Evaluation of a Non-invasive Device for Measurement of the Elastic Modulus and Pressure of Soft Tissue-Mimicking Phantoms at Various Strain Rates

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April 2023

A thesis submitted to McGill University in partial fulfilment of the requirements of the degree of Master of Science in Mechanical Engineering

CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

ACS	Abdominal compartment syndrome
AW	Abdominal wall
AWE	Abdominal wall elasticity
BMI	Body mass index
C_{ab}	Abdominal compliance
E	Elastic modulus. Also referred to as elasticity, Young’s modulus, tensile modulus, or modulus of elasticity
ECM	Extracellular matrix
IAH	Intra-abdominal hypertension
IAP	Intra-abdominal pressure
IAV	Intra-abdominal volume
ICU	Intensive care units
LBP	Low back pain
UBP	Urinary bladder pressure
US	Ultrasonography
WSACS	Abdominal Compartment Society

ABSTRACT

Background

The incidence of low back pain cases in adults is on the rise, and one potential reason for this is the instability and lack of support in the spine. The intra-abdominal pressure, in conjunction with the elastic and viscoelastic characteristics of the abdomen, plays a vital role in providing support to the spine. However, the current techniques for measuring these properties have limitations, such as being invasive, unreliable, expensive, or not widely accepted by the clinical community.

Objectives

The objective of this research is to validate a novel suction device that is non-invasive, reliable, and easy to use as a supportive biomedical tool for the measurements of internal pressure and elastic modulus at various strain rates. There are three tasks to achieve this objective. First, to refine fundamental aspects, including the theory of mechanics of biological materials, to better reflect tissue elastic and viscoelastic constitutive properties. Second, to refine, optimize the design and manufacture the novel suction device. Third, to make controlled experiments for determining reliability and sensitivity of the device.

Methods

For this study, fifteen measurements per strain rate were performed on phantom materials using a physiologically representative abdominal benchtop model. The elastic modulus and internal pressure measured by the device were calculated using the extended Hencky solution, Hooke’s law, and Lame’s equations. The validation involved performing

tensile tests and measuring the internal pressure directly.

Results

The intra-rater reliability was between poor to excellent (ICC = 0.74), and the one-way repeated measures ANOVA and the post hoc Tukey's HSD test indicated a significant effect of strain rate on the elastic modulus at the $p < 0.05$ level for the low, medium, and high-speed levels [$F(2, 28) = 78.60$, $p = 0.001$].

Conclusions

Based on the study, the developed device can detect the viscoelastic behavior of soft tissue-mimicking phantoms at varying strain rates by inducing tissue deformation and computing the modulus and underlying pressure using first principles. The results showed an increase in modulus with an increase in strain velocity, and the device was able to estimate modulus and pressure values within biological ranges. The device's potential applications include determining the boundaries between healthy and unhealthy tissues, identifying pathological conditions, tracking tissue healing process, and enhancing rehabilitation for patients with back pain.

RÉSUMÉ

Contexte

L'incidence de la lombalgie chez les adultes est en croissance, et l'une des raisons potentielles est l'instabilité et le manque de soutien de la colonne vertébrale. La pression intra-abdominale, associée aux caractéristiques élastiques et viscoélastiques de l'abdomen, joue un rôle essentiel dans le soutien de la colonne vertébrale. Cependant, les techniques actuelles pour mesurer ces propriétés sont limitées, car elles sont invasives, peu fiables, coûteuses, et ne sont pas largement acceptées par la communauté clinique.

Objectifs

L'objectif de cette recherche est de valider un nouveau dispositif d'aspiration non invasif, fiable et facile à utiliser, en tant qu'outil biomédical pour mesurer la pression interne et le module d'élasticité à différentes vitesses de déformation. Trois tâches sont nécessaires pour atteindre cet objectif. En premier lieu, l'optimisation de la théorie de la mécanique appliquée aux matériaux biologiques, afin de mieux représenter les propriétés viscoélastiques des tissus humain. Ensuite, la conception et l'optimisation d'un nouveau dispositif d'aspiration et sa fabrication. Enfin, la réalisation d'expériences contrôlées pour déterminer la fiabilité et la sensibilité du dispositif.

Méthodes

Pour cette étude, quinze mesures par vitesse de déformation ont été effectuées sur un banc d'essai en utilisant des matériaux fantômes représentant le tissu biologique

abdominal. Le module d'élasticité et la pression interne mesurés par l'appareil ont été calculés à l'aide de la solution de Hencky étendue, de la loi de Hooke et des équations de Lame. La validation a consisté à effectuer des essais de traction et à mesurer directement la pression interne.

Résultats

La fiabilité moyenne intra-évaluateur était faible à excellente (ICC = 0,74), et l'ANOVA à mesures répétées à sens unique ainsi que le test HSD post hoc de Tukey ont indiqué un effet significatif de la vitesse de déformation sur le module élastique avec une valeur $p < 0,05$ pour les vitesses faibles, moyennes et élevées [$F (2, 28) = 78,60$, $p = 0,001$].

Conclusions

L'étude a confirmé que l'appareil développé peut détecter le comportement viscoélastique des fantômes imitant les tissus mous à des taux de déformation variables suite à une déformation des tissus en calculant le module d'élasticité et la pression sous-jacente à l'aide des premiers principes. Les résultats ont montré une augmentation du module d'élasticité suite à une augmentation de la vitesse de déformation. L'appareil a également été capable d'estimer le module d'élasticité et les valeurs de pression intra-abdominale dans des intervalles biologiques. L'appareil pourrait être utilisé dans l'identification de tissus sains et malsains, ainsi que certaines conditions pathologiques, dans le suivi du processus de guérison des tissus et pour l'amélioration du suivi en réadaptation de patients souffrant de lombalgie.

ACKNOWLEDGEMENTS

I would like to express my deepest gratitude to Prof. Driscoll for the opportunity to be part of your team, and for all the advice and direction provided during the process. You are a great professor and role model for all your students, always encouraging us to stand up with confidence, to believe in ourselves and training us to build strong personal and professional relationships.

I am extremely grateful to all the members of the Musculoskeletal Biomechanics Research Lab. I am the average of all the people who surround me, and in the past two years, you were a wonderful influence. Thank you for all your practical help, time, and company. I admire you and wish you all the best in your next adventures. Special thanks to Mr. Michael Grizenko-Vida and Mr. Christopher Raczek. It was a pleasure to coincide and collaborate. I learned so much from you.

Lastly, I could not have undertaken this journey without my caring family and my sweetheart, María. Words cannot express my gratitude for all the unconditional love and support for always looking to see and bring out the best in me.

PREFACE AND CONTRIBUTION OF AUTHORS

The dissertation is structured as a manuscript-based thesis. It includes a scientific manuscript currently under review by the editorial board of Medical & Biological Engineering & Computing. The device described in this study will help clinicians to detect irregular properties and recommend further diagnostic procedures to patients with low back pain. I, Álvaro Torres Rodríguez, hereby certify that I am the primary author of the manuscript and chapters within this dissertation. I was involved in all aspects of the research, including the design, testing, data collection, analysis, and manuscript writing. Mr. Michael Grizenko-Vida and Mr. Christopher Raczek assisted me with the device design, manufacturing, and validation process. Ms. Emily Newel provided practical knowledge on statistical analyses. Professor Mark Driscoll was important in supervising and coordinating the study, as well as in funding acquisition. Furthermore, he collaborated to the manuscript review and editing process.

1. THESIS INTRODUCTION

The human quality of life highly depends on the health of the spine, and low back pain (LBP) is considered one of the most critical symptoms of lack of support and spinal instability [1], [2]. Unfortunately, LBP has been the number one cause of disability worldwide for decades. The pressure inside the abdominal cavity (the intra-abdominal pressure) and the ability of the abdominal region to expand in static (elasticity) and dynamic (viscoelasticity) settings are essential elements of the active and passive systems in charge of regulating spine stability. Even though there are different approaches to quantify these properties *in vivo*, a reliable, accessible, and non-invasive tool is still needed.

Therefore, the aim of this master's research is to evaluate a novel suction device that is non-invasive, reliable, and easy to use, as a supportive biomedical tool for the measurements of internal pressure and elastic modulus at various strain rates. To achieve this, the general objectives are the following:

Objective 1

To refine fundamental aspects, including the theory of mechanics of biological materials, to better reflect tissue constitutive properties of elasticity and viscoelasticity, while measuring internal pressures.

Objective 2

To refine, optimize the design and manufacture a novel suction device.

Objective 3

To make controlled experiments, using a benchtop model for determining the device reliability and sensitivity.

To better understand the device capabilities, benchtop tests can be performed as preliminary stages of development. For this research, a sealed testing benchtop model, representative of a human abdominal compartment, was used to study the reliability of the device to differentiate strain rates at a specific internal pressure. This novel approach has the potential to be used as a supportive tool to help clinicians evaluate patients with LBP, as it ease the early detection of irregular properties, the study soft tissue stiffness during healing and how internal pressures vary as a function of muscle activation.

The dissertation is composed of 4 chapters. This first chapter states the rationale and presents the specific research objectives. The background, the literature and current state of knowledge are reviewed in chapter 2. Consequently, chapter 3 presents a scientific manuscript on the evaluation of a non-invasive device for measurement of the elastic modulus and pressure of soft tissue-mimicking phantoms at various strain rates, which includes the use of a pressurized testing benchtop model and tensile tests for validation. The fourth chapter of this dissertation provides a general summary of the device´s capabilities and the potential application of this technology based on the findings of chapter 3. Additionally, the author offers recommendations for future research to build upon this study’s results.

2. LITERATURE REVIEW

The upper musculoskeletal system is essential for the human body. It includes 33 bones of the skeleton, over 30 spinal muscles, 24 joints, cartilage, tendons, ligaments, and the fascial system. All these elements provide a supporting structure for stability, help to keep an upright position, enable and control motion, protect nerves, and assist as a shock absorber system [2]. The quality of life is greatly influenced by the condition of the spine, and low back pain (LBP) is considered one of the most critical symptoms of lack of support and spinal instability [1], [2]. Unfortunately, there is a lifetime prevalence of LBP of over 85%, meaning that four out of five adults will experience it at some point in their lives [3], [4].

LBP has been ranked the number one cause of disability worldwide for decades: over 630 million people of both sexes are affected globally, representing 10.7% of all reported cases, and is especially prominent in all developed countries [5]. Although LBP is increasingly recognized as a complex syndrome with multifactorial etiology, 85 - 90% of the clinical cases rise spontaneously, and the pathogenic causes leading to the development of chronic pain are still not fully understood [6]. Furthermore, the deficit of objective and measurable indications of medical state (biomarkers) for diagnosis and monitoring may contribute to the statistic that 33% of patients re-experience LBP after 12 months of treatment [7].

It is also a high-cost disorder and is on the rise. Only in the United States is it estimated that the direct and indirect costs of LBP are greater than USD 100 billion per year (about $310 per person), becoming one of the top five most expensive illnesses these days [8].

Hundreds of funds have been invested in identifying the pathophysiological mechanisms leading to chronic LBP. Some of them have a focus on studying the structural pathology of the vertebrae and associated tissues [9], others on neuropsychological considerations [10], [11], irregularities of postural and motion control [12], [13], and the non-specialized connective tissues forming the fascial planes of the back [14].

2.1 Spinal Stability and Loading

There is currently a lack of consensus on the terminology and definition of equilibrium spinal stability, which makes it challenging to measure and quantify. The clinical perspective defines “stability” as integrity and codependence through motion, regardless of body position. On the other hand, the biomechanical engineering point of view defines the concept of spinal stability as the ability of all the musculoskeletal elements to hold the spine steady and return to its original (natural) position after motion [15]. From this perspective, human spine stability and low back pain disorders depend on the loading of compressive forces applied to the body. A positive correlation has been found between spine stability and muscular activity, indicating that stability increases during periods of high muscular activity and decreases for less demanding movements [16].

Mechanical stability is relevant to all ranges of loading. It has been reported that in isolation, the thoracolumbar and lumbar spine buckle under compressive loads smaller than 100 N [17]. However, forces as high as 600 N are present in everyday activities. The main load exerted in the spine is parallel to its axis (axial). However, various forms of loading and forces act on the musculoskeletal system. When standing, the total center of mass of the human body is in front (anterior) of the spine. Hence, the spine undergoes a forward bending moment with respect to the center of mass [15]. This moment is counterbalanced by the back muscles (spinal erectors), the tension from spinal ligaments, the body weight, and the intra-abdominal pressure, as illustrated in Figure 2-1.

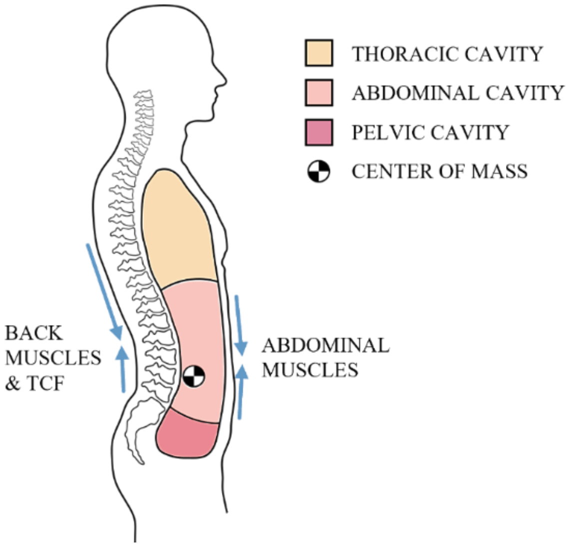

Figure 2-1 Anatomical cavities and contributors to spinal stability.

Three central systems participate in the correct distribution of loads: the passive system, conformed by all the spinal column bones, the active system, which includes all the active muscles attached to the spinal column, and the central nervous system, which includes the brain, the spinal cord, and the nerves network. The latter monitors the body's condition and constantly communicates with the active system to ensure stability [2]. Therefore, spinal stability can be explored via biomechanical parameters of the active and passive systems that stimulate and regulate spine stability, namely the fascial system, thoracolumbar fascia, and intramuscular and intra-abdominal pressure.

2.2 Active and Passive Systems

Human anatomy is connected by distinct types of soft tissue that work like biological and nonlinear viscoelastic springs. They are mostly made of collagen, but the composition, thickness, and mechanical properties vary depending on the stresses they are subjected to, their function, and their efficiency [18]. The fascial system is one particular and poorly explored classification of soft tissues. It involves fibrous and viscous sheets of organized and disorganized connective tissues, such as adipose tissues, ligaments, membranes, tendons, and all the intramuscular and intermuscular connective tissues (myofascial). It encloses, attaches, and permeates all internal organs, muscles, bones, and nerve fibers, lubricating between tissue layers, reducing stress concentrations, enhances strength and agility [19].

The fascial system is linked with movement receptors, called muscle spindles. Together play a vital role in the communication across body structures to support movement integrity and the sense of self-movement, force, and body position, called proprioception. The receptors perimysium, endomysium, and epimysium oversee detecting changes in muscle length (velocity and magnitude) and organizing intramuscular connective tissues and muscle fibers connections [20]. Any abnormal increment of connective tissue thickness or muscle pressure could lead to an increase in the levels of collagen fibers and alter the mechanical properties of muscles [20]–[23]; these imbalances could be a factor of proprioceptive reduction, bad posture, inadequate loads migration and increasing the moment arm of the body weight applied to low back [19], [20], [24].

2.3 The Abdominal Cavity

The abdominal cavity protects and provide support to vital organs, including the liver, pancreas, intestines, spleen, gallbladder, stomach, and kidneys [2]. This cavity is lined by a tissue membrane known as the peritoneum, which has a smooth surface and has a shape like a flat-bottomed spheroid that elongates into a half-cylinder shape when at rest. The peritoneum is enclosed by various structures such as bones, muscles, adipose and subcutaneous tissues, ligaments, and skin (as depicted in Figure 2-2) [2]. The physical constraints on the peritoneum can be divided into two categories; the chest's lower edge, spine, and pelvis are fixed elements that do not expand during breathing, while the abdominal wall and diaphragm possess flexible properties that allow for expansion and contraction [25]. Recent computed tomography studies have found that the intra-abdominal volume (IAV), which includes the volume of the peritoneum and its visceral contents but not fat, is on average 7.6 ± 1.0 L among healthy patients [26], [27]. This volume also includes gas content in the stomach and gastrointestinal tract, which was found to be 131 mL in healthy subjects [26]. However, the IAV can vary depending on factors such as physical features, sex, age, and other physiological responses.

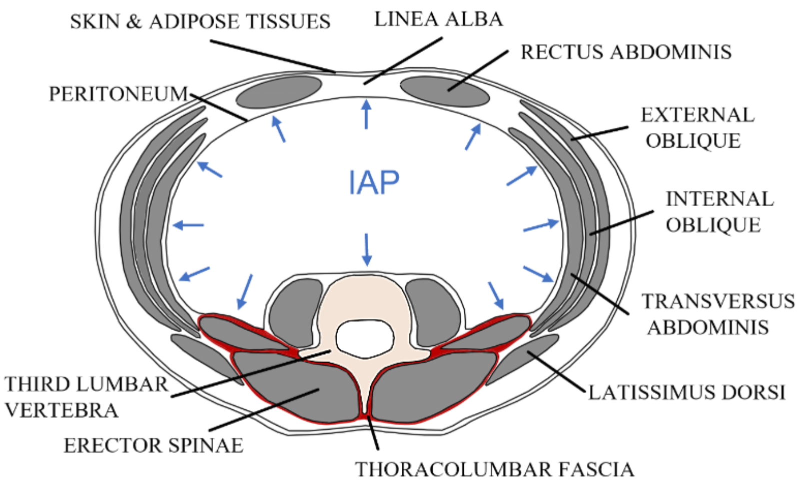

Figure 2-2 Cross-section view of the abdominal wall at L3 level.

2.4 The Intra-Abdominal Pressure

The intra-abdominal pressure (IAP) is one of the main spine stability mechanisms regulated by the neural system. According to the Abdominal Compartment Society (WSACS), the IAP is defined as the steady-state pressure inside the abdominal compartment, commonly measured in millimeters of mercury (mmHg) [28]. The IAP is determined by the ease of abdominal expansion, the body posture, and the activation of agonistic and antagonistic trunk muscles [16], [29]–[31] (Table 2-1). Normal baseline IAP is defined as between 5 and 7 mmHg (around 0.7 to 0.9 kPa) taken at a supine position during end-expiration, without abdominal activation, and measured by urinary bladder pressure (UBP) [32]. However, bounds for normality are determined by body mass index (BMI), pregnancy, and age.

The pressure within compartments and cavities in the human body, like the IAP, varies significantly in healthy patients over short periods. Body movement contract lateral, abdominal, and back muscles, causing the IAP to increase and contribute to stability by restraining and immobilizing the spinal column. The abdominal compartment contains incompressible fluids that apply a uniformly distributed force perpendicular to the chamber's surface and work as an efficient buttress, a rigid structure placed against the base of the spine to provide support and stability [15], [19].

Nonetheless, an excessive amount of something beneficial can have negative effects on one's health. Prolonged and excessive IAP can lead to increased stress on the lumbar discs and joints, leading to degenerative changes like disc herniations and chronic conditions such as osteoarthritis. It is also associated with other conditions, such as tissue ischemia, erosion, infection, pneumoperitoneum, and mechanical injuries that can contribute to the development of low back pain [20], [33]. Intra-abdominal hypertension (IAH), defined as sustained IAP $\geq$ 12 mmHg (1.6 kPa), is a vicious feedback loop that compresses the vena cava, causing a reduction in blood flow to the heart and swelling [34]. Moreover, inadequate treatment of IAH may cause a more advanced stage called abdominal compartment syndrome (ACS). It is defined as sustained IAP $\geq$ 20 mmHg (2.7 kPa) in adults and is associated with reduced cardiac output and blood flow, inadequate perfusion to distant organs, and, eventually, multi-system dysfunction [34].

Table 2-1 Intra-abdominal pressure in adults, adapted from [30].

Physiological condition	**IAP [mmHg] (kPa)**	**Ref.**
Normal - Healthy and Normal BMI	5-7 (0.7-0.9)	[25]
Normal - Critically Ill and Normal BMI	10 (1.3)	[25]
Critically Ill - Intra-abdominal Hypertension	> 12 (1.6) sustained for hours	[35]
Critically Ill - Abdominal Compartment Syndrome	> 20 (2.7) sustained for hours	[34], [35]
Sitting	10-21 (1.3-2.8)	[36]
Standing	15-27 (2.0-3.6)	[36]
Coughing	40-127 (5.3-16.9)	[36]
Jumping	43-252 (5.7-33.6)	[36]

2.4.1 The Abdominal Wall

The abdominal wall (AW) is one of the non-fixed boundaries of the IAV and is relevant to rehabilitation for treating and preventing symptoms of low back pain. It is a laminar-composite structure consisting of the skin (the external layer), subcutaneous and adipose tissues, abdominal muscles, fascia, and the peritoneum of the abdominal cavity (the internal layer). The mechanical properties of these soft tissues define the abdominal expansion and support to the spine [37], [38]. Thus, the composite properties of the entire wall, from the skin to the peritoneum, are of great interest to studying mechanics as a unit [39]. The AW is nonlinear, viscoelastic, anisotropic, and heterogeneous, like most soft tissues, and the mechanics of each of the layers depend on the thickness, the presence of ground substances, the anatomical location, and the ratio of collagen to elastin fibers [39]–[41].

2.4.1.1 Nonlinearity

Some materials exhibit linear behavior in the elastic region; in other words, the relationship between stress and strain in the material, or elastic modulus, can be considered constant and linear. By contrast, most soft tissues behave as nonlinear, displaying a significant strain phase at low-stress levels close to the neutral position, indicating the straightening out of collagen and a stiffening extension phase of the oriented collagen fibers towards the end of the range of motion [42]–[44]. This strain-stiffening effect enables spinal movements with low energy costs near the neutral position. It provides considerable resistance to prevent exceeding the ends of the physiological range of motion, preventing tissue damage by large deformations [45]–[47]. Nonetheless, assumptions related to linearity and isotropy for the AW have often considered for assessing small strain ranges [48]–[50].

2.4.1.2 Anisotropy

Anisotropic materials respond differently to stress, and the mechanical properties vary depending on the plane of motion [33], [44]. The quantity, arrangement, direction of fibers, and ratio of collagen to elastin content can differ depending on the AW layer [39]. Collagen increases mechanical elasticity, providing strength and stiffness to the structure, while elastin improves ductility, the ability to deform without damage [51], [52]. In such manner, superficial tissues, like skin, are usually loose and designed for high-frequency movement, and meanwhile, deep tissues are not primarily designed for movement but force transmission. Furthermore, the abdominal muscles, namely the transversus abdominis, the internal and external obliques, and the rectus abdominis, are the main contributors to making the abdominal wall highly anisotropic. Studies had reported an AW anisotropy ratio of 1.90 and greater compliance (less stress produced larger strains) when the composite was loaded in the longitudinal direction compared to transverse [39], [53]. The individual layers of the AW are also highly anisotropic, with anisotropy ratios from

1.3 to 9.0 [39]. Thus, the AW mechanical properties will vary depending on the method and direction chosen for the study.

2.5 The Abdominal Wall Elasticity

The active system provides the required spinal control for each body position by activating the abdominal muscles to regulate the IAP. Thus, not only is the spine stability weakened with inadequate IAP, but also with irregular abdominal wall elasticity (AWE). The elastic modulus (E), also referred to as elasticity, modulus of elasticity, tensile modulus, or Young’s modulus, is the material stress-to-strain ratio, in other words, the slope of the stress-strain curve: the steeper the slope, the stiffer the tissue, and is typically measured in kPa [54]. The AWE describes the abdomen’s resistance to strain (relative deformation), which affects how difficult it is for the abdomen to expand to avoid unhealthy levels of IAP [39].

The AWE measured outside the organism (*ex vivo*) and on living organisms (*in vivo*) often differ significantly [39], [53], [55], [56]. Even though *ex vivo* tests allow experimentation under controlled conditions and lenient regulations, it is difficult to characterize or reproduce a physiological environment, as they exclude essential mechanical elements, natural interdependencies, and dynamic pressures [57]. AWE results available in the literature are 22.5 kPa sagittal and 42.5 kPa transversely performed *in vivo*, at passive (no activation) state and supine position [53], [56]. However, the mechanics of fascia, abdominal muscles, and other soft tissue structures are defined by age, sex, hormones, immobilization, trauma, surgeries, mechanical input, and training [20]. Factors that may lead to unhealthy variations in tissue stiffness include the presence of scar tissues, disorganization, and expansion of connective tissue layers due to fluid accumulation or swelling, fatty infiltration, fibrosis, and adhesions [58]–[61]. These conditions may disrupt the natural movement of connective tissue planes, reducing the range of motion and impacting the mechanical properties of the abdominal wall [14].

It is essential to emphasize the difference in the elasticity definition between the engineering and medical fields. In an engineering background, elasticity means resistance to deformation under an applied force [62]. An increase in mechanical elasticity is synonymous with material stiffening. Meanwhile, elasticity is understood as a synonym for flexibility in a clinical context [63]. It is referred to as the ability to deform within the elastic region. In other words, it is considered the antonym of stiffness. Contrastingly, this concept is often called compliance in engineering.

2.5.1 The Clinical Abdominal Compliance

The ability of the abdominal cavity to expand, to maintain the IAP under healthy ranges is highly dependent on the AWE, the IAV, and the nonlinear, anisotropic, and dynamic mechanical properties of the composite abdominal wall and diaphragm [33]. Clinical abdominal compliance (C_{ab}) describes the ratio of intra-abdominal volume change per intra-abdominal pressure change ($\Delta IAV/\Delta IAP$) [64]. Previous investigations state that normal abdominal compliance is between 200 and 400 mL/mmHg at a supine position with no abdominal activation. In contrast, a sitting position decreases the ease of abdominal expansion to 48 mL/mmHg [38].

Graphically, the C_{ab} is represented by the slope of the abdominal pressure–volume curve. This term indicates how easily the material changes in length and the ability to recover the initial state, and can be considered as the inverse of stiffness [33], [62]. In essence, a high C_{ab} value indicates greater freedom of expansion for the abdomen, whereas a low value can result in a high IAP, restricted abdominal expansion, and often a high AWE [65]. In cases where there is an increase in IAV, patients with good C_{ab} tend to experience a minor increase in IAP compared to those with a stiff abdominal wall [38]. The C_{ab} is also determined by age, weight, height, previous surgery, and pregnancy [33]. The normal sliding movement between tissue layers in the abdominal wall can be disrupted by abdominal lesions, scars, and trauma. This can lead to alterations in fascia tension and contribute to conditions such as diastasis rectus abdominis [66]. The resulting distortion can affect a patient's posture, as well as their pelvic and trunk stability, and their ability to manage peaks in IAP [67], [68]. Relevant constitutive properties are shown in Table 2-2.

Table 2-2 Constitutive properties of the abdominal wall.

Property	**Value**	**Units**	**Ref.**
E Transverse	42.5	kPa	[53]
E Sagittal	22.5	kPa	[53]
Thickness	14.5-31	mm	[30], [40], [53]
Abd. Compliance Supine	200-400	mL/mm Hg	[38]
Abd. Compliance Sitting	48	mL/mmHg	[69]
Poisson Ratio	0.46-0.499		[53], [70]

2.6 The Abdominal Wall Viscoelasticity

Important structures of the AW have been evaluated *ex vivo* at different loading conditions, showing a time-dependent mechanical response of the material that varies the elastic modulus to the application of external stress or load, known as tissue viscoelasticity [71]–[73]. It may include stress relaxation, creep, recovery time, and nonlinear stress–strain properties or hysteresis [74]. The first two events describe the tendency of a tissue to gradually reduce stress to a constant deformation (relaxation) and increase deformation while a constant stress level is applied (creep) [74]–[78]. Recovery time describes the tissue delay in recoiling and recover the initial shape after removing the external perturbation [57], [79]. Furthermore, collagen networks are thought to govern nonlinearity, meaning that they act as linear elastic before a threshold percentage of strain; beyond that point, there is strain stiffing as the fibers align in the direction of maximum tensile strain [79]–[81]. These processes are correlated to the conversion of work, performed by the applied forces, into irreversible heat (lost energy) due to internal friction and dissipation into the surroundings, called hysteresis, illustrated by the area between the loading and unloading phases at the stress–strain curve [74], [75].

From the micromechanics point of view, viscoelasticity is determined by the bond type of the networks of collagen and fibrin fibers. Strong covalent crosslinking corresponds with a more elastic behavior, while a weakly or incomplete crosslink, with a viscoelastic material that presents dissociation rates fast enough to allow delays in the mechanical response, often found present in biological tissues [75], [82]. The mechanical properties will be dependent on the level, duration, and rate of the force applied, as well as its orientation with the fiber direction of the tissue [57], [75], [81], [82].

Theoretically, the extracellular matrix (ECM) plays a significant role in the mechanics and viscoelastic response of connective tissues [52], [77]. It is an amorphous gel-like substance with a molecular composition excellent for absorbing and storing lots of water, permeating and providing lubrication to collagen fibers and connective tissue fibrils. Similarly, elastin fibers studied *in vitro* have been shown to influence the elastic recoil mechanism of tissues at low strain values [51]. Therefore, these characteristics may have an active role in the metabolism process and healing of tissues, improve resistance to compressive forces and absorb energy [77], [83], [84], [85]. Furthermore, the time dependency of viscoelastic tissues is believed to be greater when measured in uniaxial tensile strain than it is for shear strain because the former changes the cell number and density of the ECM composition [75], [78]. When a shear strain is present, on the other hand, the deformations affect the shape but not the volume of the matrix, presumably causing less fluid motion inside the matrix. However, there are discrepancies and insufficient research *in vivo* to fully understand the impact of these structures on the connective tissue or fascia.

Data collected suggests that aging may affect the fibril organization and the properties of the fluid component of tissues [86]. This type of dehydration and variation in tissue viscoelasticity may be correlated with disease development, progression, and repair and must be a potent target for therapeutic approaches [78], [87]. Moreover, the contribution of viscoelasticity and water content in tissues may impact the proper operation of the spine, the ability to respond to changing pressure conditions, and prevent injuries in regular, everyday activities [33], [78], [80], [81], [88]. However, more work and follow-up studies are still needed to obtain enough evidence to verify these claims scientifically. Thus, there is a need for valid and reliable tools to quantify mechanical properties dynamically *in vivo*.

2.7 Current Measurement Methods

2.7.1 Measurement Methods for Intra-Abdominal Pressure

The Abdominal Compartment Society (WSACS) indicates that intra-abdominal hypertension (IAH) affects 20 to 50% of intensive care unit (ICU) patients within the first week of admission [28], [89]. To prevent abdominal compartment syndrome (ACS) and provide better care for patients with ACS, IAP measurements should be taken every four hours for critically ill patients. The WSACS recommends using urinary bladder pressure

(UBP) as the standard reference for measuring IAP and is the most accepted and popularized method nowadays [28]. Recommendations indicate that this method should be performed by a trained professional in a clinical setting, with a patient in a supine position and at end-expiration. Measurements involve monitoring the bladder pressure with 25 mL of sterile saline injected into the bladder via an indwelling urinary catheter. The pressure measured by a transducer or manometer is estimated to equal the IAP [28].

The UBP method is widely accepted, but it is not a direct measure of IAP and instead indicates the pressure in the bladder. In addition, it is a non-continuous and invasive measurement that must be repeated continuously, especially for patients in ICU, and has been correlated with side effects such as bowel perforation and peritonitis. Following the recognition of the significance of IAP in the proper functioning of internal systems and the limitations of UBP, various non-invasive alternative methods have been developed for its measurement (Table 2-3). Nevertheless, none of these techniques have been demonstrated to provide a non-invasive, reliable, direct, and accessible solution to meet the current needs [30], [69]. Non-invasive alternatives are procedures that do not need to physically cut skin and deep tissue to take measurements from inside the body. In general, these processes cause less pain and discomfort, can be performed without anesthesia, and patients do not deal with long recovery times [30]. Even though some present low accuracy or sensitivity nowadays, these technologies can be directly correlated to IAP or work in conjunction with methods that apply external forces, such as indentation or suction [69].

Table 2-3 Methods for measuring intra-abdominal pressure, adapted and updated from [30].

Method	Description	Non-Invasive	Continuous	Accepted	Portable	Direct	Advantages	Disadvantages	Ref.
Urinary Bladder Pressure	WSACS “gold standard” measurement system. The pressure in a saline-filled bladder is measured with a transducer-tipped catheter and called IAP.			X			Widely accepted	Accuracy decreases with pressure	[28], [90]
Central Venous Pressure	Veins cannulated to correlate a decrease in blood pressure to heightened IAP.		X	X			Alternative if digestive tracts compromised	Only feasible in supine patients	[91], [92]
Embedded Microtransdu-cer	A cannula connected to Codman microsensor was tapped into the abdominal wall at the junction of the anterior rectus abdominis.		X	X		X	Potential for portability	High cost, risk of visceral perforation	[93], [94]
Intra-gastric Pressure	Measurements with a transducer-tipped catheter introduced through the nasogastric pathway to the stomach.			X			Minimally invasive	Uncomfortable	[91], [95], [96]
Intra-rectal Pressure	A fluid-filled intrauterine pressure catheter is introduced into the rectum attached to an external strain gauge transducer.			X			Alternative if the bladder and stomach are not viable.	Uncomfortable	[97], [98]
Intra-uterine Pressure	A fluid-filled intrauterine pressure catheter is introduced into the uterus attached to an external strain gauge transducer.			X			High accuracy and repeatability	Only viable in females	[99]
DNS Brace	Air-deformable chambers and silicone sensors register the contraction and expansion of the AW.	X	X		X		Prospective non-invasive, portable technique	Low reliability	[97]
Bioimpedance	The impedance of the AW is correlated to IAP.	X					Prospective non-invasive	Poor sensitivity	[100], [101]
Digital Image Correlation	Use of cameras and Finite element modeling to obtain measurements of contour, deformation, and strain of tissues.	X					Non-invasive	Long calibration time	[53]
Doppler Ultrasound (US)	Correlation of IAP to blood flow.	X					Simple	Low accuracy	[69]
Indentation	AWT correlation with IAP.	X			X		Small, simple, and portable	Discontinuous	[102], [103]
Intra-vaginal Transducer	Pressure in the upper vagina is measured and compared to IAP in a rectal balloon measurement system.		X		X		Wireless data transmission, good accuracy	Only viable in females	[104], [105]
Laser US	The principle Is based on the optical excitement of tissue with a laser pulse.	X					Better accuracy than Doppler US	Complex calibration and low precision	[69]
Microwave	The reflection coefficient between an antenna and AW was correlated to IAP. The antenna received the changes in AW wave impedance as varying frequencies.	X					Prospective non-invasive technique	Limited pressure range	[100], [101]
Plethysmogra-phy	Winding wire coils within elastic bands identify alterations in compliance.	X	X		X		Simplicity and low-cost	Low accuracy	[69]
Suction/Aspi-ration	A suction force is applied to the AW. Deformation and pressure applied is translated to internal pressures.	X			X		Small, simple, and portable	Discontinuous	[48]
US & Peritoneal Rebound	Varying liquid forces are applied to the AW until the peritoneum rebounds to its neutral position, indicating a balanced system.	X					High correlation to UBP	Measurements orthogonal to tissue.	[69]
US Tonometry	The AW pushback response is measured with a probe and correlated to IAP.	X					Simple, High availability	Low accuracy	[106]
Wireless Capsule	Smart pills that provide live measurements of IAP *in vivo*.	X	X		X	X	Fast and continuous	Inaccessibility	[69]

2.7.2 Measurement Methods for Tissue Elastic Modulus

The widely accepted method for measuring IAP, the UBP method, is only suitable for use in a controlled clinical setting. Furthermore, this method does not provide any information about tissue mechanical properties, AWE, or abdominal health. As a result, many healthcare professionals generally agree that a standardized, reliable, and accessible testing system is needed to accurately measure tissue mechanics *in vivo.*

Currently, to evaluate the mechanical characteristics of underlying tissues, healthcare professionals and physical therapists are typically instructed in a diagnostic method called muscle manual palpation. This is a widely accepted technique where the examiner manually feels and applies static and dynamic transverse loading with their hands to assess the condition and mobility of the soft tissues [107]. By applying specific force and velocity during the diagnostic, clinicians assess the tissue integrity, stiffness, texture, time dependency, and temperature non-invasively without additional tools [108]. Unfortunately, even with excellent training programs, these techniques show problems of reliability, subjectivity, and bias. They typically yield binary (presence or absence) and qualitative information about the tissue's condition, making the results difficult to interpret, and the clinical judgment of the tissue may vary from one doctor to another effectively [109].

To prevent uncertainty and bias, it is necessary to objectively quantify tissue properties. Researchers have been persistently investigating the mechanical properties of superficial and deep tissues through *ex vivo* and *in vivo* methods in recent years, employing techniques such as tensile tests, ultrasound, computed tomography scans, magnetic image instruments and bioimpedance technologies [44], [110]. However, most available or under-development methods remain invasive, unreliable, or unaccepted by the clinical community [64].

There is particular interest in developing non-invasive, portable and easy-to-use tissue characterization methods, such as indentation with the IndentoPro and myotonometry with the MyotonPro [111], [112]. The IndentoPro (Fascia Research Group, Ulm University, Germany), previously known as Tissue Compliance Meter, is a tool that registers the applied force required to deform the tissue up to a pre-set depth. On the other hand, MyotonPro (Myoton AS, Estonia) relies on external short (15 ms) low-intensity (0.58 N) mechanical impulses applied to the skin to record the oscillatory tissue response. Both have been shown to yield good intra- and inter-tester reliability in preliminary studies and the stiffness values obtained can be translated to elastic modulus by correlation functions to compare against other standard techniques [111], [112].

On the other hand, suction or aspiration devices represent a potential alternative for skin and AW characterization. In contrast to indentometry, the capacity of this method to differentiate between tissue conditions is controlled by the displacement of deep tissue layers and the skin elevation response observed due to the application of negative pressure (Figure 2-3) [113]. Portable suction devices are an effective option for tissue testing, as they are practical for fast *in vivo* measurements and compatible with other deformation detection techniques, such as linear ultrasound systems [30]. During the tests, there is a negative correlation between tissue depth and normal stress, so deep fascia experience lower stresses than superficial ones [114], [115]. The tissue deformation obtained is directly dependent on the ratio between tissue thickness (or depth) and the opening diameter of the measuring probe, also known as cup size [57], [74]. Thus, the cup size to use should depend on the target tissue or tissues to be studied; the bigger the cup size, the more tissue layers will be involved in the study [44], [116], [117]. Controlling the suction cup size could allow for distinguishing the mechanical properties of superficial and deeper tissues and the contribution of individual layers to soft tissue composites, such as the AW [44], [113].

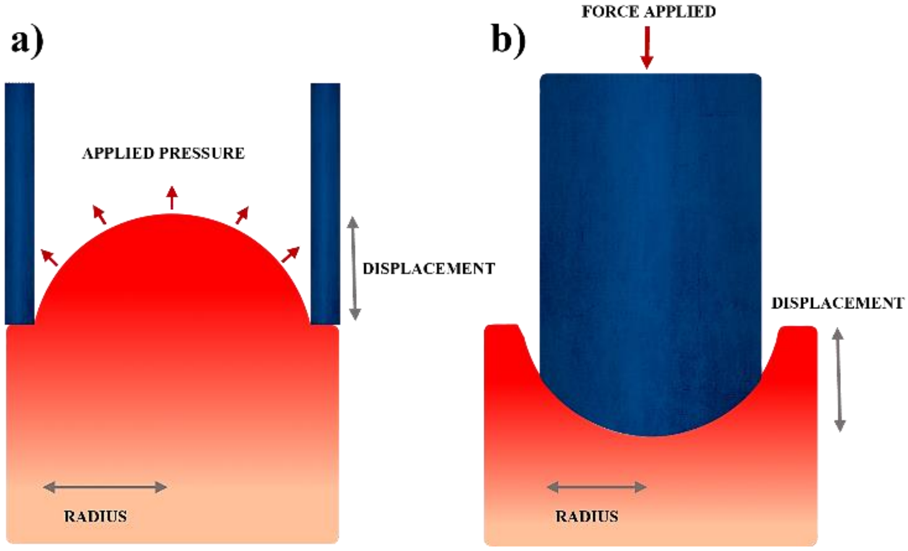

Figure 2-3 Characterization of soft tissue undergoing a) suction and b) indentation/myotonometry.

The Cutometer MPA 580 (Courage + Khazaka electronic GmbH, Germany) is considered an industry standard aspiration device [113]. The Nimble (ETH Zurich, Switzerland), is a device that weighs only 3.5 grams and operates based on the same principle as the Cutometer. Compared to the Cutometer, the Nimble has better reliability thanks to improvements in contact conditions and reduced force needed to hold the device in place during measurements. These are the main limitations commonly observed in suction devices [113], [118].

There are fundamental differences in how stiffness is determined between the two methods. The Cutometer measures the resulting vertical skin elevation caused by applied pressure using a light sensor, while the Nimble measures the pressure applied by a pre-set tissue deformation. Furthermore, the Cutometer offers the possibility of using different cup sizes (2 to 8 mm diameter), while the Nimble prioritized minimizing components and could not adopt that important feature [113], [118]. Moreover, due to the maximum cup size (8 and 10 mm in the Cutometer and Nimble, respectively) and the typical elevation obtained (1 - 2 mm), these devices struggle to study tissues beyond the skin and superficial layers [113].

The BioOptic (Musculoskeletal Biomechanics Research Lab, McGill University, Canada) is unique compared to other devices as it enables the measurement of both IAP and AW properties simultaneously *in vivo* [30]. This suction tool can introduce a localized negative pressure across a circle of tissue and measure the resulting deformation with pressure and distance sensors. A novel application of the extended Hencky solution was developed for characterizing IAP, considering the hoop stress theory for thick-wall cylinders and the mechanics of pre-tensed membranes under suction, as shown in Eq. (2-1) [30], [119]:

$$IAP = \frac{P_{app}(a^2 + w^2)(r_2^2 - r_1^2)}{4tw(r_1^2 + r_2^2) - (a^2 + w^2)(r_2^2 - r_1^2)} \quad (2\text{-}1)$$

where P_{app} is the applied pressure, a is the cup radius, w is the maximum lateral deflection, and t is the material thickness. In addition, r_1 and r_2 refer to the inner and outer radii of the abdomen, respectively [30].

To study the elastic modulus, the following micropipettes equation was used to study soft tissues under suction [120]:

$$E = \frac{\alpha(\zeta, \nu)3\phi(\eta)(P_{atm} - P_{app})a}{2\pi w} \tag{2-2}$$

where $\alpha(\zeta, \nu)$ and $\phi(\eta)$ are functions dependent on the geometry and the ratio of tissue thickness to pipette radius, a is the cup radius, w is the maximum deflection of the tissue being evaluated.

The BioOptic showed good reliability and responsiveness of IAP measurements through human and cadaveric testing [30]. In addition, the device's fixed cup size of 6 cm provides a larger suction surface for studying deeper tissues and muscle layers. The BioOptic has been employed to compute the global elasticity of the abdomen and calf and compare the results with those obtained using other commonly used stiffness measuring devices, such as the MyotonPro and the IndentoPro [30]. Even though the first studies showed positive results, the ability of the BioOptic to gather data is limited by several factors. Firstly, the accuracy of Eq. (2-2), which is commonly used for indentation purposes, decreases significantly for low strain values. As a result, the device can only measure the maximum deformation during measurements. Additionally, the rubber valve used for suction does not allow for control over the strain rate or applied pressure, further limiting the device's capabilities.

2.7.3 Measurement Methods for Tissue Viscoelasticity

The viscoelastic behavior of the AW may be crucial for properly operating the spine and responding to changing pressure conditions [55], [75], [121], [122]. However, it has yet to be profoundly studied *in vivo*. During testing, the strain rate at which soft tissues are studied will significantly affect the behavior and the outcome results. Therefore, the AW should be characterized by regulating pressure or force applied for a range of strain rates to provide a representative series of activation responses [53], [72], [113], [123]. However, most of the technologies available for mechanical characterization of biological tissues *in vivo* do not allow to test of multiple strain rates, so the results obtained will be relevant only for the speed at which the test is performed, providing limited information about the system's dynamics.

Despite the potential for portable devices to conduct viscoelasticity measurements in clinical and bench research protocols to contribute to rehabilitation practices, there are few studies available that take into account the effect of time on soft tissue behavior. Research studies utilizing the MyotonPro have evaluated the measurement reliability of viscoelastic properties in various body locations, such as the abdomen and scar tissues, by applying a fixed force of 0.4 N over 15 ms, which represents a strain rate of approximately 5.7 MPa/s (57 bar/s) [59]. Nevertheless, the MyotonPro and the IndentoPro have faced criticism for using definitions to measure elasticity, creep, and stress relaxation that differ from mechanical engineering conventions, which can hinder the comprehension and validation of results with other techniques [62]. Furthermore, the indenter size included in these devices has not been validated for investigating the viscoelasticity of tissues beyond superficial [124]. Conversely, the Cutometer and Nimble allow to control the pressure applied between 10 and 100 mbar/s, and have shown the ability to identify significant viscoelastic properties of skin, such as energy dissipation, creep, and stress relaxation [74].

In addition, the Cutometer has been able to compare the time-dependent mechanical response of various forearm skin conditions [123]. Similarly, immediate and short-term cupping tests have been performed on the abdomen with the BioOptic to assess the ability of the suction device to detect changes in elasticity *in vivo* [30]: the device could detect a short-term increase in elastic modulus, but the results were not strong enough to be conclusive.

Table 2-4 describes different technologies for stiffness characterization, where (>, =, <) refer to “More than,” “Equivalent,” and “Less than” indentation and tissue distinction refers to the ability of the technology to distinguish mechanical properties between tissue layers.

Table 2-4 Methods for measuring soft tissue stiffness, resistance, or elastic modulus. Modified and updated from [30].

Method	Mech. Property	Description	Non-Invasive	Quantitative	Tissue Distinction	Portable	Reliable	Cost	Anatomy	Ref.
Manual Palpation	Relative stiffness	Qualitative evaluation of top layer tissue stiffness.	X			X	<	<	Sup. Tissue	[109]
Robotic Palpation	Relative stiffness	Machine learning applied to qualitative evaluation of top layer tissue stiffness differentiation.	X				=	>	Sup. Tissue	[108], [125]
Myometry	Stiffness, “elasticity,” “tone,” and “creep”	An impulse of known force is applied to a soft tissue at a specific strain rate. Tissue deformation and acceleration is calculated.	X	X		X	=	<	Sup. Tissue	[126], [127]
Indentometry	Stiffness	A point load (indent) registers the applied force required to deform the tissue up to a predefined depth.	X	X		X	=	=	Sup. Tissue	[128], [129]
Aspiration/Suction	Stiffness	A closed volume of soft tissue is resected using a locally applied negative pressure. Vertical tissue displacement and applied pressure are recorded to determine stiffness.	X	X		X	=	=	Sup. Tissue	[113], [130]
Torsion Shear Rotary Shear	Shear modulus	Electromagnetic transducers capture the linear viscoelastic response of tissues under a vibrating torque.	X	X			=	=	Sup. Tissue	[131]
Durometry	Shore hardness	Measurement of resulting load impression in tissue given applied, known, point load (indent).		X		X	=	=	Skin & *ex vivo* tissue	[132]
Bioimpedance Electrode Array	Geometry	Electrodes map tissue impedance given an applied frequency. This can be correlated to mechanical properties of the tissue.	X				<	<	Sup. Tissue	[133]
Bioimpedance Piezoelectric Ceramic Material	Elastic modulus	A polymer film measures The impedance of a soft tissue given a small, applied voltage. This can be correlated to elastic modulus.	X	X		X	=	=	Sup. Tissue	[134]
Ultrasonography (US) B-Mode	Elastic modulus, thickness	Standard US can be used to evaluate the thickness of tissues by direct measurement in produced images. If combined with indentometer, can also measure elastic modulus.	X	X	X		>	<	Sup. & deep tissue	[135], [136]
Virtual Imaging Direct Image Correlation	Bulk modulus	With two cameras, a 3D image can be produced given a tissue with a defined pattern (such as fine, dark paint spray). Inputting images into FEA allows for deformation to be mapped given loading.	X	X			>	>	Sup. Tissue	[137], [138]
Virtual Imaging Virtual Fields Method	Shear modulus	Using an anatomically correct finite element model, the constitutive mechanical properties of soft tissues can be solved for given a known (experimental) applied force and resulting deformation. This is an inverse engineering problem, but only accurate for a given anatomical geometry and study participant.	X	X	X		>	>	Model-dependent	[139]
US/MRI Elastography	Shear & elastic modulus, thickness	Force or deformation mapping to visualize tissue movement given varying normal/shear stresses.	X	X	X		>	<	Deep viscera	[136], [140]
Tomoelastography	Shear & elastic modulus, thickness	Combination of an elastography method and an analysis system to reduce output noise.	X	X	X		>	<	Deep viscera	[141]

2.8 Conclusion

There is a worldwide concern with human musculoskeletal biomechanics and how the population develops low back pain, which is a massive problem in modern society. The tension in both the thoracolumbar fascia and the abdominal wall, as well as the pressure confined within those chambers, have a significant role in the actual biomechanics and stability. Currently, there exist some tools available to measure these properties. However, the most accepted and popularized methods are invasive, inconsistent, or not accepted by the clinical community. Therefore, it is necessary to develop non-invasive, reliable, and easy-to-use biomedical supportive tools to monitor these properties.

3. ARTICLE MANUSCRIPT

3.1 Rationale for Study

This study aims to evaluate the reliability and ability of a non-invasive suction device to detect a modulus variation at different strain rates and explore the device's sensitivity to viscoelasticity for clinical and rehabilitation purposes. Mainly, this objective is accomplished by taking measurements on phantom materials, using a unique custom created experimental bench set-up methodology to validate the elastic modulus results for each strain rate while measuring internal pressures.

3.2 Study

Evaluation of a Non-invasive Device for Measurement of the Elastic Modulus and Pressure of Soft Tissue-Mimicking Phantoms at Various Strain Rates

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3.2.1 Abstract

Introduction

The present work evaluates a non-invasive suction device designed to measure internal pressure and elastic modulus, while sensitive to viscoelasticity parameters for clinical and rehabilitation purposes. Specifically, this study aimed to assess the device intra–rater reliability for measuring the elastic modulus and its sensitivity to detect moduli changes between strain rates.

Methods

Fifteen measurements per strain rate were performed on phantom materials using a custom-built physiologically representative abdominal benchtop model. The results for device measured elastic modulus and internal pressure were calculated in agreement with the extended Hencky solution, Hooke's law, and Lame's equations. Validation efforts compare data to experimental bench model by performing tensile tests of phantom material and directly measuring the internal pressure of the model.

Results

The intra-rater reliability was between poor to excellent (ICC = 0.74), and the one-way repeated measures ANOVA indicated a significant effect of strain rate on the elastic modulus at the $p<0.05$ level [$F(2, 28) = 78.60$, $p = 0.001$].

Conclusions

The results suggest that the rate at which the suction is imposed influences the modulus calculated by the device. The methodology still needs to be improved to increase the device's reliability in measuring elastic modulus at various strain rates.

Key words

Tissue assessment device, elastic modulus, viscoelastic tissue phantoms, abdominal wall, intra-abdominal pressure.

3.2.2 Introduction

Low back pain (LBP) is considered one of the most acute symptoms of lack of spinal support, with a lifetime prevalence in adults of more than 85% [1]–[3]. Worldwide, it has been ranked the number one cause of disability in the workplace for decades and is especially prominent in developed countries [4]. Despite its prevalence, LBP is one of the most challenging conditions to diagnose, as several causes have been shown [5]–[7]. These include inadequate intra-abdominal pressure (IAP) for prolonged periods, which may cause excessive stress on the spine [8]. According to the Abdominal Compartment Society (WSACS), the IAP is defined as the steady-state pressure inside the abdominal compartment, and the healthy baseline in a supine position ranges between 0.7 to 0.9 kPa (5 to 7 mmHg) [9]. This compartment is bounded by the abdominal wall (AW), a flexible membrane that allows expansion and contraction. The AW's resistance to strain, or elastic modulus (E), affects the ease of abdominal expansion, the IAP regulation, and the support provided to the spine [10]–[13].

Accurate measurement of IAP is important in critically ill patients [14]. It is also an important parameter and potential biomarker of spine stability by which its contribution is direct via support under diaphragm [5], [15]–[17] or indirectly via engagement of thoracolumbar fascia in transverse plane [18], [19]. Unfortunately, the existing gold standard method, urinary bladder pressure (UBP), remains highly invasive and only relevant in a controlled clinical setting. Moreover, such measure does not give indication of abdominal wall elasticity or health. The most common technique to evaluate the abdominal wall is muscle manual palpation, a qualitative approach that relies on the clinician's expertise [20], [21]. Thus, there is a need for a non-invasive and reliable testing system to measure *in vivo* pressures and tissue mechanics.

Previous investigations have worked on developing and validating methods to measure stiffness, resistance, and modulus *in vivo* [22]–[24]. These techniques rely on applying an external force or pressure, such as indentation (quasi-static) and myotonometry (accelerated mass), to measure the tissue resistance to deflection [23], [25], [26]. Aspiration, or suction techniques, have also been employed for tissue characterization and have the potential to identify the AW time-dependent effects [26], [27]. However, some tools struggle to study depths beyond the skin and superficial tissues [22], [27], [28]. There remains a need to develop a device able to study the properties of the AW, from the skin to the peritoneum, to understand better its role in the proper operation of the spine and the response to changing pressure conditions.

Jacobson *et al.* [25] developed such a device that allowed the assessment of IAP and AW properties simultaneously *in vivo*. In addition, this device demonstrated good reliability and responsiveness to IAP measurements when compared to urinary bladder pressure [29]. Another challenge is that most technologies available to date do not allow testing deflection at various speeds, known as strain rates, and provide limited information about the system's dynamics. A range of strain rates must be tested to provide a more representative series of modulus for various levels of activation.

An issue in developing and validating such devices for reliable IAP and/or tissue properties measurements, both static and time-dependent, is in patient recruitment for clinical trials and the control or uncertainty quantification of such experimental environment. To circumvent these challenges, benchtop models and rubber-based phantom materials offer an affordable and controlled setting. They have been employed to simulate soft tissues and other anatomical dynamic structures [10], [23], [30], [31]–[33]. These materials are also promising for validating the assessment of viscoelasticity, the properties of soft tissue that exhibit time-dependent strain [34]–[36].

Thus, the objectives of this research were to assess the repeatability and intra–rater reliability of a device in measuring the elastic modulus of a phantom material at different strain rates and to study its sensitivity to detect a change in elastic modulus between strain rates.

3.2.3 Methods

The device

The device in consideration is a portable, non-invasive, and easy-to-use suction tool for assessing the mechanical properties of soft tissues and measuring internal pressures (Figure 3-1) [25], [37]. The device applies a localized negative pressure over a circular tissue area and measures the resulting deformation. By tracking and recording these variables, the device simultaneously estimates the tension within the tissue, the elastic modulus (E), and the underlying pressure the tissue confines. The device is comprised of a manual lever and piston, a microcontroller SparkFun ESP32 THING (ESP32, SparkFun, USA), a BMP388 pressure sensor (Bosch Sensortec Gmbh, Germany), and a SparkFun VL6180 distance sensor (ST Microelectronics, Switzerland).

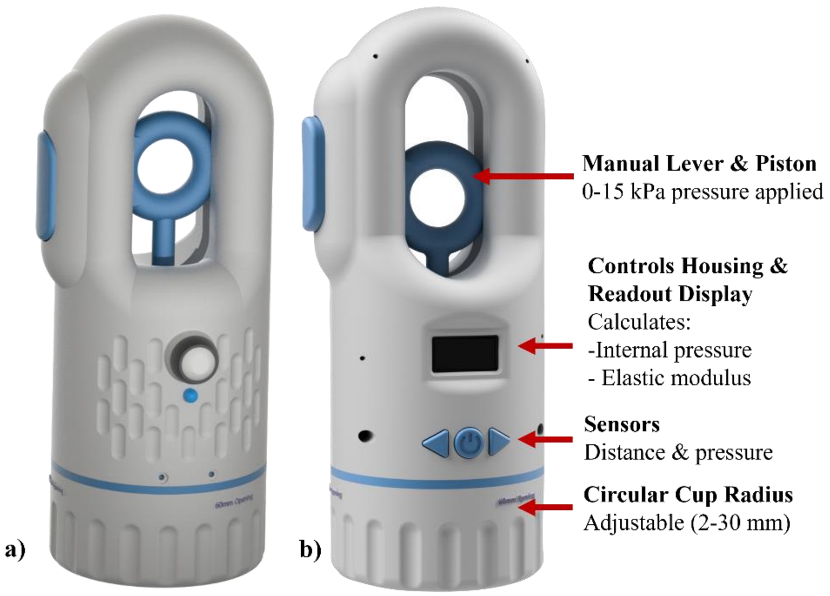

Figure 3-1 Evolution of novel non-invasive suction device. a) Early version, including ON/OFF button. b) Improved device configuration that features a display for presenting measurement data and navigation buttons.

The fundamental theory relies on applying the extended Hencky solution and hoop stress for thick wall cylinders suggested by Jacobson *et al.* [25]. This method provides the following relationship between the internal pressure (P_{in}), the external pressure applied (P_{app}), and the change of height of the spherical dome generated, considered the resultant deformation (w) [38]:

$$P_{in} = \frac{\beta P_{app}(a^2 + w^2)(r_2^2 - r_1^2)}{4tw(r_1^2 + r_2^2) - (a^2 + w^2)(r_2^2 - r_1^2)} \tag{3-1}$$

where a is the cup radius, and t is the uniform material thickness (Figure 3-2). In addition, r_1 and r_2 refer to the inner and outer radii of the abdomen, respectively [25]. The present work proposes a correction factor β, dependent on the tissue properties and thickness studied.

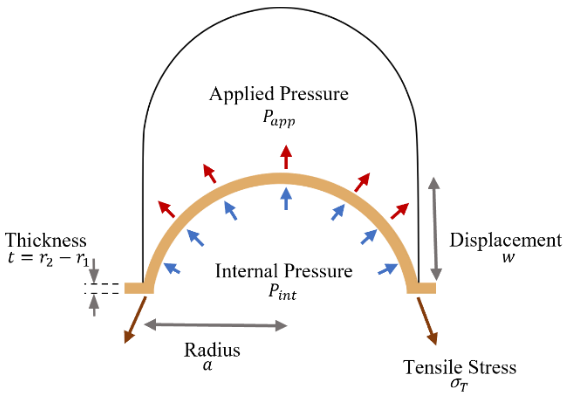

Figure 3-2 Diagram of theoretical design and formulation variables.

For AW characterization, the abdomen is assumed to be a pressurized cylindrical compartment to study the circumferential stresses in the system [39]. E is calculated from Hooke's law in terms of strain, the Poisson ratio (υ), and the stress tensor in engineering under the conditions of isotropy, incompressibility (υ= 0.499) [40], and linear elastic behavior [38]:

$$E = \frac{1}{\varepsilon_{xx}}\left[\sigma_{xx} - \upsilon(\sigma_{yy} + \sigma_{zz})\right] \tag{3-2}$$

where the strain in the circumferential direction ε_{xx} is approximately equal to w. The hoop stress σ_{xx}, the radial stress σ_{zz}, and the longitudinal stress σ_{yy} were quantified with Lame's equation for thick-walled cylinders evaluated in r_2 [38]. Both P_{in} and P_{app} contribute to the expansion:

$$\sigma_{xx} = \left(\frac{\varphi}{r_0^2 - r_i^2}\right)\frac{P_{in}r_i^2 + P_{app}r_o^2}{1} + \frac{(P_{in} + P_{app})r_o^2 r_i^2}{r_o^2} \tag{3-3}$$

$$\sigma_{zz} = (\frac{\varphi}{r_0^2 - r_i^2})\frac{P_{in}r_i^2 + P_{app}r_o^2}{1} - \frac{(P_{in} + P_{app})r_o^2 r_i^2}{r_o^2} \tag{3-4}$$

$$\sigma_{yy} = (\frac{\varphi}{r_0^2 - r_i^2})\frac{P_{in}r_i^2}{1} \tag{3-5}$$

An experimental correction factor φ is also proposed in the present study, dependent on the study material and thickness.

The benchtop model

The measurements were performed on a pressurized testing benchtop model representative of the human abdominal compartment, inclusive of a pressure sensor. The pressurized benchtop was custom 3D printed with dimensions 11.4 ⌀ x 10.7 cm and had a volume of 1.1 L (Figure 3-3). The top layer was a commercial Polyurethane Rubber (8514K63, McMaster-Carr, Elmhurst, Illinois) was used as the phantom material to represent the human abdominal wall [23]. Two pads with a Shore hardness of 30 (on 00 scale) with a thickness of 4.8 mm were tested according to the biological range of thickness and mechanical properties of abdominal soft tissues [41], [42]. The correction factors β in Eq. (3-1) and φ in Eqs. (3-3)-(3-5) were experimentally defined as 0.8 and 0.08, respectively, based on the material properties and thickness (4.8 mm) used in this study.

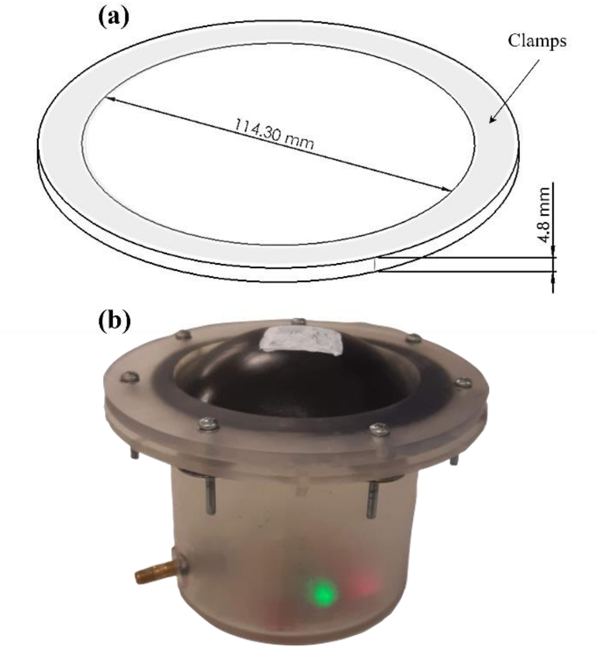

Figure 3-3 The benchtop model. a) The sample dimensions. b) Picture of model.

The device tests

Fifteen measurements were performed for each strain rate, for a total of 45 measurements distributed into two sessions (one rubber pad/per session). Each measurement consisted of five consecutive suction pulses applied to the material using a ⌀ 45 mm cup size, and the results were averaged. The stain rates assessed were low (8 ± 3 mm/s), medium (14 ± 3 mm/s), and high (20 ± 3 mm/s), calculated with the sampling rate (20 readings/s) and the number of points gathered per measurement. A 3-minute rest period between sequential testing was considered to start each test from initial conditions. The order of measurements was randomized with permuted block randomization to ensure equal distribution and to prevent bias. A single rater was selected to conduct all measurements on the material samples. The results were blinded until the end of the session to minimize bias.

The initial internal pressure was set to 0.8 ± 0.02 kPa (6 ± 0.15 mmHg), which is reflective of normal IAP in critically ill adults [9]. The material height was measured using a height gauge before and after the benchtop pressurization to estimate the external radius of curvature (r_2 = 102 mm). A pre-strain value of 20% was considered, corresponding to the 15% change of length in the membrane due to the P_{in} and an additional 5% to neglect the initial toe region when using the device. Therefore, the device could study this material's modulus from 20 to 45% strain.

The validation tests:

Pressure

A BMP388 pressure sensor (Bosch Sensortec Gmbh, Germany) inside the benchtop model was synchronized with the device via Bluetooth to track and validate the internal pressure during the measurements (Figure 3-4). This sensor was also used to standardize the pressure applied to the system to ensure airtightness during the measurements, called device sealing pressure [28]. This additional pressure was set to around 0.37 kPa (2.8 mmHg), corresponding to the device weight without additional pressure by the user. Thus, the total internal pressure during measurements was 1.17 kPa (8.8 mmHg).

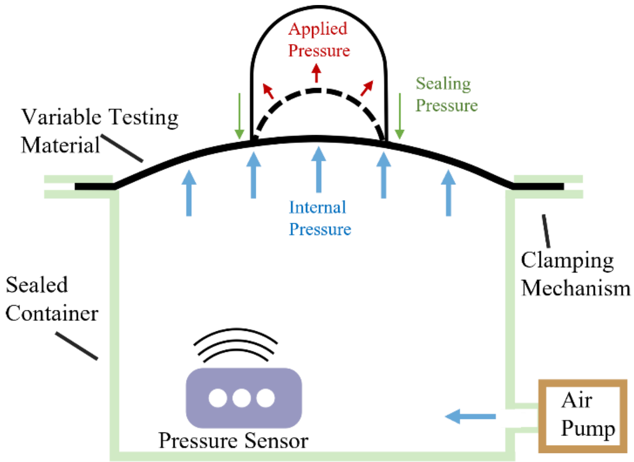

Figure 3-4 The benchtop model diagram depicting the position of the novel suction device, the displacement of the material during measurements, and the directions of the internal and sealing pressures.

Modulus

Uniaxial tensile tests were conducted to calculate the material stress-strain curve and assess the device's accuracy in measuring the elastic modulus. The tests were performed on Instron ElectroPlus E10000 (Instron ElectroPlus Systems E10000 electric testing machine, Canton, MA) with custom 3D-printed grips. The test settings included a 3, 10, and 20 mm/s ramp and 100 Hz data acquisition rates. The linear displacement control mode was chosen to limit the strain to 110%.

Rectangular specimens were cut down from the material using a metal cutter mold of 20 mm x 50 mm (gauge length) (Figure 3-5). According to the standard ASTM D412, three samples were tested to assess repeatability and consistency. The thickness and width of each specimen were measured in three locations to determine an average cross-sectional area. The dog-bone shape was not required because no failure tests were performed.

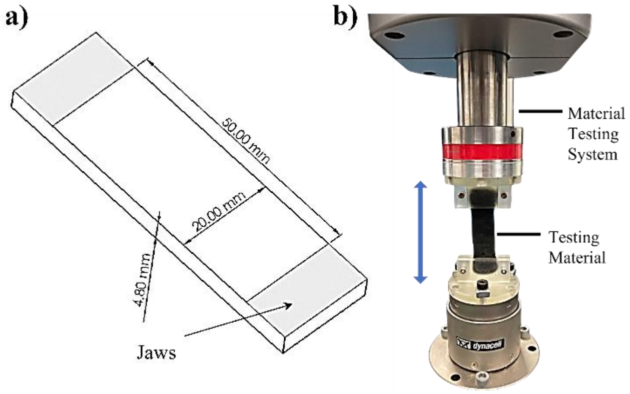

Figure 3-5 The tensile test. a) The sample dimensions. b) The tensile test machine setting.

A standard of five cycles (three preconditions + two measurements) was considered for the tensile test to pre-tense the material before the measurements, reduce errors, and ensure repeatability [43]. From the load-displacement data, the elastic modulus was calculated from the longitudinal and uniaxial stress version of Hooke's law: $E = \sigma / \varepsilon$, where σ is the stress and ε is the material strain, considering isotropy, incompressibility, and linear elastic behavior [38]. The linear regression of E, at the explored strain rate, was modelled to compare with the device measurements.

Analyses

Intra-rater reliability analyses assessed the degree of correlation and agreement between measurements. The intra-class correlation coefficient (ICC) and their 95% confidence intervals were calculated using the Python 3 (Python Software Foundation) statistical module called Pingouin 0.5.3 based on a single rater/measurement, absolute agreement, and two-way mixed-effects model [44]. The ICC was defined according to the following guideline: values below 0.5 indicate poor reliability, between 0.5 and 0.75 indicate moderate reliability, between 0.75 and 0.9 indicate good reliability, and above 0.90 indicate excellent reliability.

The device's ability to detect a change in material modulus due to strain rate was assessed using a one-way repeated measures ANOVA and post hoc Tukey test using Python 3 SciPy 1.9.2. The normality of the distribution of modulus results was verified for all states using the Shapiro-Wilk test. The standard error of the measurement (SEM) and minimum detectable change (MDC) were calculated according to Weir [45].

To assess the minimal change in the score that is meaningful for patients, called the minimal clinically important change (MCIC), the stiffness S (N/m) results for C-section scar and unscared tissue reported by Gilbert *et al.* [46] were considered. Eq. (3-6) describes the direct relationship between stiffness and modulus used for indenters, assuming soft tissue as homogeneous, isotropic, linear, elastic, and minimal friction contact [26]:

$$E = \frac{1 - v^2}{2d} S \tag{3-6}$$

where d is the indenter radius used (1.5 mm), and v is assumed to be 0.499 [40], [46]. As a result, the MCIC was determined to be 8.5 kPa. Finally, the Bland and Altman method was considered to compare the device pressure measurement to the internal pressure sensor measurement (direct method).

3.2.4 Results

Device validation

The 15 measurements per strain rate validate the device's ability and reliability to study viscoelasticity. Figure 3-6a shows the modulus interpretation process. The device applied a negative pressure of around 9 kPa and collected multiple readings for each measurement to exhibit the stress-strain diagram. The distance sensor detected an average strain value of approximately 28%. Figure 3-6b depicts the tensile test results to validate the phantom mechanics. The moduli at 8 and 14 mm/s were interpolated for further comparison to the device results. A positive correlation was found between the modulus and the strain rate.

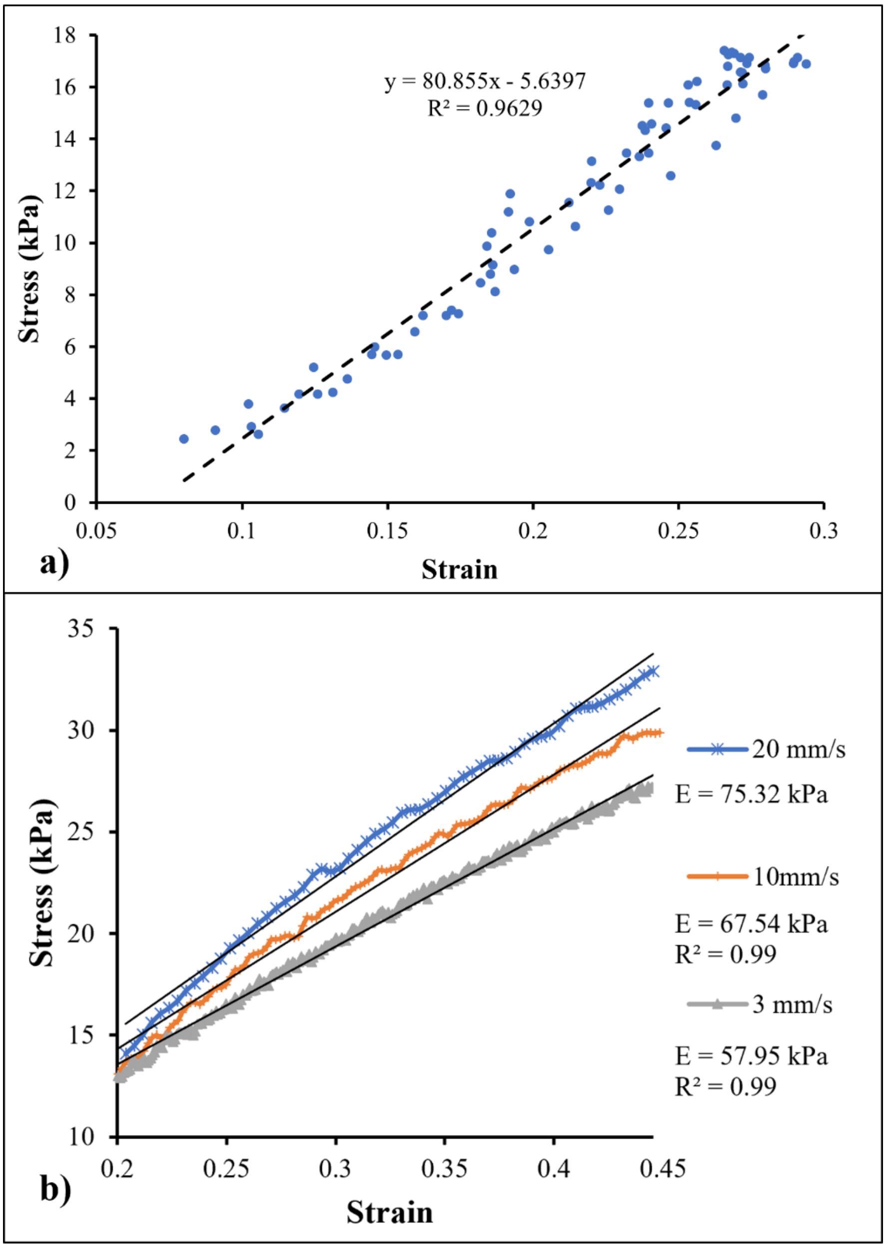

Figure 3-6 Stress-strain diagram and elastic modulus calculation for the rubber phantom material. a) Example of the device measurement at the high strain rate. b) The tensile test results, including 20% pre-strain, to validate the phantom mechanical behavior at 3, 10, and 20 mm/s.

Figure 3-7a illustrates the measurement's repeatability and distribution between groups. The Shapiro-Wilk test did not show evidence of non-normality for low (W = 0.93, p-value = 0.25), medium (W = 0.94, p-value = 0.33), or high (W = 0.95, p-value = 0.50). Figure 3-7b compares the device and the tensile test results. The modulus for the C-section scar (54.4 kPa) and unscarred tissue (45.9 kPa) calculated by Gilbert *et al.* [46] define the MCIC as 8.5 kPa.

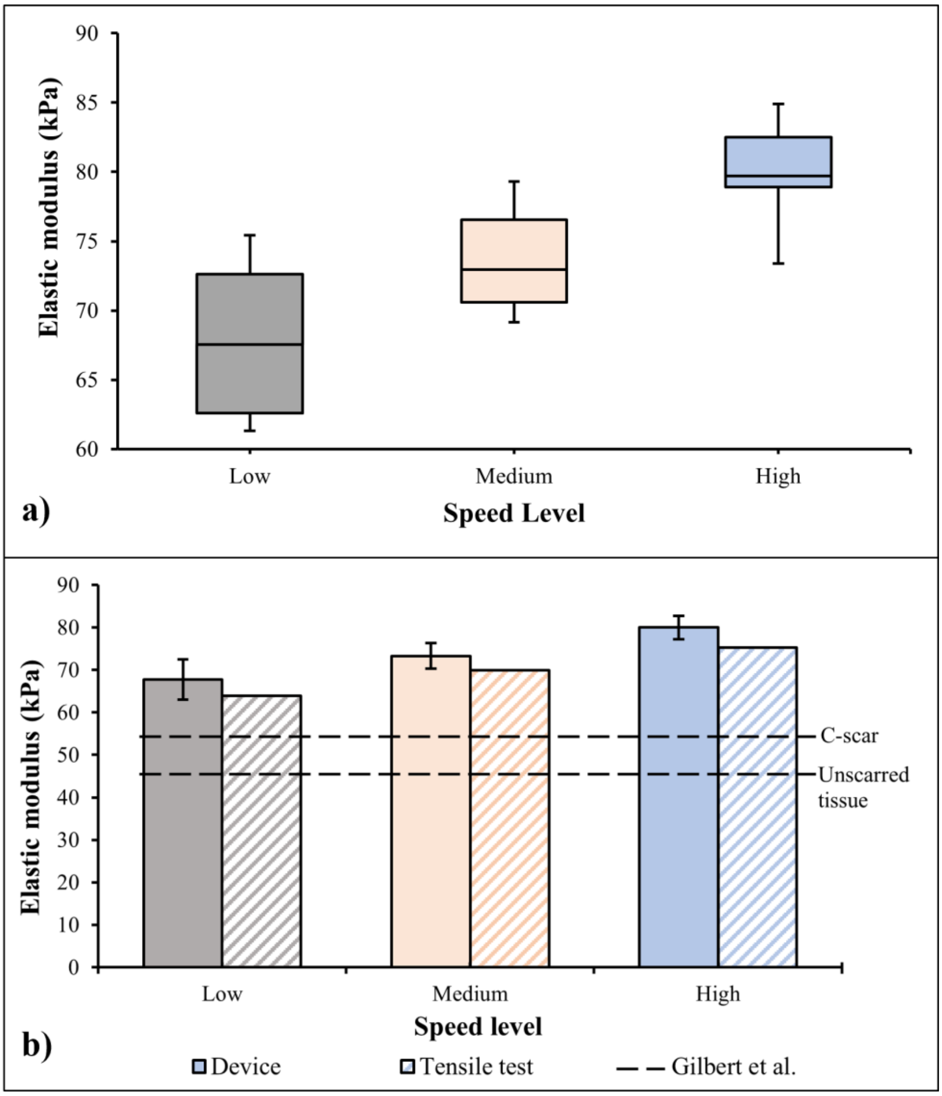

Figure 3-7 Elastic modulus results at different strain rates. a) Device results. b) Elastic modulus validation.

Intra-rater reliability

The intra-class coefficient was analysed using a single-measurement, absolute-agreement, 2-way mixed-effects model, with an ICC = 0.74 and 95% confidence interval = 0.40-0.99 (Table 3-1). The ICC results demonstrate reliability between poor to excellent.

Table 3-1 Results of ICC calculations using single-rating, absolute-agreement, 2-way mixed-effects model.

	Low	**Medium**	**High**
ICC (95% IC)	0.74 (0.40, 0.99)		
CV%	6.96	4.14	3.44
SEM [kPa]	2.32	1.5	1.35
MDC [kPa] (%)	6.44 (9.50)	4.15 (5.66)	3.75 (4.69)

Differentiation assessment

A one-way repeated measures ANOVA compared the effect of low, medium, and high-speed levels on material modulus in a range of 20 to 45% strain. The results indicated a significant effect of strain rate on modulus at the $p<0.05$ level for the three conditions [$F(2, 28) = 78.60$, $p = 0.001$]. The post hoc Tukey's HSD test found a statistical difference in elastic modulus between low- medium- high (Table 3-2).

Table 3-2 Post hoc Tukey's HSD test. Comparisons between elastic modulus based on the velocity condition.

Groups	**Mean difference**	**Lower CI**	**Upper CI**	**P - value**
High - Medium	-6.68	-9.88	-3.48	<0.001
High - Low	-12.23	-15.43	-9.03	<0.001
Medium - Low	-5.55	-8.75	-2.35	<0.001

Internal pressure

The device showed a good capacity to measure the pressure inside the benchtop model. The measurements for the initial pressure inside the benchtop model are described in Figure 3-8. In addition, Table 3-3 depicts the results for the bias (mean difference between the two methods), the precision (standard deviation of the bias), the coefficient of variation, and the percentage error (limits of agreement divided by the mean internal pressure). The device slightly overestimated the internal pressure of 0.92 kPa compared to the direct measurement (0.8 kPa).

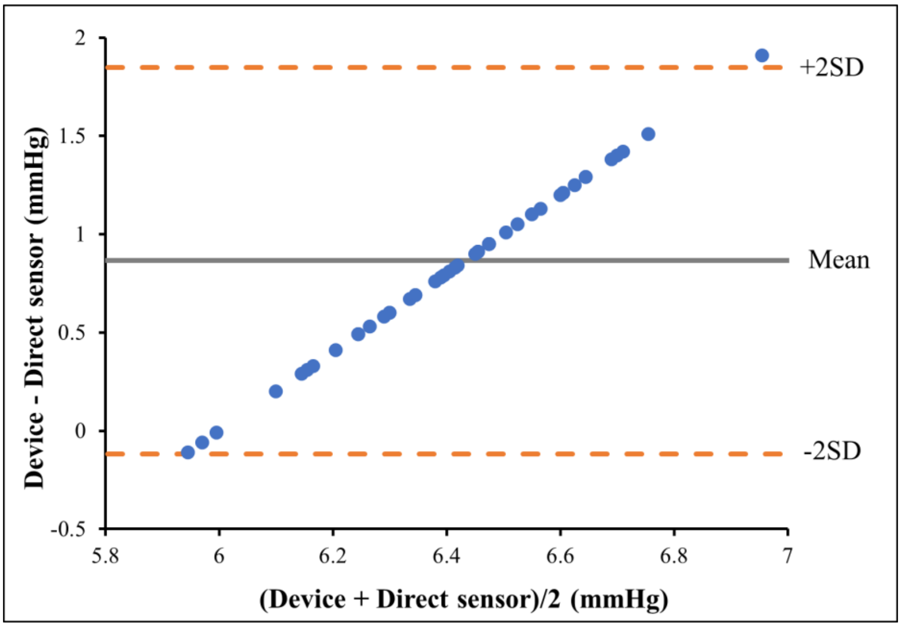

Figure 3-8 Bland and Altman analysis comparing the internal pressure measurement using the device against the direct pressure sensor measurement.

Table 3-3 Initial internal pressure measurement.

Internal pressure P_{in}	
Mean. Device [kPa](mmHg)	0.92 (6.86)
Mean. Pressure sensor [kPa](mmHg)	0.80 (6.00)
Bias [kPa](mmHg)	0.07 (0.50)
Coeff. of variation	8%
Percentage error	31%

3.2.5 Discussion

This study aimed to evaluate the device's repeatability and reliability in measuring the elastic modulus of a phantom material at varying strain rates and its ability to detect changes in elastic modulus between such rates. To the authors' knowledge, this is the first study that reports changes in modulus at different strain rates while measuring internal pressures using a soft tissue characterization tool. Regarding the intra-rater reliability, the 95% confidence interval of the ICC estimated a level of reliability regarded as poor to excellent. The total internal pressure variability during measurements contributed to the large interval of reliability. On the other hand, One-way repeated measures ANOVA and the post hoc comparisons using the Tukey HSD test indicated that the mean modulus score for the low, medium, and high strain rate conditions were significantly different from each other at the $p < 0.05$ level. In addition, the device was able to calculate the pressure inside the benchtop model, and the results were compared to the direct measurement with Bland and Altman analysis, showing low bias and coefficient of variation.

When characterizing the mechanical properties of soft tissue using different tools, the results can vary due to differences in factors such as strain rate, depth of indentation, and tissue boundary conditions unique to each method. The device detected a direct correlation between modulus and the strain rate of each test, which was validated by the tensile tests performed. The results between both methods differed by 5.62, 4.54, and 5.81% for slow, medium, and high conditions, respectively. However, in each method, the material is subject to different mechanical effects; while the tensile test involves stresses only in the longitudinal direction, the device applies a suction that accounts for the hoop, radial and transversal stresses, which may account for the difference.

The elastic moduli calculated are close to the abdominal wall reported in the literature [31], [39], [47], [48]. The results suggest the device can perform in the stiffness ranges desired for the biological application. Limited research studies consider the effects of different strain rates on the abdominal wall. Song *et al.* [39] reported a modulus of 22.5 kPa sagittal and 42.5 kPa transversely via abdominal insufflation *in vivo* at a strain rate of around 0.1 mm/s. These outcomes agree with our study, representing lower modulus results at a lower strain rate.

Previous studies with tools that employ suction indicated that the application of 2 kPa suction pressure on the AW *in vivo* resulted in a strain of approximately 13%, corresponding to a total stress of around 3.8 kPa [25]. This reference for the AW stress-strain relationship coincides with this study's results (Fig. 6a), suggesting the capacity of the methodology described in our research to mimic the suction movement of healthy abdominal tissues.

One of the strengths of this study is the measurement and quantification of the tissue phantom pre-strain value caused by internal pressure, a measure that has not been extensively investigated. This is essential in research involving soft tissue testing *ex vivo* to account for the tissue strain conditions within the body. Hernández *et al.* [49] measured the AW of rabbit specimens *in situ* prior to dissection and *ex situ* after dissection. They obtained an average pre-strain value of 23.3%, which is higher than that obtained with the pressurized benchtop (15%). The phantom pre-strain result for normal IAP is a valuable reference for future stiffness and viscoelastic studies.

The reference of the MCIC is essential to define the minimal change in the score that is meaningful for patients and to determine if the device accuracy is clinically significant [50]. The modulus increment for the C-section scar compared to unscarred tissue, calculated by Gilbert *et al.* [46] represents a reference for defining the MCIC as 8.5 kPa. This alteration can potentially produce myofascial pain or alter the connective structure between tissue layers [51]. Considering the MDC results for low (6.44 kPa), medium (4.15 kPa), and high (3.75 kPa) strain rate, the device could potentially detect viscoelastic alterations of soft tissues found in C-section scars or other irregular connective structures between abdominal tissues [51], [52], [53]. On the other hand, the international agreement for research and development of IAP diagnostic measurements recommends a bias of less than one mmHg and precision no more significant than two mmHg [14]. In addition, the coefficient of variation should be lower than 20% and a percentage error less than 25%. In Fig. 8, the Bland and Altman analysis shows good bias, precision, and coefficient of variation. However, the percentage error obtained (31%) exceeds the limit recommended for diagnosis of intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS). However, in a rehabilitation application, changes of IAP by around 30 mmHg have shown to impact spine stability significantly [15], [17]. These results suggest that the device is suitable to be used as a supportive tool for measuring internal pressures in rehabilitation settings.

The methodology employed herein allows tracking the total internal pressure inside the benchtop model, and the contact conditions during measurements, a constant limitation reported in the literature [26], [28]. The total internal pressure (1.17 kPa considering the sealing pressure) decreased by 12.5% during measurements, contributing to the modulus variability. This variation was attributed to the volume increase produced by each suction and a sealing pressure variation employed by the tester when moving the piston while holding the device against the material. According to Accarino *et al.* [54], the intestinal gas content varies between 131 mL in healthy patients to over 1200 mL in patients with intestinal dysmotility, representing only a small fraction of the total abdominal volume [54]. The abdominal fluid and solid contents are not expected to be affected significantly by the volume change when using the device. They will provide better stability to the tester to maintain a perpendicular position to the material surface and keep a steady sealing pressure during suctions. Thus, using an air-pressurized benchtop model represents the worst-case scenario, in which even slight changes in volume or contact force can significantly affect the reliability and the ICC [28]. In addition, the curvature and uniform tension in the system is restricted by the relationship between internal pressure and the phantom weight, meaning that using a heavier or thicker material would require internal pressures higher than the normal IAP intended for this study, representing a limitation for material thickness and the number of tissue layers that can be tested. Improving the methodology in this study will increase the device's reliability for measuring viscoelastic properties on a phantom benchtop.

The results of this study are limited by homogeneity in material selection and the strain rates selected. In addition, the results only represent the reliability of the specific rater. These limitations narrow the focus of this study and only permit restricted conclusions to be reached. An inter-rater reliability test, including a more extensive range of materials with different structures and compositions, would be required to generalize the results. Furthermore, the modulus and internal pressure calculations assume the AW to be homogeneous (material with uniform composition), incompressible, isotropic (same mechanical properties in all planes and all directions), and a linear elastic cylindrical vessel that diverges from reality. In addition, the methodology assumes a static situation, where the patient is in a supine position and at end expiration. Any dynamic movement, muscle activation, or irregular breathing during the measurements would cause a spike in the internal pressure and abdominal wall stress, significantly affecting the assumptions' accuracy [25].

Future benchtop models should integrate solid and liquid components to simulate the abdominal cavity better. This improvement would provide a more stable surface, easing the device's position perpendicular to the surface. Furthermore, it is recommended to test various cup sizes to explore the device's ability to measure the elasticity of composite soft tissues, differentiate between tissue layers, and understand the contribution of a specific layer to the global AW elasticity and viscoelasticity. Future studies could include the device's ability to measure viscoelastic effects, changes in hysteresis, and energy dissipation at a broader range of strain rates or after a certain number of cycles. Finally, given the inherent positivity results for internal pressure calculation, future work must focus on increasing the device's accuracy in a static and dynamic setting, significantly contributing to rehabilitation practices and a broader clinical significance [55].

3.2.6 Conclusion

This study suggests that the explored device, that imparts deformation in tissue and computes from first principles modulus and underlying pressure, can detect the viscoelastic behavior of soft tissue-mimicking phantoms at various strain rates. Specifically, the results showed a modulus increase due to increased strain velocity. Furthermore, the device could estimate modulus and IAP values within biological ranges. The main benefit to directly computing, vs. correlating or inferring by way of calibration, is that measurements could be linked back to inherent characteristics of the tissue and cavity under consideration.

Acknowledgment

We gratefully acknowledge funding from the Natural Sciences and Engineering Research Center (NSERC).

Conflict of interest

To the best of our knowledge, this research has no conflict of interest for any of the authors.

3.2.7 References

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4. GENERAL DISCUSSION

4.1 Summary

The thesis discusses the development of a novel suction device for the non-invasive measurement of the modulus and viscoelasticity of soft tissue. The research covers fundamental aspects of the device design, reliability, and sensitivity validation in studying phantom materials while measuring internal pressures (Figure 4-1).

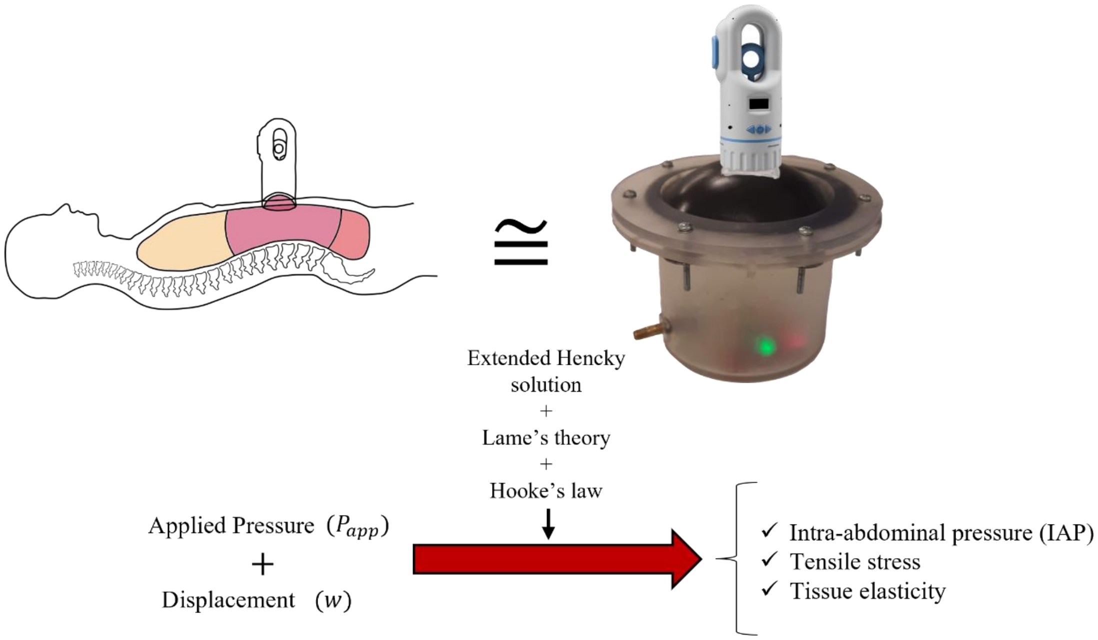

Figure 4-1 Graphical summary of the research methodology.

This technology offers research novelties for studying internal pressures, such as IAP, and soft tissues' static and dynamic mechanical properties, by applying negative pressures and recording resultant deformations (Figure 4-2).

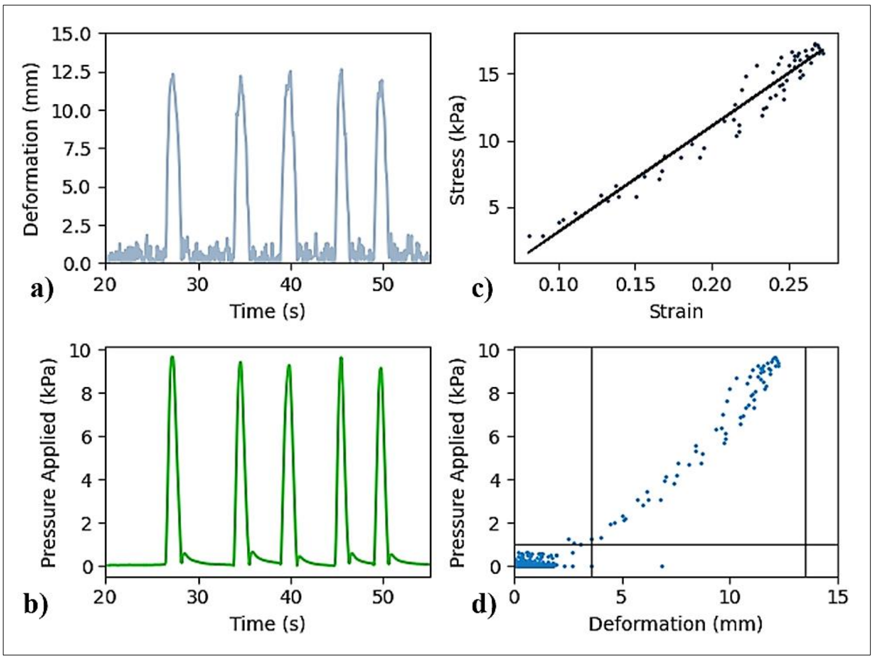

Figure 4-2 Device measurement results. a) Material deformation. b) Pressure pulses applied. c) Stress-strain diagram and average elastic modulus. d) Discretization process showing the pressure-deformation relationship.

The device sensitivity analysis, shown in Table 4-1, quantifies how the pressure and distance sensor's uncertainty affected the target variables (IAP and modulus). Particularly, the relative accuracy and resolution of the distance sensor, in a range of 0–30 mm, is critical to improving the repeatability and reliability of the measurements.

Table 4-1 Device sensitivity analysis.

	Accuracy	Resolution	Internal Pressure	Elastic Modulus
Pressure Sensor	±8 Pa	0.016 Pa	±0.003 kPa	±0.6 kPa
Distance Sensor	±2 mm	1 mm		

The relative accuracy and resolution of each sensor are ±8 Pa (0.06 mmHg) and 0.016 Pa (0.0001 mmHg) for the pressure sensor and ±2 mm (considering a distance filter added) and 1 mm for the distance sensor, respectively. The sensitivity analysis indicates that the sensor's accuracies account for errors up to 0.003 kPa (0.02 mmHg) and 0.6 kPa for internal pressure and modulus, respectively. However, the distance sensor's accuracy depends on the material tone (reflectance) and distance range of study. By minimizing the distance accuracy to ±1 mm, the device could improve performance, which is recommended for future creep and stress relaxation studies.

4.1.1 Application

The minimum requirements for accuracy, reliability, and acceptable uncertainty ranges are determined based on the project application or device's purpose. The model diagram shown in Figure 4-3 helps identify typical device risk levels, to understand better the implications of the assumptions made and establish the informed credibility goals [142].

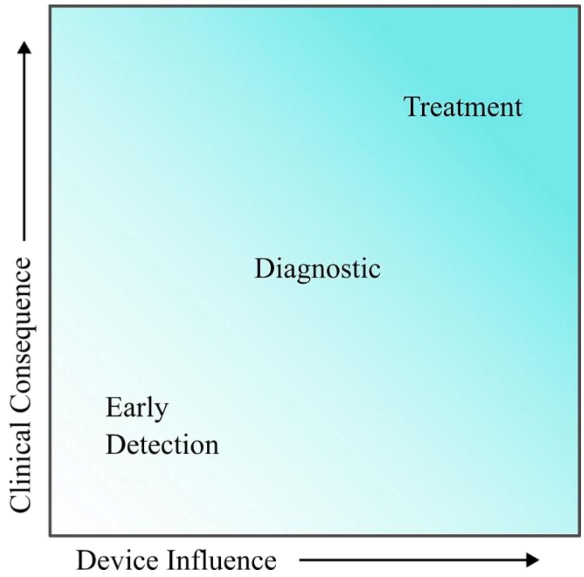

Figure 4-3 Model risk diagram for a tissue characterization device.

The main clinical application of the device is early detection: this is a support device for IAP, AWE, and viscoelasticity assessment, to make quick measurements and recommend further diagnostic procedures. The current target is to detect and isolate the patient's IAP into three classifications: low, normal (healthy), and high (unhealthy, requiring monitoring). Similarly, it is helpful to evaluate bounds for regular and irregular stiffness and viscoelasticity based on the physiological condition, disease, or healing stage. The AW thickness, pretension value, and the correction factors could be estimated by the device based on the patient's age, BMI, waist circumference and height. After that, the user could select the cup size depending on the anatomical location.

This device could provide insight into the mechanics that affect the ability to move and support balance and posture in patients with congenital AW defects. Furthermore, it could quantify the alteration and reorganization of collagen fibers during the scar healing process or after cupping therapy, offering physiotherapists more clarity of the patient's current state and guidance in medical decision-making. Other essential applications are the prevention of injuries and performance: the device could help clinicians develop specialized or patient-specific warm-up routines, activation strategies, or compensatory movements by monitoring potential changes in local rigidity as a patient, manual worker, or athlete warms up, performs repetitive motions, and cools down [143]. These future applications represent a minimal risk to the patients.

In conclusion, the device's accuracy and uncertainty are within an acceptable range for its category, and it remains as a promising complementary tool for measuring IAP, AWE as well as assessing tissue viscoelasticity *in vivo*.

4.2 Future Direction

4.2.1 Correction Factors

The methodology proposed correction factors to solve the divergence between the mathematical assumptions and reality. The extended Hencky solution considers a uniform lateral loading, where all force vectors acting on the membrane are parallel and where the maximum stress is equal to the pre-tension in the abdomen, meaning that the stress due to pressure applied is assumed negligible. Meanwhile, the pressure applied results in force vectors perpendicular to the membrane surface. The following studies could explore a methodology to define experimental correction factors based on the patient's characteristics, body location, and posture.

4.2.2 Benchtop Testing

The current study did not fully confirm the device's ability to deform the AW as a whole, which creates a knowledge gap about the movement mechanics between layers during suction. The AW is comprised of several layers, each with unique mechanical properties that may restrict them from moving together. Future benchtop testing should involve using various cup sizes and multiple layers to evaluate the device's ability to measure the modulus of composite soft tissues, differentiate between tissue layers, and determine the contribution of a particular layer to the AW behavior.

4.2.3 Device Design

The study focused on measuring internal pressures in a static state inside the benchtop model, and the current device design requires both hands to take the measurements. Future ergonomic enhancements for one-hand use would ease potential studies to measure pressure dynamic changes, which would have broader clinical consequences. The measurements could be taken while mimicking peaks of IAP during continuous ground impacts, vibrations, irregular breathing, or abdominal contractions. Additionally, enhancing the manual lever mechanism and regulating the unloading motion could ease the measurement of significant viscoelastic properties, such as hysteresis and energy dissipation. After that, the Burgers model, which includes both spring and dashpot elements, could be implemented to characterize the elasticity and viscosity of soft tissues without requiring multiple tests for varying strain rates.

5. CONCLUSION

This dissertation has provided various innovations, significances, and contributions to the evolution of knowledge. The global objective has been successfully met, whereby a novel suction device was designed and validated for internal pressure, elastic modulus, and viscoelasticity measurements. Specifically, the fundamental theory behind the device functionality was refined to accomplish the first goal by applying the extended Hencky solution for measuring internal pressures, Hooke's law equations to measure the elastic modulus, and Lame's equations for measuring the stress tensor values. In addition, experimental correction factors were proposed, dependent on the tissue properties and thickness studied. The second part of the central objective was also achieved. A novel device was designed, developed, and manufactured, prioritizing portability, non-invasive, and an easy-to-use suction tool. One of the main design enhancements included optimizing to apply negative pressures at different velocities. The last part of the global objective was also met, whereby a physiologically representative abdominal benchtop model and phantom material were used to assess the device's reliability, differentiate the elastic modulus obtained at various strain rates, and measure internal pressures. At this point, the next step can be to address the future work proposed in this research.

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