFM) training, aimed at reducing leakage episodes by strengthening these muscles. However, many women struggle with performing correct PFM contractions or have misconceptions about their contraction. To address this issue, we present a novel PFM contraction quality assessment system. This system combines a PFM contraction detector with a maximal PFM contraction performance classifier. The contraction detector first identifies whether a PFM contraction was performed. Then, the contraction classifier autonomously quantifies the quality of maximal PFM contractions across different features, which are also combined into an overall rating. Both algorithms are based on artificial intelligence (AI) methods. The detector relies on a convolutional neural network, while the contraction classifier uses a custom feature extractor followed by a random forest classifier to predict the strength rating based on the modified Oxford scale. The AI algorithms were trained and tested using datasets measured

by vaginal dynamometry, combined in some cases with digital assessment results from expert physiotherapists. The contraction detector was trained on one dataset and then tested on two datasets from our databased measured with different dynamometers, achieving 97% accuracy on the first dataset and 100% accuracy on the second. For the contraction performance classifier, the results demonstrate that important clinical features can be extracted automatically with an acceptable error. Furthermore, the contraction classifier is able to predict the strength rating within ± 1 scale point with 97% accuracy. These results demonstrate the system's potential to enhance PFM training and rehabilitation by enabling women to monitor and improve their PFM contraction autonomously.

5.2 Introduction

Urinary incontinence (UI) is defined by the International continence society (ICS) as the complaint of involuntary loss of urine [10]. UI is highly prevalent, affecting approximately 30% of women [3]. This condition reduces the patient's quality of life and self-esteem, while also placing financial pressure on both patients and healthcare organizations [12, 15].

Continence is multi-factorial but relies mainly on the urethral closure and detrusor control function. Pelvic floor muscle (PFM) integrity is of high importance in the closing of the urethra. When there is an increase in intra-abdominal pressure, a weak PFM will not be able to support and close the urethra, and thus a leakage will occur [10, 115]. Pelvic floor muscle training (PFMT), the first-line treatment for UI, has been shown to improve urethral closure pressure and pelvic organ support thereby preventing urinary leakage [28, 115].

ICS and the International urogynecological association (IUGA) recommend assessing the PFM function prior to and during PFMT to teach effective PFM contraction and measure improvement, thereby giving the best training program for specific PFM dysfunctions [28]. According to ICS, a normal PFM contraction involves "a constriction and inward (ventrocephalad) movement of the pelvic openings" [17]. The ability to perform a correct PFM contraction is a prerequisite for PFMT. However, as the PFM are invisible inside the pelvis, research indicates that many women lack the knowledge and ability to perform a correct PFM contraction [116–118]. Further, women reporting prior knowledge of PFMT may still perform PFM contractions incorrectly [119]. Studies have shown that the prevalence of women with PFM dysfunctions who cannot contract their PFMs correctly ranges from 12 to 55% [108, 120, 121].

In 2014, a study conducted with 998 women, showed that 70% were unable to voluntarily contract their PFM correctly (ventrocephalad), without the feedback of a physiotherapist. Of

those not able to perform a PFM contraction, 33.4% were personally convinced to be able to do it. 73.6% of participants showed an improvement in their PFM contraction after receiving verbal instructions [118]. Although verbal instruction has a positive effect, some women still need more than verbal instructions to correctly perform a PFM contraction [118, 119, 122].

In 2019, another study conducted on 82 women showed that only 33 of the women who participated in the study had an accurate self-perception of their own PFM contraction in relation to the categories of the Modified Oxford scale (MOS) [116]. Therefore, for effective PFMT, it is essential that women have a proper understanding and confirmation of their ability to perform a correct PFM contraction.

Currently, there is no universal standard for assessing the correctness of PFM contractions in women. By far, the most common assessment method is digital palpation, which is used to assess, teach, and give feedback on the PFM contraction. However, this method relies on digital sensation by a physiotherapist and is subject to interpretation. A physiotherapist is expected to give instruction during different tasks, evaluate the task, and monitor the correctness of PFM contractions in participants. Beyond being a subjective measurement, this is not feasible, nor is it possible especially in group treatments, online rehabilitation, or during home PFM exercises. Therefore, there is a need for an objective and reliable PFM measurement tool to assess PFM function and to confirm the correctness of women's PFMT techniques.

Various techniques have been developed for the evaluation and training of PFM [25, 123]. Recently, PFM dynamometry has been suggested as a direct, reliable, and objective measurement tool for the PFM function [25,27,123]. However, presently, available dynamometers are limited to one functionality, either providing reliable measurements or offering feedback on the correctness of PFM contractions—but not both. Most marketed devices measure PFM force, yet fall short of guiding users through correct exercise contraction. Consequently, there is a need for a device that measures the PFM function and accurately detects PFM contractions [116].

Recognizing the importance of a real-time PFM contraction feedback assessment system in rehabilitation intervention, our objective is to design a PFM contraction quality assessment system. The latter aims at detecting PFM contraction in real-time as well as assigning a rating to the contraction based on different features and an overall rating. Different tasks were used to define PFM contraction and non-contraction. The proposed quality assessment system is designed to be implemented in PFM function measurement tools which include a recent portable vaginal dynamometer built by our own team. The newly achieved vaginal dynamometer enables the measurement of PFM forces in the standing position, which is

the naturally occurring position for UI [123]. With a PFM contraction quality assessment system, women could use the portable dynamometer to train with direct feedback on PFM contraction, at the rehabilitation center as well as at home.

The remaining parts of this paper include a summary of the main related prior-art publications in Section II. Section III outlines the design of the novel PFM contraction quality assessment system. We present in Section IV the experimental results of the system, which are subsequently discussed in Section V. Finally, Section VI provides the conclusion and outlines directions for future work.

5.3 Related Work

Based on our thorough review of the literature, and to the best of our knowledge, no previous work exists describing the implementation of a neural network model to differentiate between PFM contraction and non-contraction. Additionally, there is no previous work using AI algorithms to classify PFM strength based on digital palpation data. While several PFM dynamometers have been developed for research purposes, none of them incorporate the evaluation of PFM contraction. Notably, only two personal PFM dynamometers utilize hardware and/or an algorithm to differentiate between correct and non-PFM contraction [59, 124].

Pericoach, a commercially available personal PFM dynamometer, reported in a conference paper that the device was upgraded to detect and monitor exercise techniques using an algorithm that distinguishes specific movement patterns and scores them from good (1) to bad (-1) [124]. However, no definition is given for the specific movement pattern, and no information is available about the algorithm itself, the technique used for score development, the data used to train the algorithm or to create the technique scores, and whether validation was done for both the algorithm and technique scoring. Furthermore, the psychometric properties of this home trainer are not yet studied. More research is needed to assess the reliability and validity of measurements taken with Pericoach in different populations and conditions [25].

Elvie, another personal PFM dynamometer available commercially, reported the ability of the trainer to specify the correct/incorrect contraction of a PFM maximum voluntary contraction (MVC). The device uses an accelerometer to measure the angular rotation of the device in situ, with the antero-cranial rotation (pitch) indicating the correctness of the PFM contraction. Theoretically, the cranial lift and anterior squeeze action of the PFMs during a correctly performed MVC generates positive antero-cranial rotation of the Elvie Trainer,

while the caudal descent and relaxation of the posterior aspect of the PFMs during bearing down generate negative antero-cranial rotation. In a study done in 2020 on 22 women, Elvie was able to correctly classify pelvic floor contractions and Valsalva in supine and standing positions [59]. However, Elvie was tested solely on women who were already trained on PFM contraction. The accuracy of this classification should be tested on women who are naive to the task. Further, Elvie Trainer had a poor correlation between the forces measured by the device and an intra-vaginal dynamometer, which may limit its ability to detect improvements in strength over time. As such, the device's contractile force values and antero-cranial rotation values are not recommended as objective measures of PFM strength or for monitoring improvements in PFM strength with treatment. Further research is needed to evaluate whether the Elvie Trainer could be an effective home training tool to improve symptoms of pelvic floor dysfunction [59].

Currently, there exists no PFM dynamometer in either research or industry that offers a complete reliable system of measuring PFM function while evaluating the PFM contractions. There is a lack of research on integrating systems that can detect and assess the quality of PFM contractions. To address these drawbacks, we propose a PFM contraction quality assessment system that detects PFM contractions and evaluates their quality across different features.

5.4 Materials and Methods

In this section, we describe the proposed quality assessment system which is designed to differentiate between PFM contraction and non-contraction and quantify the quality of the maximal PFM contraction across different features (Figure 5.1).

Correct contraction of the PFM involves the precise activation of these muscles which results in a constriction and upward (ventrocephalad) movement of the pelvic openings. Correct contraction can be quantified using a dynamometer by measuring a maximal voluntary contraction.

Non-PFM contraction is any action that deviates from the cranioventral movement, such as no movement or movement opposite to cranioventral. To define PFM contraction and non-contraction we used different tasks. During the rest task, there should be no movement of the PFM, making it a suitable proxy for a non-PFM contraction. In the pushing task, participants are asked to do the opposite of a contraction, usually resulting in minimal or no cranioventral movement which is another proxy for non-PFM contraction.

For the cough task since women may perform a pre-cough contraction known as the knack

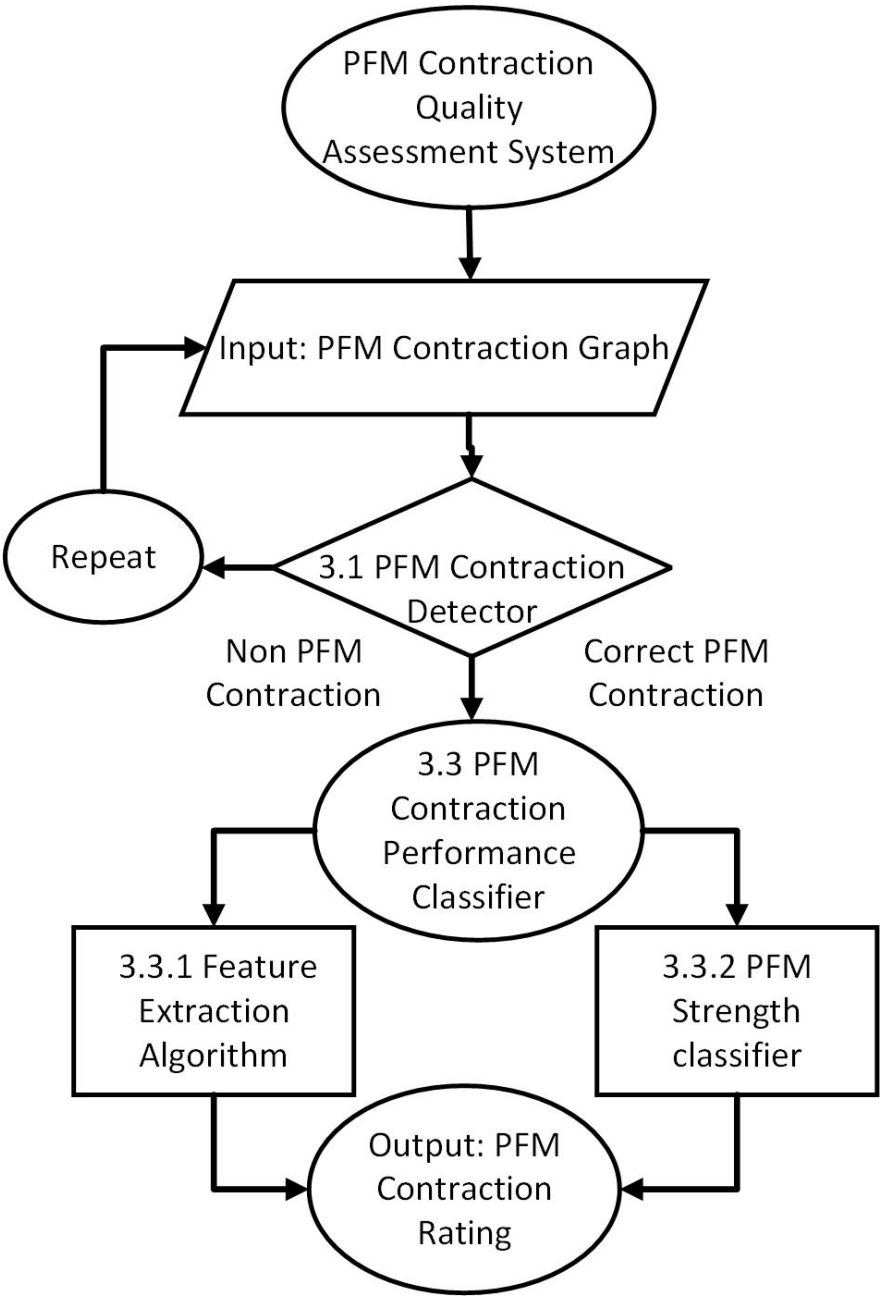

Figure 5.1 Overview of the quality system developed.

movement, only dynamometric recordings from participants who did not perform a knack during the digital palpation test preceding the dynamometric measurement in the same session were included. These tasks and assessments provide a comprehensive framework for differentiating between PFM contraction and non-contractions using a dynamometer.

5.4.1 PFM Contraction Detector

The PFM contraction detector is based on a CNN model. Key considerations for training the CNN include the training data and the design of the model architecture.

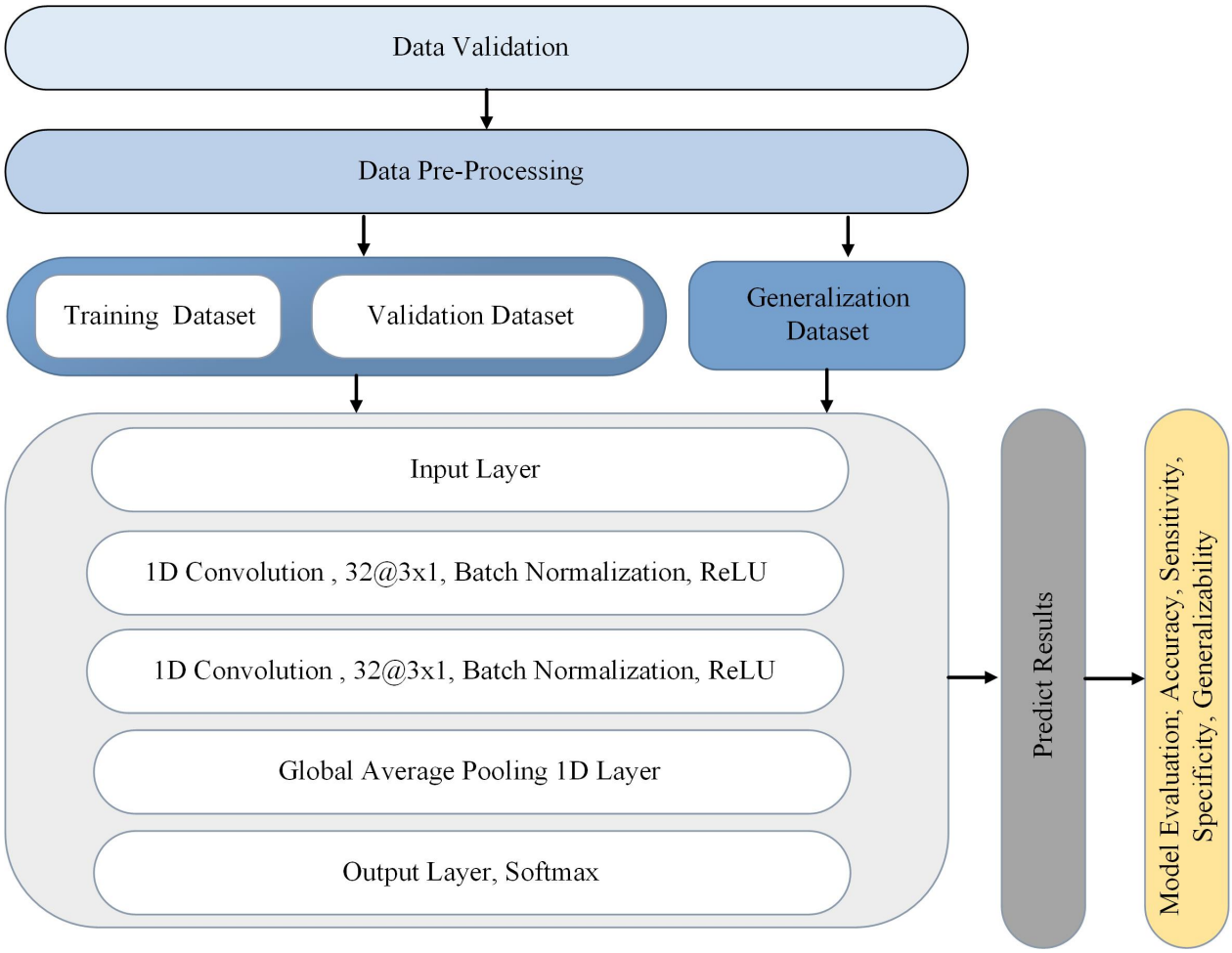

Figure 5.2 CNN Model architecture.

Training Dataset 1

To train and test the CNN model, PFM contraction and non-contraction measurements are needed. Dynamometric data were obtained from a previous study [93]. The study is

Table 5.1 Summary of Dataset for CNN Model.

Dataset	Sample Size	Contraction Data	Rest Data	Cough & Push Data
Dataset 1	318 [125]	1800	908	1851
Dataset 2	13 [126]	33	32	48

a randomized non-inferiority trial that compared the effectiveness of group rehabilitation and individual physiotherapy in treating symptoms of stress/mixed urinary incontinence in community-dwelling older women. The trial was assessor-blinded, and 362 eligible participants were enrolled [93], however only 318 had dynamometric data. After receiving instructions on how to contract their PFM, participants underwent 12 weeks of PFM training either individually or as part of a group of eight women. Baseline, post-treatment, and one-year follow-up measurements were taken using an intra-vaginal dynamometer [93, 125]. It is important to note that participants were not naive to PFM contraction: they were required to demonstrate their ability to contract correctly to be eligible for participation [127].

Details on the participants' inclusion/exclusion criteria are provided in the trial protocol [127] as well as details of the study that have been previously published [93]. The study protocol was approved by the research ethics board at both recruitment sites and each volunteer provided written consent before participation (trial registration ClinicalTrials.gov Identifier: NCT02039830).

From the dynamometric data acquired from participants, we were interested in the following recording: (1) 5-s rest at a minimal dynamometer opening (11 mm) recorded twice, (2) 10-s maximal PFM contraction, repeated three times, and (3) three strong coughs in succession, repeated twice. The aforementioned data have been extracted for the 318 participants. For some participants, there was less than what was required due to the unwillingness of the participants to complete the procedure and occasionally due to inadequately recorded data [93].

The data are time-series recordings of force (N) as a function of time. Graphs were examined visually to ensure the quality of the data. Any recording that did not include the corresponding task (rest, contraction, or cough) was excluded. For example, recordings of contractions or coughs that did not contain any movements were excluded. Graphs that were recorded partially (recording started late or recording ended early) were excluded as well. Additionally, the rest recordings that included any movement were also excluded.

For training the CNN model, maximal PFM contraction data were categorized as correct

contraction. In contrast, data from rest periods were categorized as non-contraction. Cough data were classified as non-contractions if no knack movement was detected during digital palpation performed during another task by the participant at the same session but at a different time. Although it might seem counterintuitive to classify rest periods as non-PFM contractions, since patients are instructed to relax during these times, this classification helps differentiate between actual muscle contractions and the absence of contraction. Specifically, rest periods were labeled as non-PFM contractions because they represent a lack of desired muscle activity. Similarly, cough data were classified as non-contraction if no knack movement was detected during digital palpation.

Signal Pre-processing

Dataset 1 was recorded using an older version of the Montreal PFM dynamometer at a frequency of 1024 Hz [27]. For Dataset 2 recorded using a newly designed portable PFM dynamometer [123], and as a part of a recently developed exergame [128], a frequency of 20 Hz has been selected to meet the functional requirements of the exergame [128]. Considering that the future goal was to implement the CNN model in the newly designed PFM dynamometer [123], Dataset 1 has been down-sampled to a frequency of 20 Hz.

Prior to down-sampling, the triple cough recordings were partitioned such that each cough was represented as a separate graph. To down-sample Dataset 1 and ensure that the shape pattern remained unaffected, several steps were employed. First, a fourth-order Butterworth low-pass filter was used to remove any possible high-frequency components. The filter is designed with a cutoff frequency of half the new sampling rate, which is the maximum frequency that can be represented in the down-sampled signal according to the Nyquist-Shannon sampling theorem. Then using the decimation method, the filtered data were down-sampled to 20 Hz which is represented by:

$$y[n] = x_{\text{filtered}}[nM], \tag{5.1}$$

where $y[n]$ is the down-sampled signal, $x_{filtered}[nM]$ is the filtered signal. The downsampled signal is obtained by selecting every Mth sample of the filtered signal. To be able to compare the original and downsampled signal using the same support (the set of x-values for which a discrete signal f(x) is defined), the original signal is then reconstructed from the down-sampled signal based on the zero-order hold method. A fourth-order Butterworth low-pass filter is then used to smooth the reconstructed signal curve.

To show the difference between the original and the reconstructed signal, root mean squared

percentage error (RMSPE) has been calculated based on the following formula [129]:

$$\text{RMSPE} = \sqrt{\frac{1}{n}\sum_{i=1}^{n}\left(\frac{y_i - y_p}{y_i}\right)^2} \times 100, \tag{5.2}$$

where y_i is the measured value at time t for the original signal and y_p is the predicted value at time t for the reconstructed signal. Additionally, the top three dominant frequencies were calculated for both the original and down-sampled signals to compare the signal frequency spectrum. The RMSPE was also used to compare the dominant frequencies of the original signal and the down-sampled signal.

CNN Architecture and Testing Setting

The overall CNN architecture is shown in Figure 5.2. The proposed CNN model is a one-dimensional stacked CNN (1DSCNN) model. This CNN model is composed of a 1D input layer, two convolutional layers (each with 32 filters and a kernel size of 3), and a global average pooling layer. Batch normalization is applied after each convolutional layer to adjust the activations of the previous layer across the batch. Rectified Linear Unit (ReLU) activation functions are used to introduce non-linearity in the network after each batch normalization layer. Global Average Pooling is applied after the second convolutional layer to convert the feature maps into a single feature vector by taking the average of all feature maps across each channel. This reduces the dimensionality of the feature representation. A dense layer with a softmax activation function is used as the output layer to map the feature vector to the class probabilities. The number of neurons in the output layer is equal to the number of classes in the classification task.

The model is trained with the Adam optimizer, sparse categorical cross-entropy loss function, and sparse categorical accuracy metric. The model is trained for 100 epochs with a batch size of 32. The training is stopped early if the validation loss does not improve for 50 epochs. The learning rate is reduced by a factor of 0.5 if the validation loss does not improve for 20 epochs. Finally, the model is evaluated on a test set, and its accuracy, loss, specificity, and sensitivity are reported.

5.4.2 Validation of the CNN Model

The validation of the CNN model was done in two steps. The first step was to validate the model with data from the original training data series. This step was intended to validate that the model works successfully within the same device. The second step was to validate

the model across a different dataset from a different device which will allow testing the generalizability of the model, that is the ability of the model to perform effectively with new data.

Validation of the CNN Model on Dataset 1

To estimate the performance, Five-fold cross-validation was used. Five-fold cross-validation is a common cross-validation technique in machine learning. It splits a dataset into five subsets or "folds" of roughly equal size. Each of these folds is used as a test set, resulting in five different runs of the model. During each run, the model's performance metrics (accuracy, sensitivity, specificity) are recorded. Then the average accuracy, sensitivity, specificity across all five runs is calculated to get a robust estimate of the model's performance.

Generalization Testing on Dataset 2

To test the generalization of our model we used Dataset 2, which is obtained from a feasibility study. This study is a clinical trial that compares the effectiveness of individualized video game training (VITAAL Exergame) for older adults with mobility impairments and/or urinary incontinence [126]. A total of 38 eligible participants were enrolled, however only 13 had dynamometric data. Participants were randomized into a 12-week stepping exergame training or traditional exercise (active control group). Baseline and post-treatment measurements were taken using the newly developed portable PFM dynamometer [123].

Eligible participants were incontinent community-dwelling women, aged 60 and over with symptoms of mixed UI or Urge UI, who reported at least three episodes of urine loss per week during the preceding three months. Mixed/Urge UI was confirmed by the Questionnaire for Urinary Incontinence Diagnosis. Exclusion criteria included body mass index $\geq$ 40, important pelvic organ prolapse (POPQ $>$ 2), physiotherapy treatment or surgery for UI or pelvic organ prolapse in the past year, or any medication and co-morbidities/risk factors interfering with the study. The study protocol was approved by the research ethics board at both recruitment sites and each volunteer provided written consent before participation (trial registration ClinicalTrials.gov Identifier: NCT04587895).

From the data acquired from participants on the baseline, and post-treatment we were interested in the following recording: (1) rest recorded twice, (2) maximal PFM contraction, repeated twice, (3) three strong coughs in succession, repeated twice, and (4) a push, if possible. The data have been extracted for the 13 participants. For some participants, there was no or less than what was required due to the unwillingness of the participants

to join/complete the procedure, malfunctioning of the phone application, and occasionally inadequately recorded data. The data are time-series recordings of force (N) as a function of time. Graphs were examined visually to ensure the quality of the data. Any recording that did not include the corresponding task (baseline, contraction, cough, or push) was excluded.

For training the CNN model, maximal PFM contraction data were categorized as correct contractions. In contrast, data from the rest task were categorized as non-contractions. Additionally, all triple cough and push data were classified as non-contractions. Knack movement was not taught nor instructed to be applied during the cough/push tasks. The triple cough recordings were partitioned so that each cough was represented as a separate graph, and no down-sampling was required.

Table 5.1 shows a summary of the datasets used for the CNN model.

5.4.3 Maximal PFM Contraction Performance Classifier

We propose a novel algorithm to autonomously quantify the PFM function in women. Our algorithm takes PFM contraction graphs as input and outputs a rating across different features. This is accomplished by extracting specific features from the PFM contraction graphs and evaluating them. The PFM contraction graphs are recorded during the maximal voluntary contraction task, following a cue to contract and maintain the contraction for 10 seconds [27, 93].

Table 5.2 presents the definition of each feature used to evaluate the different aspects of PFM contraction. Hence, this study aims to introduce an autonomous algorithm capable of extracting and evaluating PFM contractions through the identification and evaluation of these specific features.

To extract the required features from a PFM contraction graph, we developed a mathematical piecewise linear model. This model approximates the typical trapezoidal shape of the contraction graph by dividing it into five distinct linear segments. Figure 5.3 illustrates an example of fitting a PFM contraction graph into this trapezoidal model. The key parameters of the model are the time values at points B, C, D, and E, which define the critical phases of the contraction. The model autonomously identifies these time values to accurately capture the essential features of the contraction. The trapezoid model can be described by the following equation:

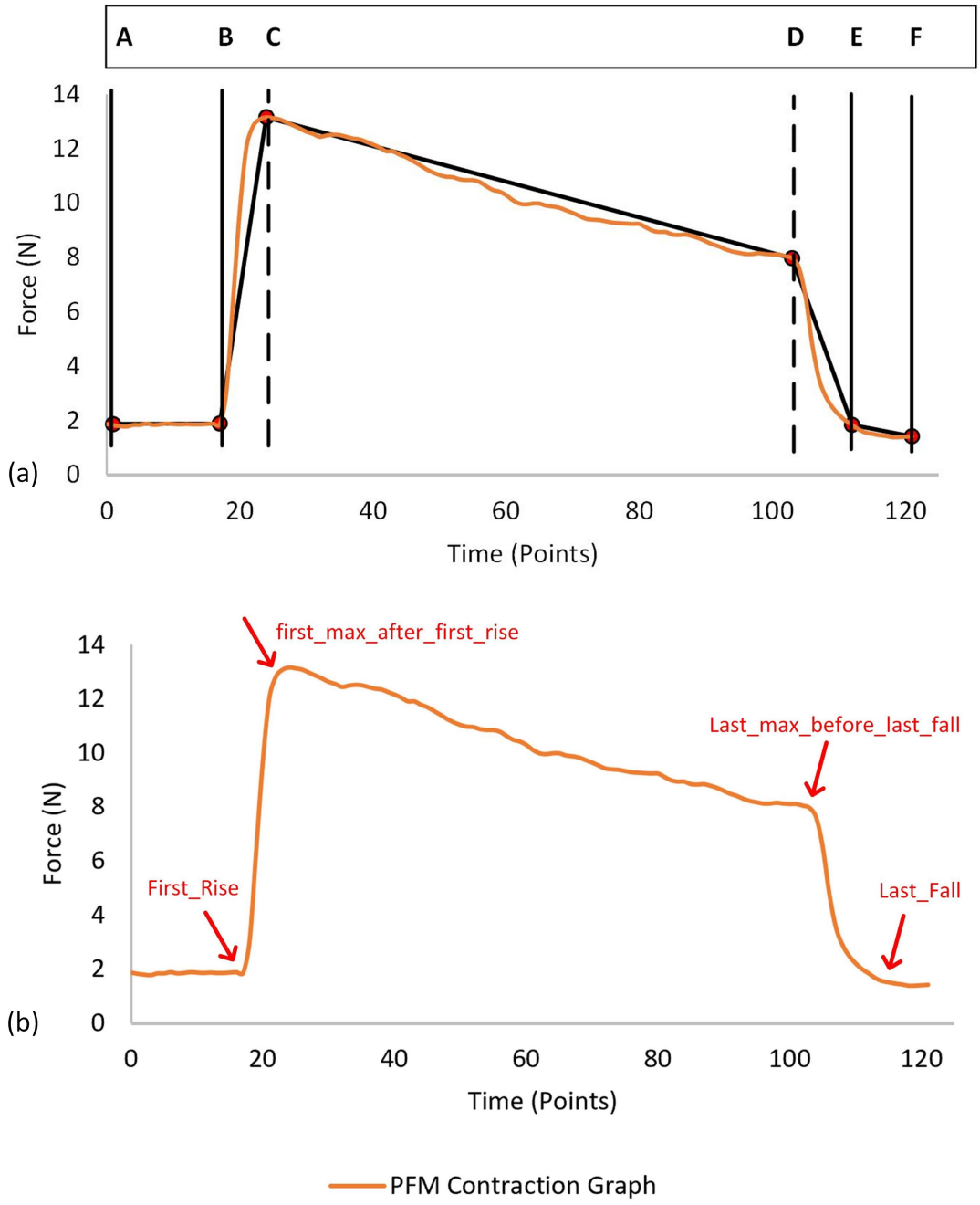

Figure 5.3 (a) Example of the quadrilateral fit to a contraction graph (b) Feature Extraction Algorithm key aspects.

Table 5.2 Features Extracted

Definition	**Features**	**Symbols**
Force-generating capacity of a muscle [26].	Maximum force; Average contraction force	$\Delta F_{\max}$, $\bar{F}_c$
The ability of the PFM to maintain a sustained contraction over a period of time [26].	Contraction time; Area under the curve	T_c , AUC_c
The ability of the PFM to work together effectively and efficiently to perform their various functions [26].	Rising slope, Falling slope	m_r, m_f
The ability to relax the PFM muscle to its original resting tone following the voluntary contraction [26].	Difference between pre and post contraction baseline	ΔF_{f-i}

$$F_c(x) = \begin{cases} m_i t + b_i & A \leq t < B, \\ m_r t + b_r & B \leq t < C, \\ m_c t + b_c & C \leq t < D, \\ m_f t + b_f & D \leq t \leq E. \end{cases} \tag{5.3}$$

Note that the line parameters and the time values A to E depend on each other, such that the model has in total of eight degrees of freedom that must be identified.

Figure 5.3 shows the key aspects of the feature extraction algorithm. The vertices of the contraction are autonomously extracted based on the following steps. First, each signal's baseline mean value is subtracted from the corresponding contraction signal. Then, the first derivative of each signal is calculated. Next, to detect the first rise (refer to Figure 5.3), we created a function called "Detect the first rise". The first rise is defined as the point where the contraction starts and is characterized by the point where a drastic increase starts (point B in Figure 5.3). The "detect first rise" function uses the threshold-based method, taking the derivative data array and a list of threshold values as arguments. Multiple thresholds are required because a single threshold cannot account for the substantial variations in y-values across different datasets: this ensures the correct detection of point B in diverse data. The function loops through the derivative values and finds the indices where the derivative data is greater than the first threshold. If none is found, the function repeats the step taking the second threshold, and so on until the function returns the index of the first point where the derivative is higher than the given threshold.

To detect the last fall (refer to Figure 5.3), we developed a function called "Detect Last Fall." The last fall is defined as the point where the contraction ends, marked by a significant decrease in the signal (point E in Figure 5.3). Similar to the detection of the first rise, the "Detect Last Fall" function utilizes a threshold-based method. It takes a derivative data array and a list of threshold values as inputs. To transform the last fall point into a first rise scenario, the y-values of the derivative signals are reversed and mirrored with respect to the x-axis. This inversion effectively turns the detection of the last fall into the detection of a first rise, simplifying the process. Figure 5.4 illustrates an example of a PFM contraction signal along with its corresponding first derivative and inverted first derivative curves. The function then iterates through the list of threshold values, searching for indices where the derivative data exceeds the current threshold. Once the function identifies the first point where the derivative surpasses the threshold, it returns this index as the last fall point. The actual index of the last fall is then calculated by subtracting the obtained index from the total number of points, effectively mapping the detected point back to its original position in the signal.

After identifying the start and end of the contraction (first rise and last fall), the algorithm detects the first maximum after the first rise and the last maximum before the last fall using the two created functions "Detect first max after first rise" and "Detect last max before last fall," respectively. These functions first calculate the zero-crossings of the derivative data, which are the points where the derivative changes sign (a zero derivative is a derivative of a maximum or a minimum). Then the "detect first max after first rise" function finds the index of the first maximum point after the first rising point (point C in Figure 5.3). Similarly, the "detect the last max after last fall" function finds the index of the last maximum point before the last falling point (point D in Figure 5.3).

Once the coordinates of the key parameters (B, C, D, and E) are determined, the trapezoid equation is computed, and a mathematical fit is created for each signal, as described in Equation 3. Using this equation, the algorithm calculates various features essential for evaluating different PFM training tasks. The following are the features along with their respective computation methods:

Rising Slope: defined as the slope between points B and C and is calculated according to the following equation:

$$m_r = \frac{F_C - F_B}{t_C - t_B}, \tag{5.4}$$

where F_C is the force value at C, F_B is the force value at B, t_C is the x index at C, and t_B is the x index at B.

Falling Slope: defined as the slope between points E and D and is calculated according to the following equation:

$$m_f = \frac{F_E - F_D}{t_E - t_D}, \tag{5.5}$$

where F_D is the force value at D, F_E is the force value at E, t_D is the x index at D, and t_E is the x index at E.

Area Under the Contraction Curve: The area under the contraction curve of the piecewise linear model signal, between points B and E, is calculated using the trapezoidal rule equation:

$$\int_a^b f(t)dt \approx \frac{2}{w}\left[f(a) + 2\sum_{i=1}^{n-1} f(t_i) + f(b)\right], \tag{5.6}$$

where a and b are the t indices of the first rise and last fall respectively, n is the number of subintervals (trapezoids) used in the approximation, t_1, t_2, ..., t_{n-1} are the equally spaced points within the interval [a, b] where the function f(t) is evaluated, and w is the width of each trapezoid, given by:

$$h = \frac{b-a}{n}, \tag{5.7}$$

The limits a and b are flexible and can be adjusted based on the instructions given for the task.

Global Maximum: The $\Delta F_{\max}$ is defined as the global maximum force of each signal and is calculated by identifying the maximum force value:

$$F_c(t) \leq \Delta F_{\max} \ ; \ A \leq t \leq E, \tag{5.8}$$

The Average Force: defined as the mean of forces, between the points B and E, and is calculated as follows:

$$\overline{F_c} = \frac{1}{T_E - T_B}\sum_{i=B}^{E} F_c, \tag{5.9}$$

The Contraction Time: defined as the difference between the point E index and point B index, which is dependent on the instruction given during the task:

$$T_c = t_E - t_B, \tag{5.10}$$

Muscle Relaxation: The ΔF_{f-i} is defined as the baseline force average:

$$\Delta F_{f-i} = \overline{F}_{AB}, \tag{5.11}$$

Finally, the features of each signal are normalized to within the range of 0 to 1 and saved as a row in an Excel file along with the ratings of each category.

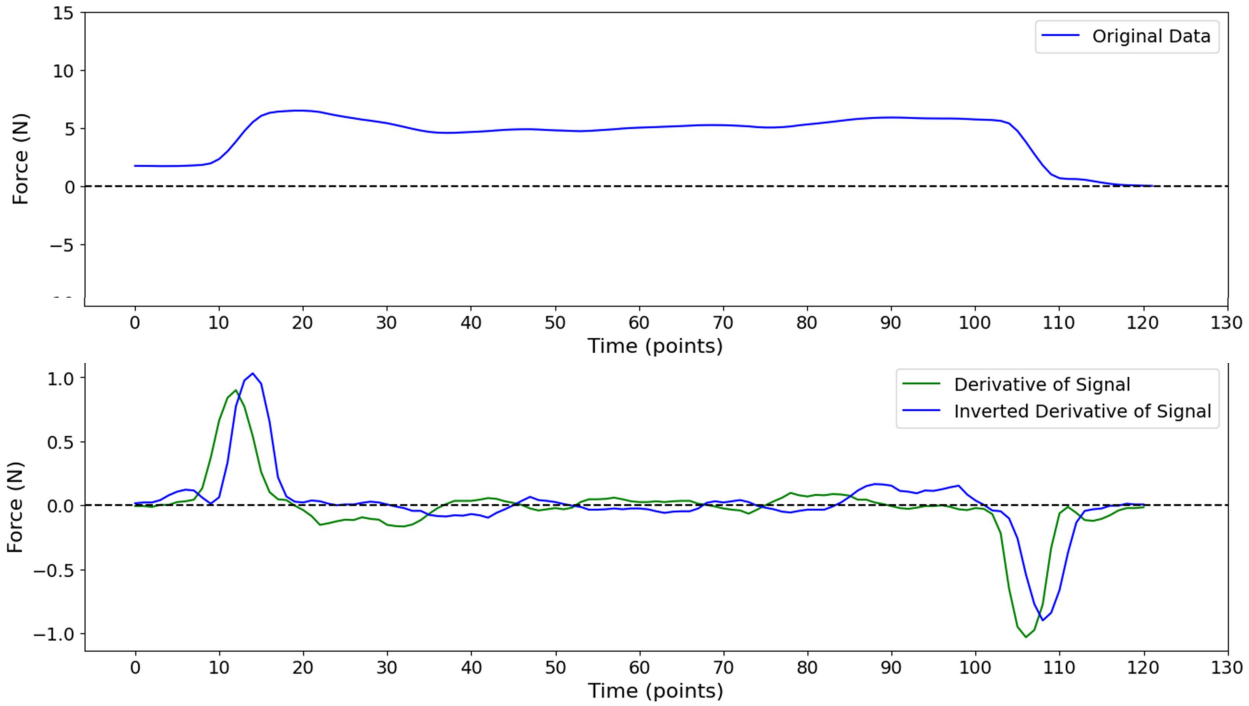

Figure 5.4 Example of original data derivative and inverted derivative.

Further, we introduced an overall rating scale to assess PFM contraction performance strategy regardless of the task. This scale provides a comprehensive assessment of the PFM contraction and takes into account all relevant features. The overall rating is calculated based on the following formula:

$$\textit{Overall rating } (\%) = (c_1 \cdot \Delta F_{max} + c_2 \cdot T_c + c_3 \cdot \overline{F_c} + c_4 \cdot \frac{(mr + mf)}{2} + c_5 \cdot \Delta F_{f-i}) \times 100, \quad (5.12)$$

where c_1, c_2, c_3, c_4, and c_5 are the weights of each feature contributing to the overall rating.

PFM Strength Classifier

A data-driven approach was adopted to predict the classification of the maximum PFM contraction graphs based on MOS. The MOS is a grading system used to evaluate the strength of PFM during a digital palpation exam, with six different grades ranging from 0 to 5 based on the level of contraction strength as follows [130]:

0 = nil;

1 = flicker;

2 = weak;

3 = moderate;

4 = good;

5 = strong

Maximum PFM contraction graphs from Dataset 1 were used in the development of the classification model. A digital palpation examination of the 318 participating individuals was done during pre and post-evaluations by 6 expert physiotherapists. Data labeling was done by correlating the digital palpation labeled MOS with the PFM contraction graphs.

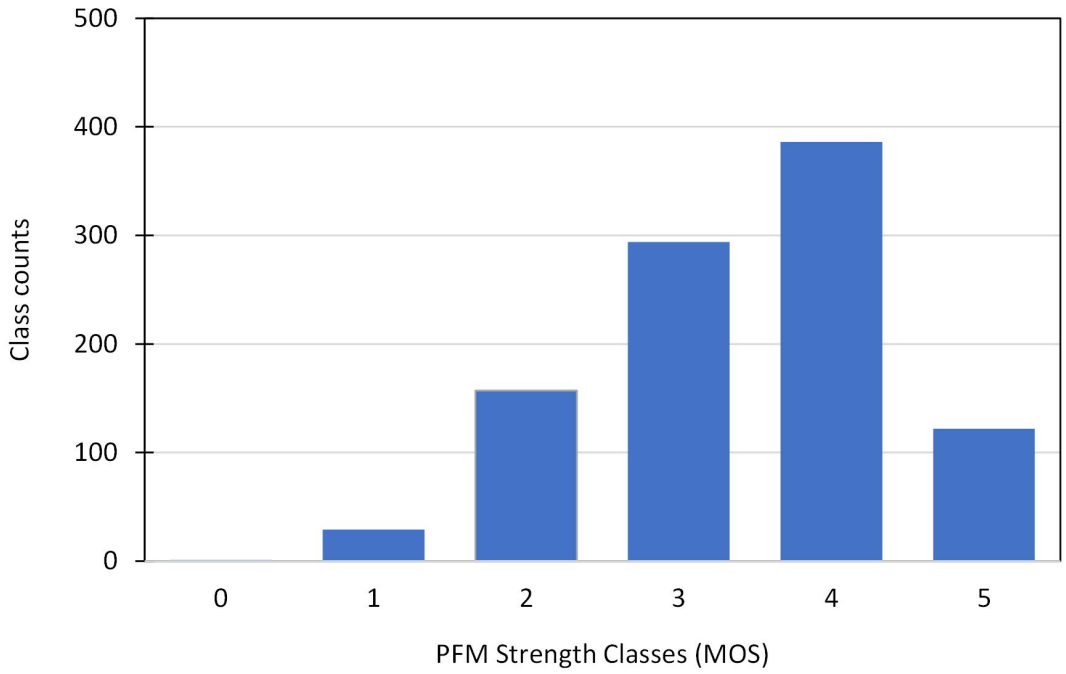

Figure 5.5 Bar chart of class distribution of PFM strength recordings.

The input data consisted of the features extracted normalized to within the range of 0 to 1. The output labels are the different MOS classes.

Figure 5.5 shows the class counts for each MOS class used in the classification process. Since this dataset represents real MOS grading from a previous study with no control over PFM strength variations, class imbalances are expected. For example, as can be seen in Figure 5.5, there are more participants with an MOS grade of 3 than participants with an MOS grade

of 0. Due to a lack of sufficient data for MOS grade 0 (1 participant out of 318), this class has been excluded from the classification process.

A combination of decision tree-based classification models, a statistical model, and a tree-based ensemble learning model were used. A random forest classifier (RFC) and a TOP random forest classifier (TRFC) have been used to classify the input data. The RFC and TRFC models work by creating multiple decision trees on randomly selected subsets of the data and then aggregating the results of these trees to make the final classification. The only difference is that the TRFC model incorporates an extra feature selection step by selecting a subset of features based on their importance scores, which are computed by the RFC algorithm during the training phase.

An eXtreme Gradient Boosting (XGB), implementing a gradient boosting framework, was also used to classify the aforementioned data. The XGBoost technique uses iterative training to sequentially train a set of weak prediction models, often decision trees. Every new model aims to correct the flaws of the prior models to produce a more precise forecast model.

Finally, a logistic regression (LR) classification model has been used as well. The XGB works by fitting a logistic function to the input data, which converts the input variables to the output likelihood of the observation falling into a specific class.

Data were split into a training set (80% of total data), and a testing set (20% of total data). Each model has been trained on the labeled data. Once trained, the models were used to predict the class of the testing set. The performance of each model was evaluated to compare between models.

5.5 Results

5.5.1 CNN Model Performance Evaluation

In this section, we evaluate the performance of our CNN model in classifying PFM contraction graphs. We present the results in terms of accuracy, sensitivity, and specificity, demonstrating the effectiveness of the model in distinguishing between PFM contraction and non-contractions.

Down-sampling Dataset 1 Evaluation

Figure 5.6 displays an original PFM contraction signal from Dataset 1 alongside its corresponding reconstructed signal. The average RMSPE calculated for Dataset 1 between original and reconstructed signals has been computed to be 2.58%.

Furthermore, Figure 5.7 illustrates an example from Dataset 1 of the frequency spectrum with the top three dominant frequencies for an original signal and its corresponding down-sampled signal. The average RMSPE for the top three dominant frequencies between the original and down-sampled signals was computed to be 0.65% for Dataset 1.

Validation on the Dataset 1

The CNN model performance has been evaluated on Dataset 1 by computing the model accuracy, sensitivity, and specificity. Figure 5.9 shows examples of PFM contraction signals and their corresponding trapezoid model fit.

The model performance evaluation based on the 5-fold cross-validation is shown in Table 5.3. The model achieves high accuracy (96.66%), high sensitivity (96.66%), and high specificity (93.75%). Figure 5.8 shows the receiver operating characteristic curve (ROC) for the CNN model along with the area under the curve (AUC) values for each class. The model exhibits excellent AUC for both classes (99%).

Generalization testing on Dataset 2

The generalization ability of our CNN Model was evaluated using Dataset 2. We directly applied our CNN model to Dataset 2 without training the model on it. Similarly, the model performance was evaluated in terms of accuracy, specificity, and sensitivity.

Figure 5.8 shows the confusion matrix obtained from Dataset 2 using the CNN model implemented and tested with Dataset 1. Table 5.3 shows that the model exhibits high accuracy (100%), high sensitivity (100%), and high specificity (100%).

Table 5.3 CNN model performance results

DataSet	Accuracy	Sensitivity	Specificity
Dataset 1	96.66%	96.66%	93.75%
Dataset 2	100%	100%	100%

5.5.2 Quality Algorithm

Validation of the PFM Strength Classification

The classification of PFM contractions into the different MOS classes has been evaluated across the four different statistical classification methods. To evaluate the performance of

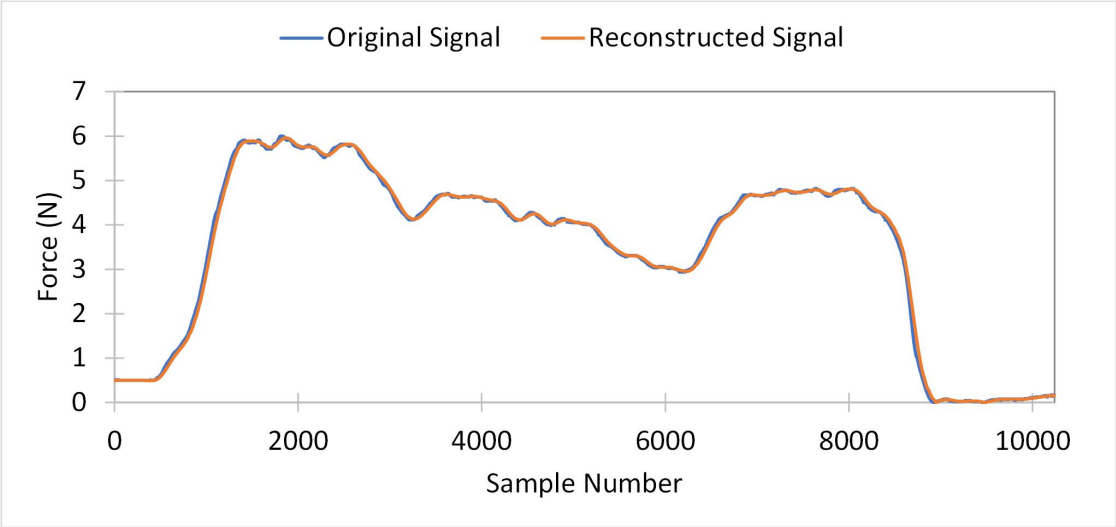

Figure 5.6 Original signal versus reconstructed signal of one PFM contraction from Dataset 1.

each method, accuracy (A), precision (P), recall (R), and F1 score (F1) have been computed based on the following formulas [131]:

$$Ac = \frac{TPc + TNc}{TPc + TNc + FPc + FNc}, \tag{5.13}$$

$$Pc = \frac{TPc}{TPc + FPc}, \tag{5.14}$$

$$Rc = \frac{TPc}{TPc + FNc}, \tag{5.15}$$

$$F1c = \frac{2 \times Pc \times Rc}{Pc + Rc}, \tag{5.16}$$

where TP_c represents the number of data from class c identified as class c, TN_c represents the number of data not from class c identified as a different class from class c, FP_c are data that are not from class c identified as class c, and FN_c are data from class c identified as a different class from class c.

The quality of the overall classification is assessed in two ways: macro averaging and weighted averaging. Macro averaging computes the measured average regardless of the class distribution. The weighted average takes into account class imbalances by computing the average with respect to the class counts in the training set as follows:

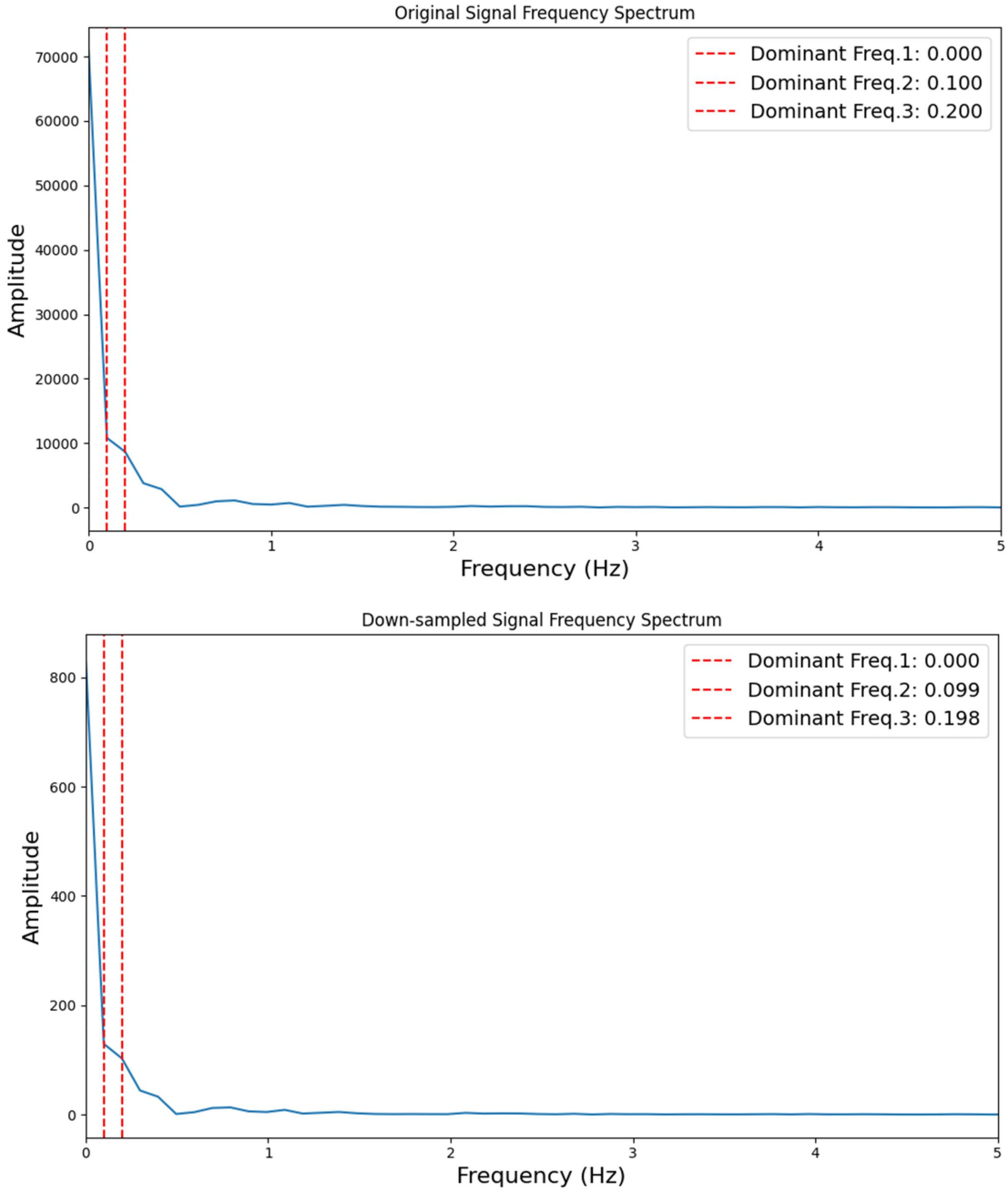

Figure 5.7 Top 3 dominant frequencies for original signal versus down-sampled signal for one PFM contraction from Dataset 1.

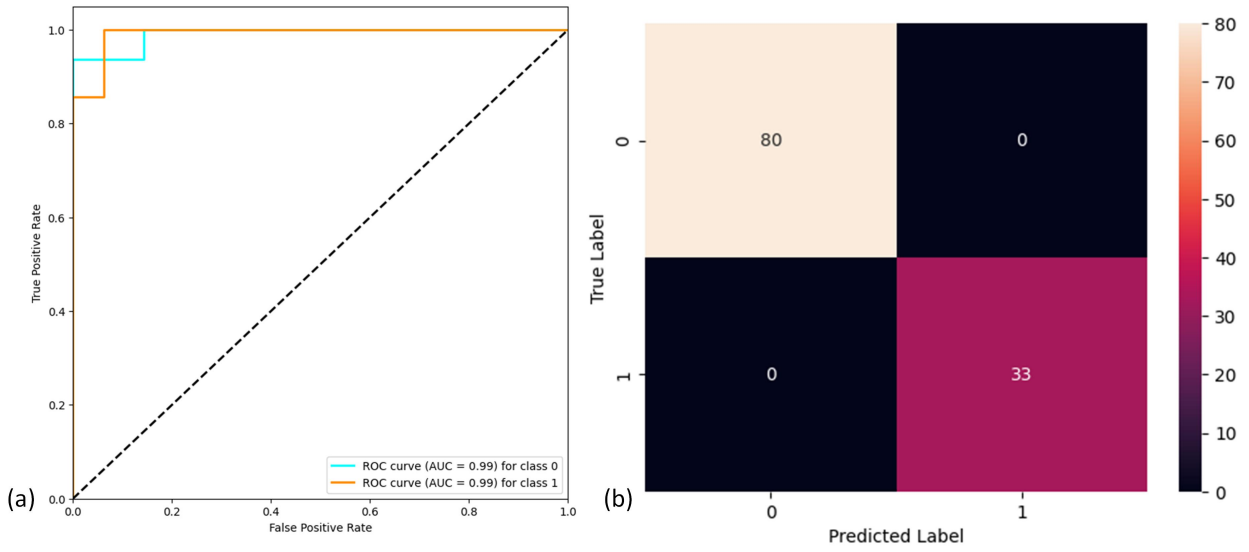

Figure 5.8 (**a**) Receiver Operating Characteristic Curve for the CNN Model, (**b**) Confusion matrix for CNN Model Dataset 2.

$$Pm = \frac{1}{c}\sum_{c=1}^{c} P_c, \qquad Rm = \frac{1}{c}\sum_{c=1}^{c} R_c, \qquad F1m = \frac{2 \times Pm \times Rm}{Pm + Rm} \tag{5.17}$$

$$Pw = \frac{\sum_{c=1}^{c} TP_c}{\sum_{c=1}^{c}(TP_c + FP_c)}, \qquad Rw = \frac{\sum_{c=1}^{c} TP_c}{\sum_{c=1}^{c}(TP_c + FN_c)}, \qquad F1w = \frac{2 \times Pw \times Rw}{Pw + Rw} \tag{5.18}$$

where m indexes macro averaging and w indexes weighted averaging.

Table 5.4 Digital palpation classification report based on different methods

Method	**Accuracy**	**Precision**	**Recall**	**F1 Score**
XGB	90.09%	0.76	0.77	0.76
LR	92.47%	0.83	0.83	0.82
TRFC	92.93%	0.83	0.82	0.81
RFC	95.56%	0.89	0.88	0.88

Table 5.4 presents the overall accuracy, precision, recall, and F1 score for the four classification methods within ±1 of each MOS class. The RFC classification model achieved the highest accuracy (95.56%), precision (89%), recall (88%), and F1 score (88%), outperforming the other methods including XGB, LR, and TRFC. Therefore, the RFC classification model was

considered the most effective approach for this particular classification task.

Table 5.5 shows the RFC method in-class scores for the precision, recall, and F1 score within ±1 of each MOS class. The RFC method exhibits medium to high precision scores (from 77% to 100%), medium to high recall scores (from 62% to 100%), and high F1-scores (from 76% to 100%) on each activity class. The overall weighted average precision, recall, and F1-score across all activities are 89%, 88%, and 88%, respectively.

Further review of the data where the RFC method's predictions did not match the MOS revealed that 23% of these mismatches were due to participants moving their buttocks when they were supposed to only contract their pelvic floor muscles. After removing these particular cases and analyzing the data again, the accuracy increased to 96.53%, the overall weighted average precision remained at 89%, but the recall improved to 93%, and the F1 score went up to 90%.

Table 5.5 Classification report for PFM strength based on digital palpation

Classes	**Precision**	**Recall**	**F1 Score**	**Support**
MOS = 1	1.00	0.83	0.90	6
MOS = 2	0.77	0.75	0.76	32
MOS = 3	0.89	1.00	0.94	59
MOS = 4	0.90	0.94	0.92	77
MOS = 5	1.00	0.62	0.76	24
Macro Avg	0.91	0.83	0.86	198
Weighted Avg	0.89	0.88	0.88	198

Algorithm Result

Table 5.6 Error evaluation of extracted features

Category	**MAE**	**Standard Deviation of Error**	**RMSPE**
Rising Slope m_r	0.0018	0.0039	1.138%
Area under the contraction curve AUC_c	0.6343	0.8556	0.256%
Global maximum $\Delta F_{\max}$	0.0700	1.1505	1.65%
Average Force F_c	-0.0009	0.0284	0.654%
Muscle relaxation ΔF_{f-i}	0.0017	0.0043	0.718%

In our efforts to analyze PFM contraction data, we first used a code designed to fit the data to a trapezoidal function. This approach aimed to minimize the difference between

the function and the actual data by adjusting parameters while adhering to constraints on the slopes of the rising and falling edges. Despite the theoretical robustness of this method, our rule-based feature extraction algorithm proved to be more effective. The superior performance of the rule-based algorithm can be attributed to its ability to incorporate specific clinical constraints—key parameters of the model—into the feature extraction process. These constraints include points B, C, D, and E, which define the critical phases of the maximal pelvic floor contraction. By ensuring that the extracted features align with these clinically relevant parameters, the rule-based algorithm enhances the practical utility of the analysis in real-world clinical settings.

The algorithm's autonomous ability to extract the features specified in table 5.2 from PFM contraction graphs was evaluated using a set of PFM MVC graphs from Dataset 1. The dataset used in the verification of the algorithm consisted of 900 PFM MVC graphs. First, features were extracted autonomously using the algorithm. Then, the four corners of each MVC were manually identified, and the features' values were re-calculated. The features' values obtained from the algorithm were then compared to the manually extracted values.

The comparison between the features' values obtained from the algorithm and the manually extracted values was done by calculating the mean absolute error (MAE) and standard deviation of the absolute forecasting error e_i based on the following formulas:

$$e_i = y_i - \hat{y}_p, \tag{5.19}$$

where y_i is the manually calculated value and y_p is the value calculated by the algorithm for the PFM contraction signal.

$$\text{MAE} = \frac{1}{n}\sum_{i=1}^{n}|e_i|, \tag{5.20}$$

The RMSPE for each feature was also calculated based on equation (2). The RMSPE values obtained were then compared to a predetermined threshold (5%). The RMSPE values obtained were less than the threshold, indicating that the features were correctly extracted (Table 5.6).

5.5.3 PFM Quality Assessment System Comparison to State-of-the-Art

Table 5.7 presents a comparison of the method used and results achieved in this study with the state-of-the-art. The table shows that the proposed novel quality assessment system is the first to incorporate a CNN algorithm for the detection of PFM contraction and an autonomous

maximal PFM contraction performance classifier. The obtained results indicate that the proposed quality assessment system outperforms the other state-of-the-art methods/devices in terms of accuracy, sensitivity, and specificity.

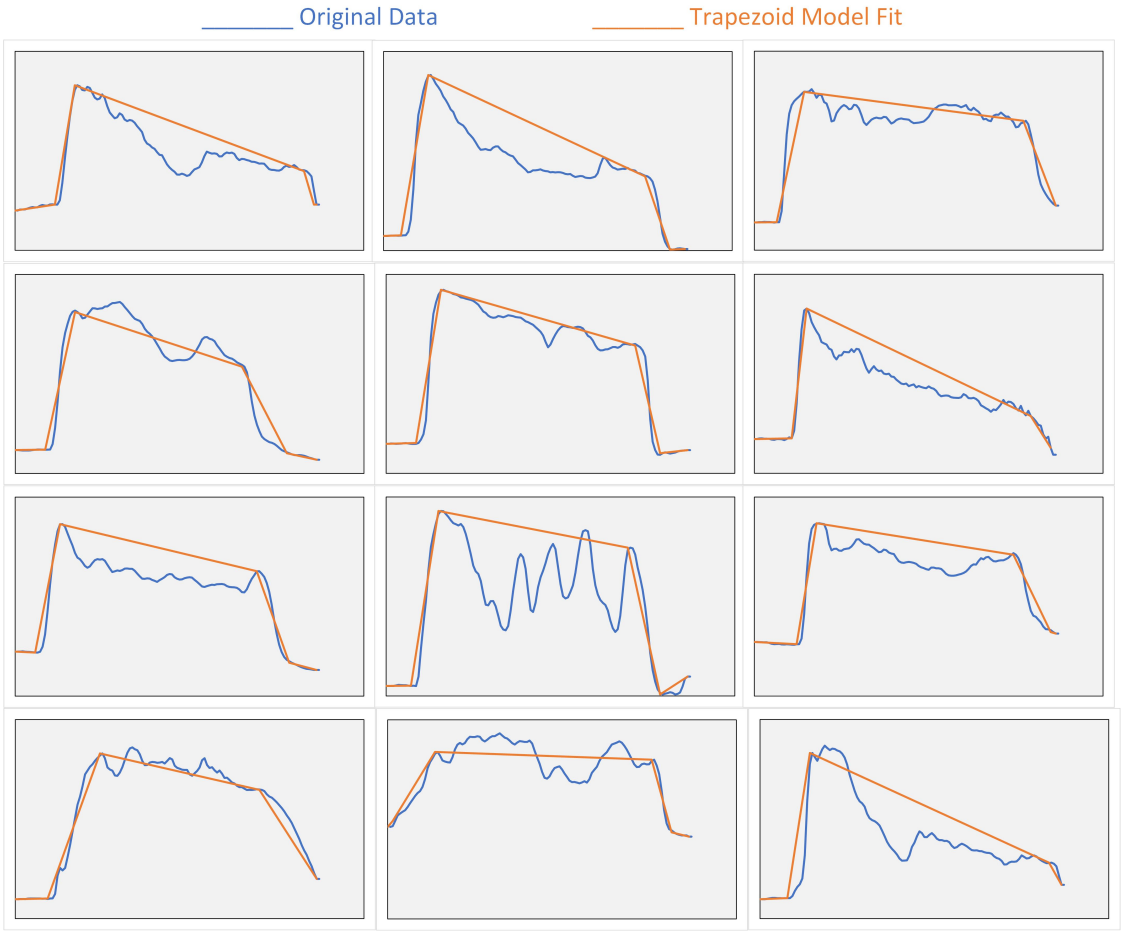

Figure 5.9 Example of PFM contraction signals and their corresponding trapezoid model fit.

5.6 Discussion

We accomplished a novel quality assessment system for the classification and quantification of maximal PFM contraction in women. To the best of our knowledge, this is the first reported quality assessment system of this kind.

This paper presents three significant contributions. Firstly, we introduce a CNN-based PFM contraction detector specifically designed for the classification of PFM contractions. To the best of our knowledge, this is the first application of a CNN model for this purpose. Secondly, we provide an automated method for the evaluation of PFM strength based on MOS. Lastly,

Table 5.7 Comparison with state-of-the-art

Method	**Visual Inspection [25, 132]**	**Catheter Pressure Transducer [73]**	**Ultrasound [59, 133, 134]**	**Pattern Recognition Algorithm [124]**	**Accelerometer [59]**	**AI-CNN Algorithm (This work)**
Technique	Direct Observation	Direct Observation and Sensor	High-frequency sound waves	AI	Sensor	AI
Type of method	Manual Evaluation	Manual Evaluation	Imaging technology	Machine learning	Rule based	Machine learning
Data used	Perineum movement	Perineum movement and intravesical pressure values	Sonograms	Exercise technique	PFM contraction force	PFM contraction force
Training Requirements	Expert	Expert	Expert	No training needed	No training needed	No training needed
Applicability	Clinical/ Research	Clinical/ Research	Clinical/ Research	No constraints	No constraints	No constraints
Evaluation Scheme	Correct, incorrect	Correct, incorrect	Correct, incorrect	Bad (-1) to Good (1)	Correct, incorrect	Contraction, non contraction Features and overall rating scores
Dataset	N/A	N/A	N/A	Sample: 28	Sample: 30	Sample: 331
Accuracy	Operator-dependent	Operator-dependent	Operator-dependent	Not reported	92-100%	96.66-100%
Sensitivity	Operator-dependent	Operator-dependent	Operator-dependent	Not reported	80.3-93.1%	96.66-100%
Specificity	Operator-dependent	Operator-dependent	Operator-dependent	Not reported	90.7-93.1%	93.75-100%
Efficiency	Limited speed	Limited speed	Time consuming	Automated calculation	Automated calculation	Automated calculation
Ease of use	Complex	Highly Complex	Complex	Simple	Simple	Simple
Limitation	Subjective, expert need	Subjective, expert need, complex	Subjective, expert need, high cost	Method lacks evaluation	Additional validation testing is required	Wider range of incorrect cases needed

we propose a universal algorithm for autonomously rating the quality of maximal PFM contractions across different features. These contributions demonstrate the potential of our system to improve accuracy and efficiency as well as to facilitate the clinical evaluation of PFM function.

The CNN model implemented for PFM contraction detection achieves an average accuracy of 97%, indicating its potential for accurately distinguishing between PFM contraction and non-contraction. After validating our CNN model through an independent dataset obtained from a newly developed PFM dynamometer, we observed a generalizability accuracy of 100%. This indicates that the model has been effectively trained to distinguish between PFM contraction and non-contraction. Results obtained in this study represent a significant step in the development of an accurate and reliable method for assessing pelvic muscle function. This achievement is particularly noteworthy given the importance of performing correct PFM contraction during PFMT for pelvic floor disorders management such as UI.

The CNN model designed in this study has the potential to be integrated into different PFM assessment tools that can assist both patients and clinicians in accurately providing feedback on PFMT contraction. Regardless of the type of device used to record the PFM contractions, it is expected that this model could effectively detect PFM contractions. Additional research is necessary to determine the applicability of the accomplished CNN model to different PFM strength-measuring devices with different contraction tasks such as endurance, rapid contractions, and muscle relaxation.

The RFC classifier based on digital palpation exhibited a high classification accuracy of 96.53% for classifying PFM contractions within ± 1 MOS class, which is notable given the subjective nature of digital palpation. A within ± 1 MOS class classification was deemed acceptable due to the inherent discrepancies in the MOS grading between clinicians. It should be noted that inconsistencies between the RFC classification and the MOS were observed in some cases. For example, a high MOS accompanied by a low PFM contraction strength or a low MOS score accompanied by a high PFM contraction strength. Based on the physiotherapists' observations during the study, in the cases with high discrepancies, a high MOS accompanied by a low PFM contraction strength could be caused by the patient's discomfort or pain during the examination, resulting in incomplete contraction. Conversely, a low MOS score accompanied by a high PFM contraction strength could be attributed to compensatory movements such as buttock lifting during the examination.

These findings suggest that the subjective nature of digital palpation remains a challenge for accurate PFM contraction assessment, and highlight the potential of the implemented RFC algorithms in improving the reliability of the assessment. One of the limitations of this study

is that all participants in Dataset 1 were able to contract their PFMs, leading to a skew in the data toward a MOS score of 3 or higher. Further studies should therefore be conducted on a larger population in patients with a wide range of PFM strengths and MOS classifications from 0 to 5. In addition, effort should be made to choose patients with no prior PFM pain to reduce bias. Moreover, this study represents an important step toward developing a reliable and objective method for assessing PFM contraction strength based on MOS.

In this study, a maximal PFM contraction performance classifier was designed to rate various features of a PFM contraction and provide direct autonomous feedback. Currently, PFM contraction is evaluated through digital palpation tasks or post-evaluation of recorded tasks using an assessment tool. However, digital palpation tasks are subjective and lack a global reference for comparison, while post-evaluation is time-consuming. The performance classifier results showed that the classifier was able to correctly extract the specific features of the PFM contraction graphs, with RMSPE values below a threshold of 5% for each feature. Therefore, it can be concluded that the classifier has the autonomous ability to extract specific features from PFM maximum contraction graphs accurately.

One of the key strengths of the maximal PFM contraction performance classifier accomplished in this study is its ability to provide sub-ratings for different underlying features. This allows for a more detailed analysis of maximal PFM contractions and identification of areas of weakness in participants, which can be used to provide the best training program for specific PFM dysfunctions. However, the importance of specific features depends on the evaluator's instructions given during the task. While our classifier has effectively identified a range of features for analyzing maximum voluntary contraction during the strength task, these features can also be applied to other tasks such as endurance, muscle relaxation, or rapid contractions. By adjusting the evaluator's instructions, we can determine which features are most relevant for each type of assessment, allowing for a tailored analysis of different tasks.

To advance standardization and simplify the evaluation of PFM contraction, we developed an overall rating scale integrating multiple features into a unified metric. This scale aims to provide a comprehensive assessment by incorporating all relevant features of PFM contraction. However, the successful implementation of this scale necessitates ongoing collaboration between clinicians and engineers to ensure that the features and instructions are both well-coordinated. While the initial formula provides a foundational example, further refinement might be required such as incorporating additional features. This collaborative approach between clinicians and engineers is crucial for optimizing the overall rating scale and ensuring that it meets clinical needs, thus enhancing the reliability of PFM contraction assessments.

The implementation of the autonomous maximal PFM contraction performance classifier

represents an important advancement in the objective assessment of PFM contraction. Future research should focus on validating the accuracy of the algorithm across different tasks and exploring its potential for integration into clinical practice. The use of objective assessment tools, such as the maximal PFM contraction performance classifier, has the potential to improve the accuracy of PFM contraction assessment and ultimately lead to better assessment and treatment of pelvic floor disorders.

Standardizing the process for evaluating the PFM function is crucial since the features evaluated are dependent on the specific task instructions. Therefore, it is necessary to establish standardization across protocols and normalize the different measurement data. In the past, comparing measurements obtained from different devices was challenging due to variations in device design and measurement conditions [123]. However, by standardizing each task, the performance classifier can be generalized across all devices, regardless of the range of PFM force measured. The performance classifier is a promising tool in the standardization of PFM function evaluation across different devices, however, testing of the performance classifier on different PFM strength measuring devices should be further assessed.

The PFM contraction performance classifier is designed to be agile through accommodating changes in specific task instructions. For example, if a task requires multiple features, the classifier can be adjusted accordingly for rating purposes. This characteristic makes the classifier adaptable to various clinical settings where tasks and instructions may vary.

In future work, the quality assessment system presented in this study is to be integrated into the novel portable PFM dynamometer utilized at Centre de recherche de l'Institut universitaire de gériatrie de Montréal (CRIUGM). Incorporating the quality assessment system into the PFM dynamometer would offer an automated and reliable tool for evaluating PFM function and assessing the efficacy of PFMT, enhancing the PFM contraction assessment and enabling real-time feedback to patients and clinicians.

Nevertheless, this study has some limitations. The data for evaluating different PFM functions are dependent on the specific tasks and cues provided. Each dynamometric task (rest, contraction, push, and cough) was performed according to explicit instructions from the evaluator, leading to variability in how participants executed the tasks. For example, during the maximum contraction task, some participants gradually increased their contraction strength, while others reached maximum contraction rapidly. This variability in individual strategies can result in differences in the contraction profiles which affects the consistency of the data. Although our PFM contraction detector was trained to recognize and classify a wide range of contraction profiles, the variability introduced by personal responses to task cues remains a limitation. In future studies, more standardized task instructions could help reduce this

variability and improve data consistency.

Further, although our system demonstrates high generalizability accuracy, it is important to recognize that its applicability may be influenced by the specific criteria used to define PFM contractions and non-contractions. Additionally, the data used are dependent on specific clinicians' instructions given for each task. This highlights the need for standardized criteria and protocols. Standardizing how PFM contractions are measured would improve the applicability of the system, making it more consistent across various clinical and research settings.

A final limitation of our study is the use of rest, push, and cough tasks as proxies for non-PFM contraction. We used the tasks at our disposal, which provided indirect information that we hypothesized to represent non-contraction. As these tasks serve as proxies, further studies should aim to test with data recorded directly from incorrect contractions to validate and enhance the accuracy of the quality assessment system.

5.7 Conclusions

In this paper, we presented a novel PFM contraction quality assessment system for the detection and evaluation of PFM contractions in women. The proposed system is composed of a CNN-based PFM contraction detector and an original maximal PFM contraction performance classifier. The CNN model predicts PFM contraction from non-PFM contractions, providing women with feedback on their training. The performance classifier introduces an original algorithm that autonomously evaluates the quality of maximal PFM contraction across different features and gives an overall score. The new quality assessment system is designed to be implemented in PFM function assessment devices, specifically a newly developed portable PFM dynamometer used at CRIUGM. Overall, the proposed system represents a significant advancement in PFM function evaluation and training, as it provides a smart solution for the assessment of PFM contraction. This system has the potential to improve PFM training and rehabilitation, enabling women to better monitor their PFM contraction.

CHAPTER 6 GENERAL DISCUSSION

Our aim in this thesis was to propose a force-measuring and performance-monitoring system for PFM assessment. Specifically, our objective was to build an electronic device that is wearable, portable, and wirelessly operable, which includes a biofeedback real-time measurement interface for the assessment and monitoring of the PFM function in women. Introducing such a medical device is a complex task with several challenges.

The first challenge laid in the design of the dynamometer-based PFM measurement probe, particularly in determining its dimensions and shape for clinical use. Designing a probe that can effectively accommodate the varying vaginal sizes and morphologies across different age groups of women poses a primary challenge for several reasons. Firstly, vaginal length tends to decrease with age, which imposes limitations on the probe's length. Secondly, there are variations in the tolerated aperture range (probe's diameter) among different populations. For instance, nulliparas or women with vaginal atrophy typically have smaller vaginal openings compared to parous women with levator ani defects.

To approach the first challenge, we conducted an extensive literature review to determine the initial dimensions for the probe design. These dimenions were then used to design and implement a first iteration of the PFM dynamometer probe. The probe design was then refined based on feedback from four expert physiotherapists. Additionally, a usability study involving ten women with UI was performed to identify problematic issues and offer recommendations for enhancing the vaginal dynamometer design. Three major issues were identified: the lock mechanism, the stability of the connecting wire, and the inadequacy of a one-size-fits-all approach. The lock mechanism was upgraded from a push-fit to a welded design. To address the instability of the connecting wire, part of the wire was embedded within the probe body to prevent it from being pulled out. Recognizing that a single-size probe would not suit all users, we developed two different sizes to accommodate variations in vaginal hiatus dimensions and address the challenges associated with size variability. These improvements led to the development of a final optimized prototype.

The second challenge was ensuring the stability of the probe inside the vagina during exercises in both standing and supine positions. One of the main objectives of this thesis was to have a portable device that can be used in functional positions such as the standing position. Ensuring the PFM probe remains stable within the vagina in both standing and supine positions is crucial for enhancing patient comfort during assessment and training sessions. It also ensures the validity and repeatability of the measurements. To achieve this objective, a

robust design was needed.

To overcome the second challenge, the PFM probe was uniquely designed to allow for stabilization inside the vaginal cavity. Side elements located on the left and right surfaces of the PFM probe were added. The side elements are designed to prevent the PFM probe from turning or falling down through widening the probe's radial dimension. Further, during the design phase, the weight of the probe was a critical factor that influenced our design choices, especially given that UI and other lower urinary tract symptoms are more common among elderly women, where weight tolerance is a significant issue. Through careful design choices relating to both intended function and weight, we were able to achieve a lightweight device. The combination of the unique probe design and lightweight design ensured the stability of the dynamometer. No vaginal probe movement was reported during the usability study.

The last challenge was autonomously fitting the contraction graph into a quadrilateral, which is a crucial component of the quality assessment system. This task presented several difficulties due to the significant graph variations and the shape and data distribution characteristics. The most important obstacle was accurately identifying the contraction's edges. The clinical significance of each corner made precise corner detection essential. Any deviation or error in estimating these corners would lead to substantial inaccuracies in the derived features, potentially compromising the reliability of the assessment.

In our efforts to address the last challenge, we initially used an optimization approach to fit the data to a trapezoidal function. This method aimed to minimize the difference between the function and the actual data by adjusting parameters while adhering to constraints on the slopes of the rising and falling edges of the contraction. However, despite the theoretical robustness of this approach, fitting the contraction graph into a trapezoid did not yield the most accurate feature extraction due to the clinical significance of the graph's corners. To overcome this issue, we employed a statistical approach alongside a rule-based algorithm. The contraction curves were first divided into three distinct threshold groups, which were then used in a threshold-based method to develop an autonomous algorithm that more precisely identified the start and end points of contractions. This rule-based algorithm was designed and implemented to incorporate established clinical practices for accurately identifying critical contraction points.

The superior performance of the rule-based algorithm can be attributed to its ability to incorporate specific clinical constraints and requirements into the feature extraction process. These clinical constraints ensure that the extracted features are not only mathematically accurate but also clinically relevant, thus enhancing the practical utility of the analysis in a real-world clinical setting.

With the above three solutions, we were able to successfully design and implement a force-measuring and performance-monitoring PFM dynamometer. The proposed system presents a promising direct and objective force-measuring system for the evaluation and assessment of PFM function in women with UI and other urinary dysfunctions. Moreover, the autonomous proposed quality system could be utilized in different PFM function measurement devices and tools, saving both time and effort for clinicians and physiotherapists in the field.

While the portable PFM dynamometer shows promising results, there are still some limitations. One key issue involves the silicone covering used on the device. Challenges related to disinfection and durability were observed, with the silicone tearing after repeated testing and cleaning. Further investigation is needed to identify more resilient and easily maintainable materials in research/clinical settings.

Additionally, connectivity issues were noted with the processing unit. These may be influenced by environmental factors, such as room conditions, or application-related problems. However, the exact cause remains unclear and requires further investigation.

CHAPTER 7 CONCLUSION AND RECOMMENDATIONS

In this thesis, we presented a portable system aimed at assessing and monitoring PFM function in women. Our primary objective was to design and implement a direct, and objective portable measurement tool for evaluating and training women with urinary dysfunctions. The proposed measurement tool is a main component of PFMT, the first line of treatment for UI in women.

To achieve our objective, we initially designed a proof-of-concept force measuring system based on an existing dynamometer. The functionality and capability of measuring forces, and the system's portability, were successfully demonstrated through bench testing. Design requirements were derived from the proof-of-concept prototype.

Second, we designed and implemented a functioning, novel prototype of a portable vaginal dynamometer. The vaginal dynamometer consisted of two blocks, the PFM probe, and a processing unit. The PFM probe design was tested for usability and improved based on the usability study results. The system's functionality was assessed through bench testing. The system exhibits high linearity and high repeatability, with minimal noise and heat effects. Additionally, the testing results demonstrated the potential of the newly designed system to measure PFM function under functional conditions, such as the standing position.

Lastly, we designed an autonomous quality assessment system for the monitoring and evaluation of the PFMT performance. This system combines a CNN-based PFM detector and a maximal PFM contraction performance classifier. The CNN model was tested through 5-fold cross-validation and exhibited high accuracy, sensitivity, and specificity. The generalizability of the CNN model was assessed, yielding high accuracy, sensitivity, and specificity as well. The maximal PFM contraction performance classifier was validated by comparing predicted values with real values, demonstrating an error rate of less than 5%.

The system proposed in this thesis introduces a promising approach for directly and objectively measuring forces to evaluate and assess PFM function in women with UI and other urinary dysfunctions.

7.1 Contributions

The main contributions of this thesis relate to the design and implementation of a portable platform for women's PFM function monitoring and assessment. Detailed contributions are summarized as follows:

1. **The design and implementation of a portable proof-of-concept prototype for a force measuring system based on an exisiting dynamometer.**

   This was a short-term objective aimed at identifying design requirements. The dynamometer used in this study was an existing device, whereas the processing unit and graphical user interface (GUI) were re-designed, and the complete system was implemented and tested for functionality. The system was successfully built, integrating a minimal number of components. This approach resulted in a lightweight design, which is advantageous for portability and ease of use. Conducting rigorous testing, the system's capabilities and performance were assessed, ensuring its functionality and suitability for portable force measurement.

2. **The design and implementation of a novel functioning prototype of a portable vaginal dynamometer for the evaluation and training of women with urinary dysfunctions.**

   To address the need for a portable measurement system, we designed and implemented an electronic device that is wearable, portable, and wirelessly operable with a real-time biofeedback interface. The system allows for the portability and flexibility of PFM measurements, enabling more natural and accurate assessments, particularly in the standing position relevant to UI studies. By capturing data in the natural standing posture, we provide a more comprehensive understanding of PFM function and its impact on continence.

3. **The design of a novel autonomous quality assessment system compromising a PFM detector based on a convolutional neural network model, a maximal PFM contraction performance classifier, and an automated method for measuring PFM strength based on MOS, designed specifically for PFM performance evaluation.**

   We designed and implemented an autonomous quality system for the assessment of PFMT performance. To the best of our knowledge, this represents the first utilization of a CNN model for this specific application. This robust model improves the reliability and accuracy of PFM contraction classification. The versatility of this model holds the potential to be widely applicable.

The presented work is a significant contribution to the field of PFM assessment and training.

The development of a portable PFM dynamometer with artificial intelligence capabilities is a novel approach that has the potential to enhance the assessment and training of incontinent patients, providing them and their physiotherapists with new technologies that are currently not available in research or industry.

7.2 Recommendations for Future Work

The research work presented in this thesis lays the foundation for further developments and improvements of the proposed medical device. Potential directions for future work are presented based on the domain of improvement:

1. Enhancing PFM detector validation:

    - To enhance the versatility of the CNN-based PFM detector, it is crucial to focus on acquiring more data, particularly incorrect contractions data, such as push or Valsalva maneuvers confirmed by a physiotherapist during recording. This step is essential in establishing a robust model that not only between PFM contraction and non-contraction but also between correct and incorrect contractions. By expanding the dataset with a higher emphasis on capturing diverse examples of incorrect contractions, we can improve the model's ability to generalize and make accurate classifications. The inclusion of more data not only enhances the overall performance of the model but also increases its versatility, enabling it to effectively handle a wider range of real-world scenarios. As the current results are based on datasets in our database, it is essential to test the CNN-based PFM detector across external datasets. Testing the model on diverse external datasets will help assess its ability to generalize across different populations and conditions. By comparing results across various datasets, potential biases or limitations can be identified and addressed, ultimately strengthening the model's credibility and clinical applicability.

2. Manufacturing readiness:

    - One way to enhance the PFM dynamometer is by integrating the quality assessment system into its functionality. This can be achieved by integrating the quality assessment system with the newly designed app at the Canadian research chair of urogynecological health and aging laboratory. This integration would involve incorporating features and mechanisms within the app that allow for the assessment and evaluation of the PFMT performance in real-time.

- To ensure the prototype can be brought to market as a product, it is important to enhance the prototype for manufacturing. This involves improving the design and making necessary modifications to ensure it meets the FDA requirements in terms of sterilization and cleanliness and is scalable for mass production. The prototype can also be optimized for ease of manufacturing, cost-effectiveness, and overall product quality.

3. Psychometric evaluation:

    - Acknowledging the importance of evaluating the psychometric properties of the system, it is important to evaluate the proposed PFM dynamometer's validity and reliability. To achieve this, a feasibility study can be conducted, which involves recruiting a sample of participants and assessing their PFM function using the PFM dynamometer prototype and another measurement tool, supposedly digital palpation. The measurements are to be repeated within and between two sessions. The study will allow us to evaluate the repeatability within and between sessions of the intra-vaginal dynamometer.

4. Clientele and condition-specific studies:

    - Acknowledging the importance of evaluating the effect of intra-abdominal pressure on the system's measurements, future studies should focus on assessing the effect of intra-abdominal pressure on the proposed PFM dynamometer measurements.
    - To ensure the prototype's versatility, it is important to evaluate its feasibility with different client populations. Future studies can explore the feasibility of using the prototype with pregnant women, individuals with obesity, and those with conditions such as pelvic organ prolapse. These studies can provide valuable insight into the prototype's usefulness and effectiveness with diverse patient populations.

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