Design synthesis and preliminary evaluation of a novel tool to non-invasively characterize pressurized, physiological vessels

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ABSTRACT

A prolonged increase in intra-abdominal pressure (IAP) is life-threatening, yet commonly seen in intensive care units. Despite this, existing clinically-accepted IAP measurement techniques are invasive and not inter-rater reliable. As such, it is the effort of this research to develop a direct, non-invasive, handheld tool to measure internal pressures in pressurized, physiological vessels. The novel device uses a localized known pressure (namely aspiration) to measure resulting tissue deformation, from which internal pressures can be divulged considering the extended Hencky solution. Two male participants were tested with the device to confirm feasibility of the theoretical device function for IAP measurement. Participants' Young's moduli of the abdominal wall were calculated with measured IAP values. Results were consistent with participant body mass indices and overall health. Average measured IAP was 0.42 kPa and 0.46 kPa at supine and inclined positions, respectively. Average measured abdominal wall elasticity was 14.91 kPa and 23.09 kPa at supine and inclined positions, respectively. These preliminary findings suggest the potential use of the

device described herein as a measurement system for pressurized vessels, whereas the system will be tested on a larger sample size before recommending clinical use.

INTRODUCTION

The human body is comprised of a series of pressurized vessels, including muscles, organs, abdominal and thoracic compartments. One such vessel is the intra-abdominal volume (IAV), or volume contained by the peritoneum, pressurized by intra-abdominal pressure (IAP) [1]. The World Society of Abdominal Compartment Syndrome (WSACS) defines “normal” (or, baseline) IAP as between 5 and 7 mmHg taken at a supine position during end-expiration with a bladder catheter [2]. High levels of IAP are denoted by the terms intra-abdominal hypertension or abdominal compartment syndrome, depending on measured values [3]. Both conditions are prevalent in Intensive Care Units (ICUs) and are often caused by peritoneal inflammation and/or abdominal fluid build-up, typically because of acute abdominal injury or surgery [4]. Rates of intra-abdominal hypertension have been recorded between 20 and 50% in ICU patients, with rates increasing further in ventilated patients [5]. This increased IAP can reduce blood flow to vital organs, perpetuating further pressure build-up as organs become unable to drain excess fluids [3, 4]. These life-threatening complications are diagnosed by IAP measurements collected over 4-6 hours that are consistently greater than 20 mmHg and 12 mmHg for abdominal compartment syndrome and intra-abdominal hypertension, respectively [3, 6]. Conversely, low levels of IAP have been linked to spinal instability [7, 8]. Despite known risks associated with IAP, there remains no “gold standard” tool for measuring the property [9, 10]. As such, it is the effort of this research to develop a direct, non-invasive, handheld device to measure internal pressures and material mechanical properties in pressurized, physiological vessels.

EXISTING TECHNOLOGIES

Though no “gold standard” IAP measurement method exists, numerous methods of evaluating physiological pressures have been developed. “Direct” IAP readings use microtransducers embedded just under the abdominal wall [11, 12]. That said, embedded microtransducers are not widely recommended measurement methods, given the invasive nature of the procedure [1, 10], high cost [12], and fragility of the system [11]. The WSACS recommends IAP measurement via the bladder (known as urinary bladder pressure (UBP)), as most patients requiring IAP monitoring already have a catheter implanted, making measurements minimally invasive [4, 13]. Differences between microtransducers and pressure via a bladder catheter have been measured between 0.286 +- 0.938 mmHg [12] and 0.1 +- 2.8 mmHg [11]. However, some researchers disagree with UBP measurement, especially in dynamic testing, as the system is position dependent and prone to air bubbles that can skew readings [13]. Further, UBP measurements above 20 mmHg have demonstrated less reliable results, with Cronbach's alpha of 0.98 and 0.79 for measurements below 12 mmHg and above 20 mmHg, respectively [13]. Regardless, UBP measurement is currently the most common method of obtaining IAP and has been used as a reference method against novel technologies [14].

More recent IAP measurement tools offer non-invasive techniques. Ultrasound guided tonometry, or, the evaluation of pressure by measurement of applied force and displaced liquid volume, is one such method [15]. Ultrasound-guided tonometry has only been studied in porcine models but resulted in the ability to distinguish between three defined categories of IAP: normal (baseline to 15 mmHg), mid-range (between 15 and 25 mmHg) and high (above 25 mmHg) [15]. Though non-invasive, this technology is not portable and does not offer fine IAP measurement resolution. Alternatively, intravaginal transducers are invasive, but highly accurate means of continuous IAP measurement, while offering wireless capabilities [16, 17]. However, intravaginal transducers are limited to the female population, and intra-rater reliability has not been evaluated.

The measurement of abdominal wall tension (AWT) and its correlation to IAP has also been investigated. Due to the direct relationship between wall stress and internal pressure in pressurized cylinders, van Ramshorst *et al*. assumed the measurement of AWT could provide insight into IAP [18, 19]. In further studies, the anatomical landmarks that offered the greatest reliability in AWT testing were 5 cm caudal to the xiphoid process and 5 cm cranial to the umbilicus [18]. This reliability was indicated by the greatest slope in regression lines between IAP and AWT; 0.079 N/mm/mmHg and 0.063 N/mm/mmHg for 5 cm subxiphoid and 5 cm supraumbilical, respectively [18]. Chen *et al.* followed up on these findings by measuring AWT 5 cm subxiphoid, as recommended, on 51 living patients [14]. AWT was then correlated to IAP measured via UBP [14]. The results from this study agreed with van Ramshorst *et al*.'s, proving AWT could be used to interpret IAP, however, linear correlation equations put forth by the authors varied significantly [14, 18]. Chen *et al.* published a linear correlation equation of IAP = 9.57(AWT) - 1.369, while van Ramshorst *et al.* contradicted with IAP = 12.66(AWT) – 20.38 for the same anatomical position [14, 18]. This discrepancy was largely attributed to variation in patient population but demonstrates the unreliability of IAP measurement by correlating against AWT. Following up on the work seeking pertinent AWT correlations to IAP, David *et al*. considered the relationship between abdominal wall thickness (AWTh) and IAP using bioimpedance and microwave reflectometry [20]. Similarly, positive correlation was evident, but poor sensitivity (maximum sensitivity at 4.25 GHz) and limited pressure ranges (up to 7 mmHg) were noted [20].

To summarize, existing clinically-accepted IAP measurement techniques are invasive and not inter-rater reliable. Non-invasive alternatives allow reasonable results to be obtained, but do not directly measure pressure; ultrasound-guided tonometry, bioimpedance, microwave reflectometry, and AWT/AWTh measurements interpret results and correlate them to IAP. This correlation technique is only successful when tested patients exist in the original sample. Variations in patient geometry and physiology may result in IAPs outside the original specifications. Furthermore, such non-invasive alternatives require additional research before suggesting its clinical usage. Thus, to date, direct and non-invasive IAP measurement devices are not currently available, hence the purpose of the present innovative design manuscript.

METHODS

Research has suggested that the abdomen can be represented as a pressurized cylinder of incompressible fluid for the purpose of mathematical modeling [19]. Some successful IAP measurement tools exploit said model to evaluate the AWT and correlate this value with IAP [14, 18]. The current research looks to advance this theory, evaluating the system at a quasi-static equilibrium state to calculate, rather than correlate with, IAP. Correspondingly, a novel tool was designed. This tool induces a localized negative pressure (P_{app}) across a circle of tissue with radius, a, from which the resulting tissue deformation (w) is reported. Pressure is induced with a standard pressure bulb through an open end in the device. The device is 25 cm tall, 7.5 cm at its widest, and weighs approximately 250 g when fully assembled (Fig. 1). The device comprises a pressure sensor (BMP388), a distance sensor (VL6180), and luer-lock connections (Qosina) to improve air-tightness. The maximum lateral deformation reading of the VL6180 is 10 cm (100 mm), with noise of 2 mm (2%). The relative accuracy of the BMP388 is 8 Pa (0.06 mmHg). A microcontroller (ESP32) and rechargeable battery are also housed in the device for on-site analysis. Cup diameter (5 cm) and wall thickness (2 mm) matched similar commercial products to maintain frame rigidity and allow for deep tissue resection. Additionally, a biocompatible lubricant was used to improve device seal against skin.

To correctly use the device, the system must be placed orthogonal to the abdominal wall, open end down, 5 cm subxiphoid along the linea alba. During use, enough pressure to achieve a complete seal against the skin is required. Upon patient end-exhalation, suction is induced by squeezing the pressure bulb. To release pressure, the pressure bulb can be removed. Sensors detect change in pressure and distance simultaneously and send the collected information to the microcontroller for analysis. The test is repeated three to five times for an average measure of IAP and abdominal wall elasticity.

For a circular membrane of radius, a, under uniform lateral loading (P_{net}), fixed at its bounds, and presenting large deflections (Fig. 2), the Hencky solution applies [21, 22]. The Hencky solution states that the maximum lateral deflection (w) occurs at the center of such a pressurized, circular membrane, and can be defined by

$$w = (P_{net}a/Et)^{1/3}\kappa a \tag{1}$$

where κ is a constant dependent on pre-tension in the membrane and Poisson's ratio (v) of the material, P_{net} is the net pressure, E is the material Young's Modulus, and t is the material thickness [21]. In the classic Hencky problem, as that defined by Eq. (1), where no pre-tension exists in the membrane, κ reaches a maximum value of 0.5982 for v of 0.49, or 0.5952 for v of 0.499. With the introduction of pre-tension, the extended Hencky solution applies, such that [22]

$$w = (P_{net}a^4/Et^4)^{1/3}\kappa t. \tag{2}$$

As pre-tension in the membrane increases, κ decreases.

Pre-tension (σ) may be calculated using the Lamé equation for hoop stress in thick-walled cylinders. That is,

$$\sigma = P_{in}(r_1^2+r_2^2)/(r_2^2-r_1^2) \tag{3}$$

where r_1 and r_2 refer to inner and outer radii of the abdomen, respectively, and P_{in} is internal pressure [23]. Radii may be approximated by waist circumference taken at the navel. Published averages for waist circumference, abdominal wall thickness, Young's Modulus and Poisson's ratio are compiled in Table 1.

Table 1: Published average physiological properties

	Male	*Female*	*Ref.*
Waist Circumf. (m)	0.9524	0.8129	[24]
Abd. Wall Thick: t *(m)*	0.03	0.03	[25]
E *(kPa) at Linea Alba*	0.957*t*	0.957*t*	[26]
v	0.499	0.499	[27]

In the context of IAP, published values of healthy and unhealthy pressure ranges are available. As such, these ranges may be applied to determine pre-tension, with results compiled as calculated pre-tensions in Table 2. Included is the Valsalva maneuver; a common testing method for herniation to evaluate the abdomen at peak pressures [28]. To compare, experimentally measured values for tension in the linea alba (central, vertical line of tissue in the abdomen), as determined by Konerding *et al.*, are juxtaposed [29].

Table 2: Clinical states and associated pre-tensions

Clinical State	*IAP (mmHg)*	*Calculated Pre-tension (kPa)*		*Published Pre-tension (kPa) [29]*	
		Male	Female	Male	Female
Normal – Normal BMI	5	3.04	2.56	--	--
Normal – High BMI	10	6.13	5.16	--	--
Intra-abdominal Hypertension	12	7.37	6.21	--	--
Abdominal Compartment Syndrome	20	12.26	10.32	8.89	8.33
Valsalva Maneuver	120	73.68	62.06	100.00	108.33

To illustrate the suggested theoretical framework, expected maximum lateral deformations were mapped against a series of pressures in Fig. 3. Calculations were made using Eq. (1) for a sample with no pre-tension, and (2) for samples with increasing pre-tension. Equations used published values as compiled in Tables 1 and 2. Computations were made to a higher density for physiologically relevant points. Data was fit with second order exponentials to suggest trendlines.

Figure 3 shows three distinct regions of interest with respect to IAP: (1) below normal IAP, (2) normal IAP, and (3) above normal IAP (requiring monitoring). Region (1) is between curves for no pre-tension and normal body mass index (BMI), region (2) is between normal and high BMI, and region (3) is below the high BMI curve. It should be noted that these regions are relevant in a specific set of patient conditions; that is, measured with patients in supine position at end-expiration without any abdominal activation. Of greatest interest is the difference between “healthy” (normal, or below normal IAP) and “unhealthy” (high) IAP. This difference supports clinical decision making for patients in need of medical intervention.

To isolate a patient’s IAP into “healthy” or “unhealthy” categories, a second set of equations describing maximum stress must be considered. The classic Hencky solution states that maximum stress (*S*) occurs at the centre of a pressurized, circular membrane, and can be defined by

$$S = (P_{net}a/Et)^{2/3}\Omega Et \tag{4}$$

where Ω is a constant dependent on pre-tension in the membrane and Poisson’s ratio of the material [21]. When pre-tension exists, the extended Hencky solution applies and the equation adjusts to [22]

$$S = (P_{net}a^4/Et^4)^{2/3}\Omega Et^2/a. \tag{5}$$

As pre-tension in the membrane increases, Ω increases.

To exemplify this concept in the context of IAP, a series of physiological pre-tensions were applied and graphed with respect to applied pressure and maximum stress. The results, as calculated with Eq. (4) and (5) and using published values for the abdomen, are shown in Fig. 4. Data were fit with first order polynomials to arrive at trendlines.

Of note in Fig. 4 is the relative consistency of maximum stress as applied pressure increases. At net pressures of 5 kPa, a maximum difference between maximum stress and pre-tension of 52% was seen at a pre-tension of 3.04 kPa. This difference decreases as pre-tension increases, and as net pressure decreases. As net pressures remain less than 5 kPa for supine patients at rest, an assumption is offered: the maximum stress may be approximated as the pre-tension in the abdomen ($S = \sigma$). In addition to low expected net pressures, it is anticipated that maximum stress is underestimated given original problem constraints. Rather than the uniform pressure that occurs in reality, both the classic and extended Hencky solutions consider a membrane under uniform lateral loading, in which all force vectors are parallel. Conversely, uniform pressure results in an array of force vectors orthogonal to the membrane surface. Thus, maximum stress due to uniform pressures can be expected to increase, as radial stress increases, when compared to their uniform lateral loading counterparts [21]. That said, clinically, this results in an overestimation of IAP, yielding a fail-positive system. This is deemed acceptable as it is of greater significance to incorrectly test positive than miss a patient who is critically ill.

Given the unknown nature of variables Ω and κ, another equation must be introduced. A force balance of the resected membrane is considered, resulting in

$$S = P_{net}(a^2+w^2)/(4tw). \tag{6}$$

If Eq. (3) and (6) are equated, using the proposed assumption, an equation for internal pressure is established:

$$P_{in} = P_{app}(a^2+w^2)(r_2^2-r_1^2)/(4tw(r_1^2+r_2^2)-(a^2+w^2)(r_2^2-r_1^2)). \tag{7}$$

To evaluate the robustness of Eq. (7), a relation is proposed where $x = 1.00$ in $S = x\sigma$. If x increases to satisfy the theoretical relationship between S and σ, the question remains how calculated internal pressure is affected. Thus, P_{in} is varied depending on x to evaluate the sensitivity of the solution to the proposed assumption. Additionally, sensitivity of P_{in} to changes in waist circumference was considered. Assuming a circular waist, outer radii can be calculated by dividing waist circumference by 2π.

Using κ for no pre-tension as an approximation, an appraisal of Young's Modulus can be found by adjusting Eq. (2) to

$$E=P_{net}a^4/(t^4(w/(0.5952t))^3). \tag{8}$$

Sensitivity of Young's Modulus to varying κ was also measured. Rather than using estimated κ for no pre-tension (0.5952), κ was approximated with known values for participants in supine position.

RESULTS

Following ethical approval and informed consent, a feasibility study proceeded. This resulted in two healthy males (n = 2) being tested with the novel device by one tester (k = 1). Physical details of the participants are shown in Table 3, with waist circumference, abdominal wall thickness, E, and v constrained to published averages.

Table 3: Participant physiological properties

	Male 1	*Male 2*
Age (years)	26	28
Height (m)	1.85	1.78
Weight (kg)	82.8	75.7
Body Mass Index	24.2 (Normal)	23.9 (Normal)
Waist Circumf. (m)	0.91	0.84

Each participant was tested five times 5 cm subxiphoid along the linea alba. Tests were conducted using WSACS recommendations, that is, in supine position at end expiration without abdominal activation [2]. Each peak pressure and deformation pair was mapped with time, as shown in Fig. 5, prior to data filtering.

Previous studies have indicated a direct relation between IAP and head position: 1.5 mmHg with 15^o incline, and 3.7 mmHg with 30^o incline [32]. This change is suggested to be due to the effect of gravity and visceral compression [32]. Therefore, to determine whether relative changes were evident, the participants were asked to lie with their head raised 30^o from the sternum with respect to the ground, at which time measurements were retaken. Figure 6 shows averaged results from supine and inclined tests in comparison to theoretical results.

Participant IAPs were calculated with Eq. (7) and compiled in Table 4. For participant 1, calculated internal pressure was 0.38 kPa (2.9 mmHg) and 0.47 kPa (3.5 mmHg) for supine and inclined positions, respectively. Participant 2 presented a slight decrease in pressure, with calculated internal pressures of 0.45 kPa (3.4 mmHg) and 0.44 kPa (3.3 mmHg) for supine and inclined positions, respectively. Of note is the increase in IAP with an increase in head incline for participant 1.

Table 4: Calculated intra-abdominal pressures and Young's Moduli of participants

	Body Position	*Male 1*	*Male 2*
Avg. peak app. pressure (kPa) (SD)	Supine	1.94 (0.3)	2.49 (0.3)
Avg. peak tissue deform (mm) (SD)		7.6 (3.0)	8.3 (1.6)
Avg. IAP (kPa) (SD)		0.38 (0.40)	0.45 (0.16)
Avg. E *(kPa) (SD)*		15.43 (53.8)	14.38 (13.7)
Avg. peak app. pressure (kPa) (SD)	Inclined	2.20 (0.06)	1.95 (0.3)
Avg. peak tissue deform (mm) (SD)		6.9 (1.5)	6.5 (1.2)
Avg. IAP (kPa) (SD)		0.47 (0.16)	0.44 (0.20)
Avg. E *(kPa) (SD)*		22.28 (22.8)	23.90 (22.4)

Young's Modulus for participant 1 and 2 was calculated with Eq. (8) to be 15.43 and 14.38 kPa, respectively, at supine position. This value increased at an inclined position with 22.28 and 23.90 kPa for participant 1 and 2, respectively. An increase in stiffness in both participants with increasing inclination indicates the activation of abdominal muscles, as supported by previous studies [26].

The strength of the proposed assumptions was evaluated in a brief sensitivity analysis, as summarized in Table 5. The results of the sensitivity of P_{in} to x are compiled in Table 5 for participant 1 and 2 supine results using Eq. (7). Also summarized is the sensitivity of actual participant waist circumferences to evaluate P_{in}. Finally, sensitivity of E to κ was evaluated. In each scenario, a control is set, and defined as the calculated variable using equations as set, that is, without variable adjustment. It is the effort of the sensitivity analysis to evaluate the robustness of equations, not device function.

Table 5: Sensitivity analyses as noted

	Participant 1		*Participant 2*	
	Control	*Adjust*	*Control*	*Adjust*
	Sensitivity of P_{in} to x			
P_{net} *(kPa)*	2.32	2.32	2.94	2.94
x	1.00	1.1726	1.00	1.2514
P_{in} *(kPa)*	0.38	0.32	0.45	0.34
% diff. with control	N/A	16%	N/A	24%
	Sensitivity of P_{in} to waist circumference			
Waist circumf. (m)	0.952	0.91	0.952	0.84
P_{in} *(kPa)*	0.38	0.41	0.38	0.53
% diff. with control	N/A	8%	N/A	18%
	Sensitivity of E to κ			
κ	0.5952	0.3282	0.5952	0.3603
E *(kPa)*	15.43	3.42	14.36	3.18
% diff. with control	N/A	78%	N/A	78%

DISCUSSION

A device to characterize pressurized, physiological vessels was developed and feasibility confirmed via preliminary analyses. The device uses a localized known pressure to measure resulting tissue deformation, from which the internal pressure range can be divulged. Changes in physiological pressures were correctly detected in one of two tested participants, while changes in abdominal wall elasticity were correctly detected in both tested participants.

Physically, errors in pressure and distance sensors may have propagated through calculations. These errors include noise, as previously mentioned, of 8 Pa and 2 mm in the BMP388 and VL6180 sensors, respectively. As such, sensor error accounts for errors up to 0.08 kPa (0.6 mmHg) and 6 kPa for P_{in} and E, respectively. Air leakage in the device further constrained results to peak pressures, whereas maintained suction may have offered a relaxed state in tissue with greater IAP and Young's Modulus accuracies. Thus, improved sensors and system air-tightness may strengthen outcomes.

Theoretically, the assumptions presented in this study simplify the reality of the problem, leading to potential sources of error. These simplifications include (reality versus assumption): (1) uniform pressures versus uniform lateral loading, (2) differences between maximum stress and pre-tension versus consistency between the two, (3) non-linear Young's Modulus versus constant Young's Modulus. To improve on these areas, the extended Hencky solution in a uniform pressure setting must be considered. This future research may provide insight into the exact relation between maximum stress and pre-tension. In addition, following on the research of Hayes and Zhang who studied Young's Modulus given tissue indentation, a theoretical study into the evaluation of Young's Modulus given local uniform pressure is of value [30, 31].

Functionally, the greatest limitation in this study is limited sample size. With a larger study population, the wider impact of the novel device may be revealed. It is also of value to directly compare the novel device to existing technologies to evaluate the error between measurement systems. This comparison is necessary for both IAP and Young's Modulus evaluation. Despite the lack of a "gold standard" measurement tool for either IAP or Young's

Modulus, it is recommended to compare IAP against UBP, and Young's Modulus against the MyotonPro, given both devices' existing popularity. Nevertheless, the feasibility study showed promising results while the methods put forth may serve to assists others with similar design targets.

Results in Table 4 support physiological evidence that IAP increases, and, thus, pre-tension increases, with increased head inclination [32]. The decrease in pressure from supine to inclined position in participant 2 may be attributed to early inhalation or measurement error. In this scenario, measurement error refers to procedural inconsistencies, such as holding the device at an angle, rather than orthogonal to, the abdomen, or applying excessive pressure against the abdomen to seal the device to the skin. Additionally, deformations are seen to be greater than the theoretical maximum curve for no pre-tension in Hencky's solution. This error is likely due to differences in patient physiologies when compared to published averages.

The differences shown in Table 5 represent the greatest likely differences during testing. As noted from Fig. 4, the worst-case scenario is seen at high net pressures and low pre-tensions. In other words: patients at supine position with high applied pressures. To circumvent this error, a constant applied pressure of 2 kPa is suggested, at which time x is 1.13. This adjustment still yields a greater P_{in} than actual; however, it is deemed acceptable to support a false-positive device rather than a false-negative. In this case, false-positive refers to the incorrect diagnosis of high IAP. As intra-abdominal hypertension and abdominal compartment syndrome (high-IAP conditions) are diagnosed by prolonged high IAP, a false-positive would require the monitoring of a patient's IAP over several hours before treatment is considered. The financial impact of false-positives is seen as minimal, when compared to the impact of a false-negative; a mistake that has life-threatening consequences.

Given the effect of waist circumference, it is recommended to use actual patient waist circumferences in final calculations. This is, in part, since smaller waist sizes demonstrate higher internal pressures. Therefore, if the correction is not made, results support false-negatives. As mentioned previously, this is financially and clinically inadvisable.

The sensitivity of E to κ indicates the lack of robustness in Eq. (8). Therefore, as suggested previously, a theoretical study into the evaluation of Young's Modulus given local uniform pressure is of interest in determining a corrective factor that improves equation strength.

Contrary to existing methods of measurement, the innovative design, described herein, is handheld and non-invasive. Rather than correlating measures to IAP, the novel system directly measures IAP, as well as abdominal wall elasticity, simultaneously. Initial functional tests indicate the ability of the device to deduce the correct internal pressure range; all recorded pressures were within the healthy range of patients with normal BMI, complementing the participants tested. Further, changes in abdominal wall elasticity were correctly detected given a change in body inclination. That said, clinical studies are required to evaluate the novel device in a broader physiological setting. Future work includes the evaluation of the device as a physiological internal pressure measurement tool and abdominal wall elasticity measurement tool via reliability, validity, and agreement with existing methods of measurement prior to clinical use.

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CONFLICT OF INTEREST DECLARATION

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NOMENCLATURE (in order of appearance)

IAV	Intra-abdominal volume
IAP	Intra-abdominal pressure
WSACS	World Society of Abdominal Compartment Syndrome
ICU	Intensive care unit
UBP	Urinary bladder pressure
AWT	Abdominal wall tension
AWTh	Abdominal wall thickness
P_{app}	Pressure applied by the novel tool (kPa)
a	Novel device radius (m)
ρ	Radial axis (m)
w	Maximum lateral deformation (m)
P_{net}	Net pressure (kPa)
κ	Dimensionless coefficient dependent on Poisson's ratio, pre-tension
ν	Poisson's ratio
E	Young's modulus (kPa)
t	Membrane thickness (m)
σ	Pre-tension or stress in the membrane (kPa)

r_1	Inner radii of abdomen (m)
r_2	Outer radii of abdomen (m)
P_{in}	Internal pressure (kPa)
BMI	Body Mass Index
S	Maximum stress in membrane (kPa)
Ω	Dimensionless coefficient dependent on Poisson's ratio, pre-tension
n	Sample size
k	Number of testers

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Figure Captions List

Table Caption List

FIGURE 1

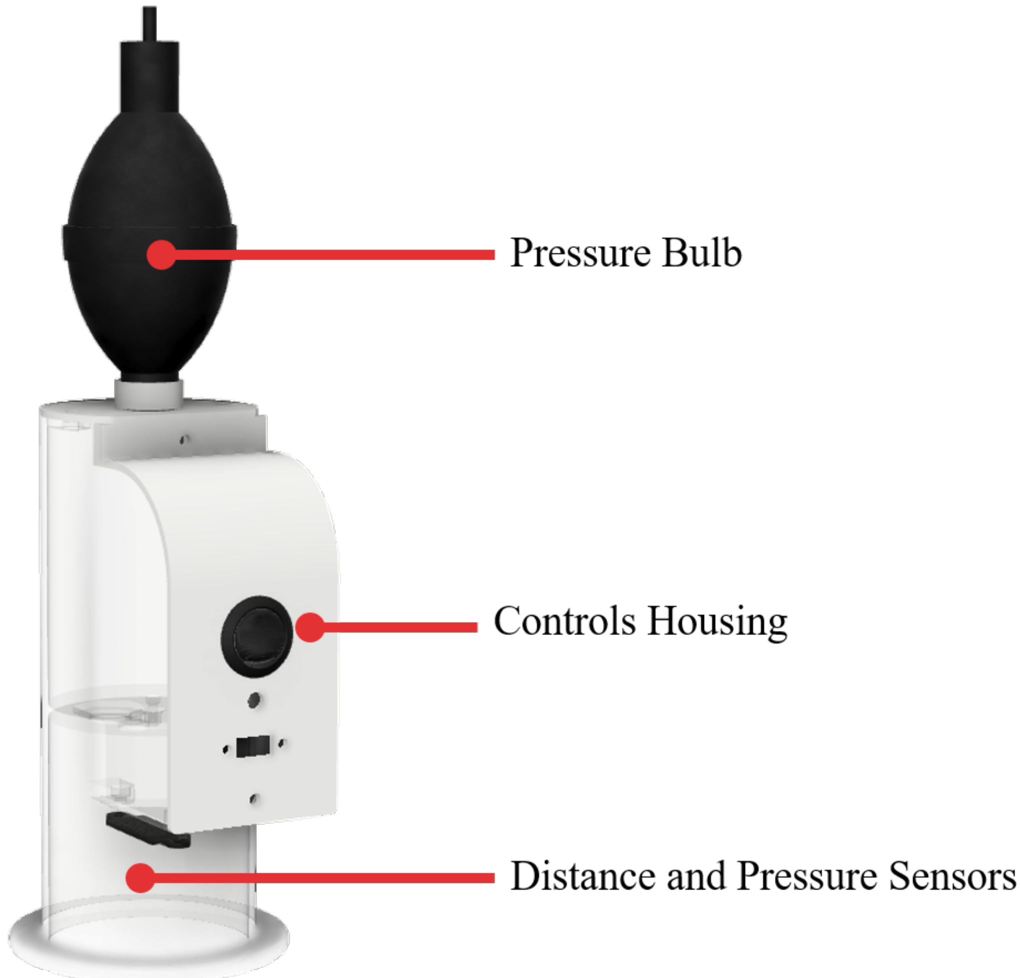

Pressure Bulb
Controls Housing
Distance and Pressure Sensors

FIGURE 2

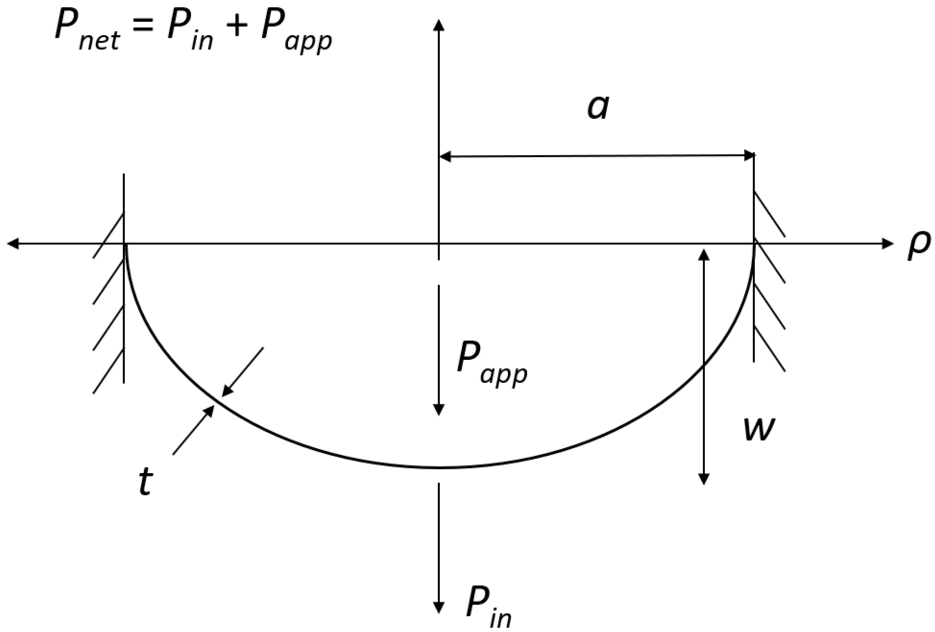


FIGURE 3

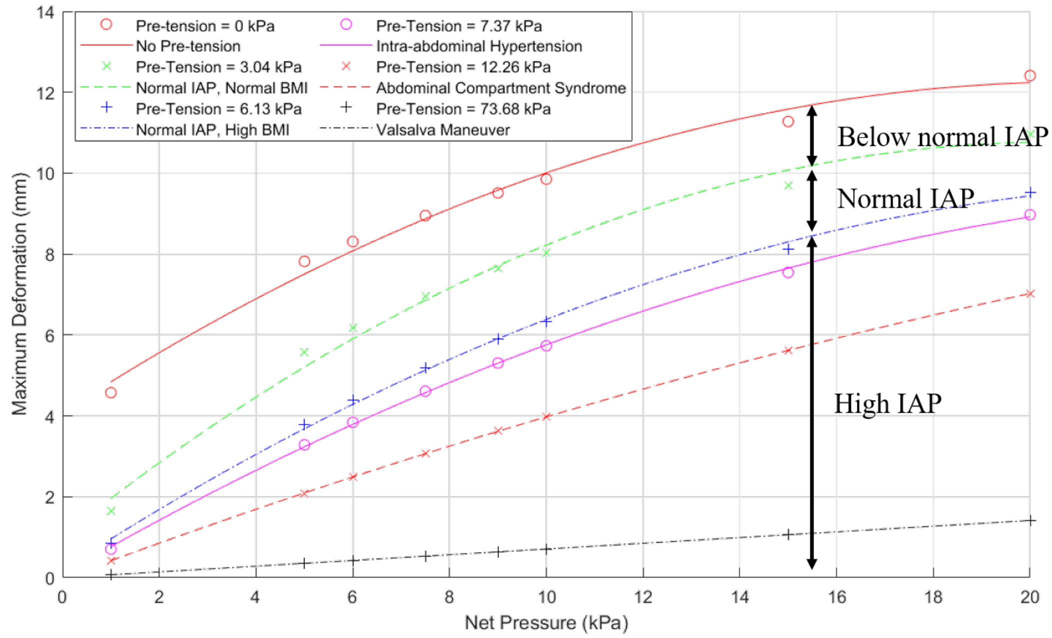

Pre-tension = 0 kPa
No Pre-tension
Pre-Tension = 3.04 kPa
Normal IAP, Normal BMI
Pre-Tension = 6.13 kPa
Normal IAP, High BMI
Pre-Tension = 7.37 kPa
Intra-abdominal Hypertension
Pre-Tension = 12.26 kPa
Abdominal Compartment Syndrome
Pre-Tension = 73.68 kPa
Valsalva Maneuver
Below normal IAP
Normal IAP
High IAP
Maximum Deformation (mm)
Net Pressure (kPa)
0
2
4
6
8
10
12
14
16
18
20

FIGURE 4

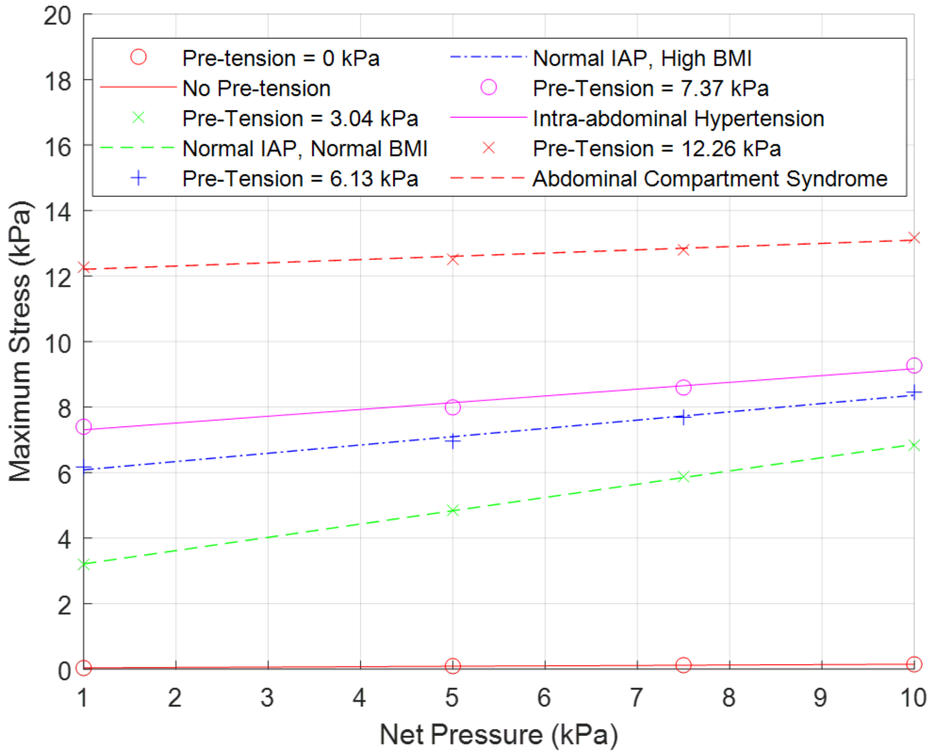

Pre-tension = 0 kPa
No Pre-tension
Pre-Tension = 3.04 kPa
Normal IAP, Normal BMI
Pre-Tension = 6.13 kPa
Normal IAP, High BMI
Pre-Tension = 7.37 kPa
Intra-abdominal Hypertension
Pre-Tension = 12.26 kPa
Abdominal Compartment Syndrome
Maximum Stress (kPa)
Net Pressure (kPa)
0
2
4
6
8
10
12
14
16
18
20
1
2
3
4
5
6
7
8
9
10

FIGURE 5

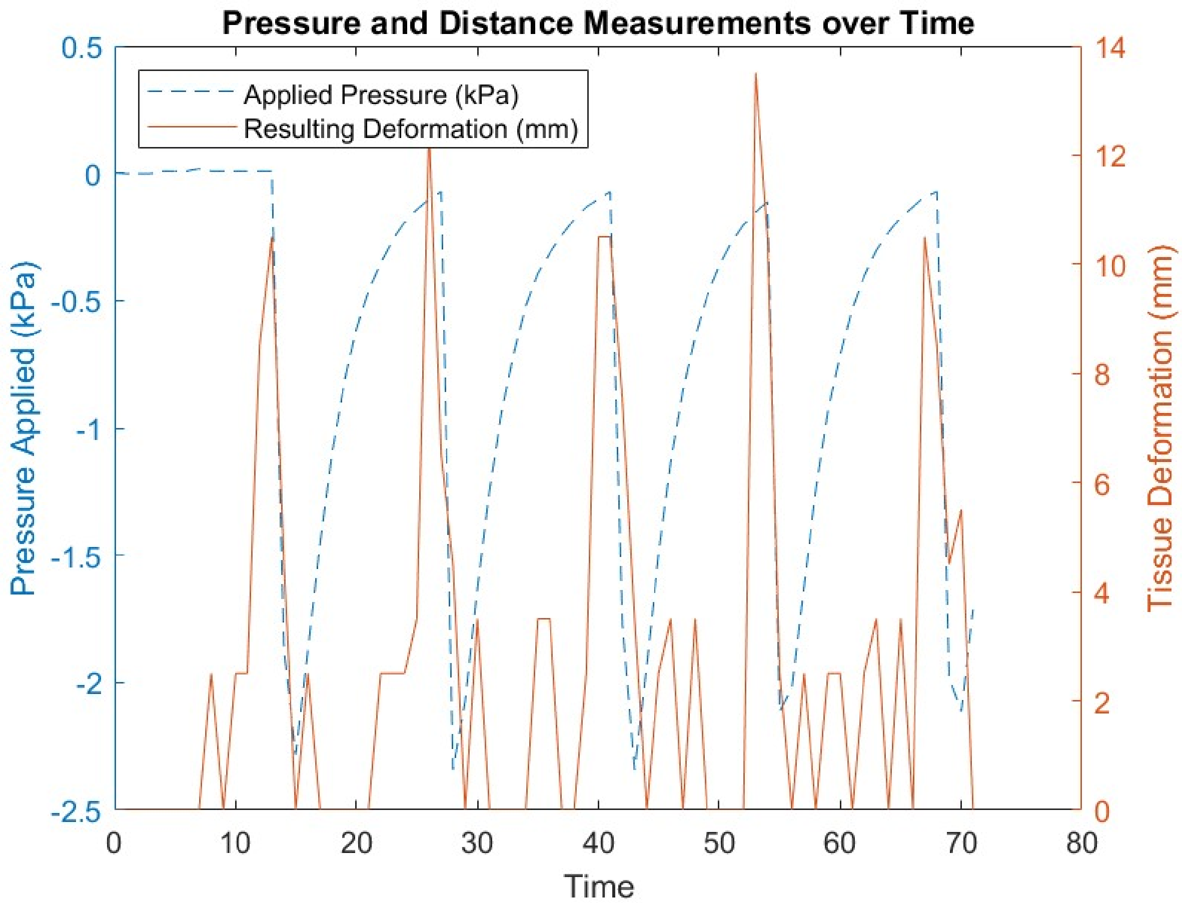
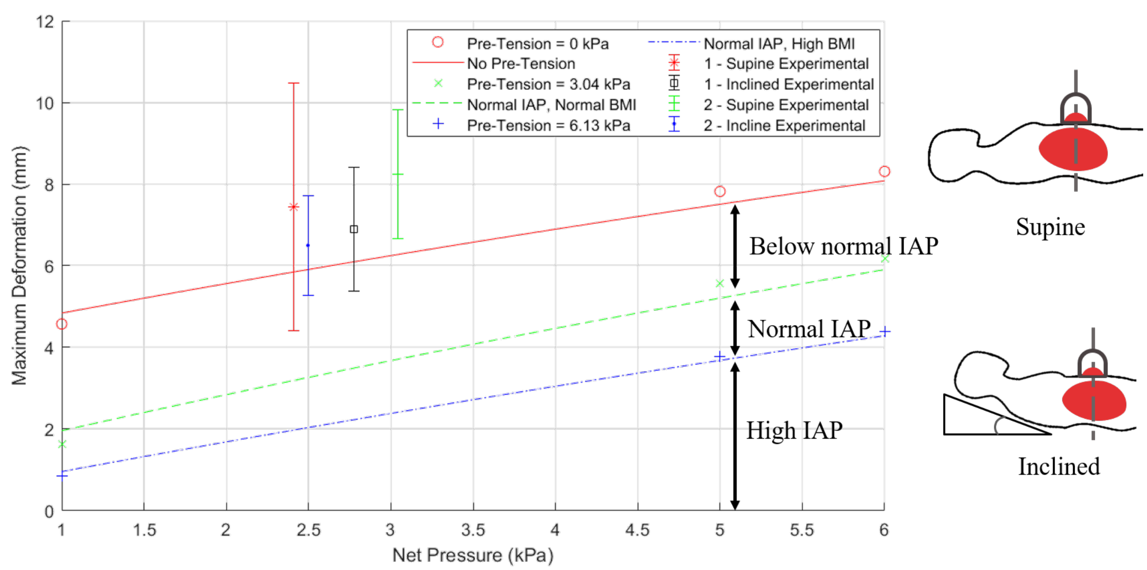

Pressure and Distance Measurements over Time
Applied Pressure (kPa)
Resulting Deformation (mm)
Pressure Applied (kPa)
Tissue Deformation (mm)
Time
0.5
0
-0.5
-1
-1.5
-2
-2.5
14
12
10
8
6
4
2
0
0
10
20
30
40
50
60
70
80

FIGURE 6


Maximum Deformation (mm)
Net Pressure (kPa)
Pre-Tension = 0 kPa
No Pre-Tension
Pre-Tension = 3.04 kPa
Normal IAP, Normal BMI
Pre-Tension = 6.13 kPa
Normal IAP, High BMI
1 - Supine Experimental
1 - Inclined Experimental
2 - Supine Experimental
2 - Incline Experimental
Below normal IAP
Normal IAP
High IAP
Supine
Inclined