THE USE OF AN INTRAVAGINAL PRESSURE TRANSDUCER IN WOMEN: A STUDY OF THE RELATIONSHIP BETWEEN INTRA-ABDOMINAL PRESSURE AND ACCELEROMETRY

by

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A thesis submitted to the faculty of
The University of Utah
in partial fulfillment of the requirements for the degree of

Master of Science

Department of Bioengineering

The University of Utah

August 2017

The University of Utah Graduate School

STATEMENT OF THESIS APPROVAL

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ABSTRACT

One in four women in the U.S. will contract a pelvic floor disorder (PFD) in her lifetime. High intra-abdominal pressure (IAP) may be a factor influencing the development of PFDs, causing women at risk for PFDs to receive physical activity restrictions. However, there is limited research as to what daily activities and exercises cause high IAPs. Our lab developed an intravaginal pressure transducer to measure IAP in women during exercise and daily activities, but utilizing the transducer as a long-term measurement device may present compliance issues. Waist-worn accelerometers, which measure acceleration and physical activity, are more commonly utilized devices and may prove to be reliable replacements for the transducer. We hypothesized that there is a positive correlation between the mean maximal vector magnitude for acceleration and the mean maximal IAP and mean area under the curve (AUC) for IAP. After measuring 25 women's IAP and acceleration during specific exercises, we found an R^2 of 0.7405 for the relationship between mean maximal accelerometer vector magnitude and mean maximal intra-abdominal pressure and of 0.5255 for the relationship between mean maximal accelerometer vector magnitude and mean area under the curve for intra-abdominal pressure. Analysis of different walking stages presented even higher R^2 values, demonstrating that waist-worn accelerometers may present a viable method for predicting IAP.

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ACKNOWLEDGMENTS

I would like to thank Ana Chacin, Harrison Padgen, and Stefan Neiderauer for fabricating the sensors used in this study and Amelia Hanson for assisting in running the exercise trials. Additionally, I would like to thank Claire de Gennaro for her help with creating the exercise protocol utilized in the study, and Ingrid Nygaard, Janet Shaw, Tomasz Petelenz, and Robert Hitchcock for providing so much support in conducting the study.

The project described was supported by Grant Number 1P01HD080629 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health.

INTRODUCTION

Pelvic floor disorders (PFDs) are medical disorders affecting one in four women in the U.S. PFDs involve the weakening of the pelvic floor muscles in women, inducing urinary incontinence, fecal incontinence, or pelvic organ prolapse [1]. Increasing age and an increasing number of vaginal childbirths are factors leading to increased likelihood of developing a PFD, but high intra-abdominal pressure (IAP) may also contribute to the development of a PFD. Many women who are at risk for a PFD or who have had corrective surgery are prescribed physical activity restrictions to limit the generation of high IAP. However, the restrictions are often based on intuition, as there is limited research into the IAPs generated by different activities [2]. Women, therefore, are being restricted in their ability to live active lifestyles despite a lack of data indicating which activities may be harmful to the pelvic floor.

One of the most significant barriers in gathering IAP data has been the methods utilized to measure IAP. Most often, researchers employ invasive sensor-tipped catheters and fluid-coupled transducers placed in the bladder, rectum, urethra, or vagina that are connected to laboratory equipment to measure IAP [3]. The tethering of the participant to the lab equipment restricts the ability of the participant to perform dynamic movements or movements outside of a laboratory setting, thus limiting the accuracy and relevance of measured IAP values and their correlations with typical physical activities. Our group developed a wireless intravaginal transducer to measure IAP [4], which has been validated in clinical studies [5]. The device employs a piezoresistive die to detect pressure, which is placed within a silicone capsule containing incompressible silicone gel. Additionally, the transducer contains wireless components that transmit data to an external base station worn on the waistband of the pants that records the IAP, device status, temperature, time, and error messages. Using the wireless intravaginal transducer, we have performed several physical activity studies to better understand the IAPs associated with different exercise and everyday activities [6-8]. Recently, the wireless intravaginal transducer has undergone a transformation to a wired intravaginal transducer (WIVT). The transformation also included changing from the previous base station to an instrumentation module (IM) that is the size of a cell phone, connects directly to the WIVT, and records IAP data, time, and accelerometry. The IM has been used previously to study partial weight bearing therapy for lower extremity fractures [9].

Both generations of the intravaginal transducer allow women to perform exercise and everyday activities without being tethered to laboratory equipment. However, use of the WIVT in real-life situations faces additional problems, especially when asking women to wear the WIVT for multiple days in order to assess IAP. Recording IAP in at-home situations over several days would allow for better understanding of the daily IAPs women generate and how their normal IAPs may relate to the development of PFDs. We believe that women would have low compliance when asked to wear the WIVT for multiple days due to the invasiveness of the sensor and bulkiness of the combined WIVT and IM. The WIVT is inserted like a tampon into the vagina and contains a tether and a data cable that require access to the external environment, causing two components to exit the vagina. The data cable connects directly to the IM on the waistband of the pants, creating a bulky apparatus for a woman to wear for several days.

Accelerometers, on the other hand, are measurement tools that are often used all day for multiple days. Many physical activity studies utilize waist-worn accelerometers to determine a person's physical activity levels based on accelerometry values, including the National Health and Nutrition Examination Survey [10, 11]. Accelerometers use acceleration to measure body movements, which is then used to estimate intensity of physical activity [12]. As the intensity of a physical activity increases, the magnitude of the acceleration also increases. We have found similar evidence that as the intensity of walking speeds increase, IAP increases [6]. Our hypothesis, therefore, is that there is a positive correlation between acceleration measurements from an accelerometer and IAP measurements from the WIVT.

In the current study, the subjects performed selected exercises in a controlled environment while wearing the WIVT and a waist-worn accelerometer. The IAP and acceleration values were recorded during all activities to determine the relationship between the two measurements. Post-exercise data analysis included the mean maximal magnitude of the acceleration vector and IAP and the area under the curve (AUC) for IAP. The primary aims in the study were to study two relationships: mean maximal accelerometer vector magnitude versus mean maximal IAP and mean maximal accelerometer vector magnitude versus mean AUC for IAP.

METHODS AND MATERIALS

We received approval from the University of Utah Institutional Review Board (IRB) before initiating the study, and participants signed an informed consent form approved by the IRB. All participants were between the ages of 18 and 54, had body mass indices (BMIs) between 19 and 30 kg/m^2, and regularly participated in strenuous exercise. Participants were excluded if they had incurred a musculoskeletal injury in the last 3 months, had undergone pelvic surgery other than hysterectomy, were currently using vaginal contraceptive or pessary, or responded "yes" to the question, "Do you have a bulging beyond your vagina?" Additionally, participants needed to pass the Physical Activity Readiness Questionnaire (PAR-Q), which identifies participants who have heart, bone, or joint problems that may be exacerbated by physical activity [13]. Such participants were excluded from the study. Participants also completed a history form detailing age, education, parity, smoking habits, hysterectomy, number of vaginal deliveries, and number of Cesarean deliveries.

The exercise sessions were conducted for one hour in an exercise physiology lab under the direct supervision of the research team. Only one participant was assessed at a time. Participants wore the WIVT and IM for all activities [4]. The WIVT contained a pressure sensing piezoresistive die and a microcontroller encapsulated in a medical grade silicone elastomeric capsule measuring 23.9 mm in diameter and 37.3 mm in length filled with incompressible silicone gel. A four-conductor cable connected the WIVT to the IM through a tip ring ring sleeve (TRRS) connector on the side of the IM, which recorded all data onto a microSD card and contained the triple-axis accelerometer. The accelerometer within the IM was an iNEMO inertial module: 3D accelerometer and 3D gyroscope (ACCEL-LSM330DLC) produced by ST that measured ±2g (Figure 1). Both the WIVT and accelerometer sampled synchronously at 32 Hz. The WIVT was zeroed at atmospheric pressure for 30 seconds before insertion, causing all IAPs reported to be in reference to atmospheric pressure. Participants received verbal instructions for inserting the WIVT and wore the WIVT for approximately 5 minutes before participating in any activities in order to equilibrate the WIVT with body temperature. The IM was clipped onto the waistband of participants' pants on the non-dominant hand side, and athletic tape was used to secure the cable to the ipsilateral hip. A member of the research team turned on the IM at the beginning of the exercise session and connected/disconnected the sensor cable at the IM before and after each exercise. The IM was turned off at the end of each exercise session. A blinking green light on the IM indicated that the data write cycle to

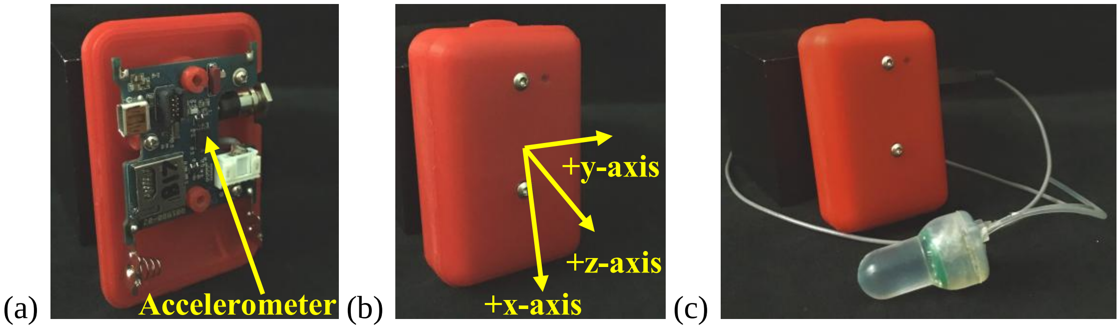


Figure 1: WIVT and IM with accelerometer setup. (a) Open IM. The IM contains the triple-axes accelerometer employed in the study and is waist-worn in the orientation shown. (b) Closed IM. The x-axis is along the length of the IM (vertical), the y-axis is along the width of the IM (mediolateral), and the z-axis runs through the depth of the IM (anteroposterior; out of the page). (c) Instrumentation setup. The entire instrumentation setup consists of the IM containing the accelerometer that is placed on the waist and the WIVT containing the pressure sensing elements that is inserted into the vagina.

the microSD card was completed correctly.

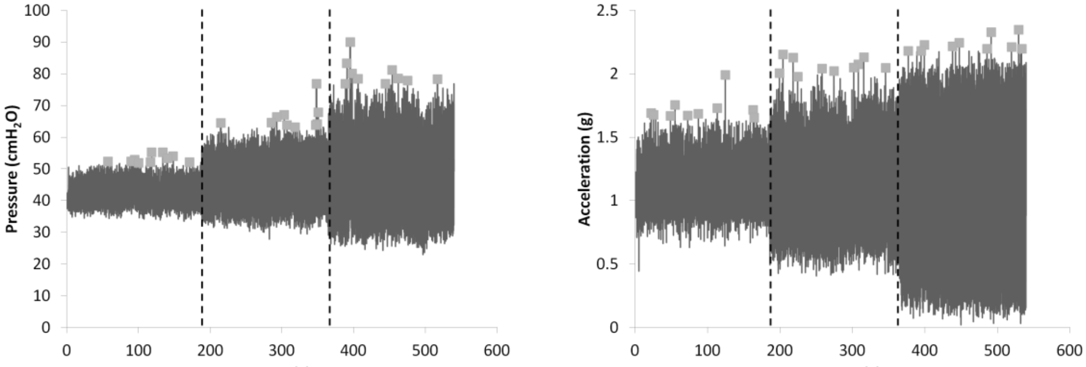
We recorded baselines for each participant for 30 seconds while the participant lay supine on the floor and while the participant stood with feet hip distance apart. Participants completed 13 exercises that consisted of three stages of the Bruce treadmill walking fitness test [14], 2-riser (20.32 cm) step-ups, 4-riser (30.48 cm) step-ups, lifting a 4.5 kg box with two hands from a 96.52 cm tall counter to the floor and back continuously, a static plank on forearms and toes, crunches, sit-ups, pushups on knees, walking alternating lunges, walking alternating lunges with 4.5 kg dumbbells in each hand, and jumping jacks (Table 1). Each stage of the walking fitness test lasted for 3 minutes, while every other exercise lasted for 30 seconds. Activities were not randomized. Participants rested for 10 seconds before and after each exercise while the IM was recording to ease identifying the start and end of each activity. Activities involving repetitions occurred at specific rhythms (beats per minute (bpm)) controlled by a metronome. We assessed the complete data at the end of each exercise session and asked participants with incomplete data to return for an additional exercise session.

Using a customized MATLAB (R2013a, Mathworks, Natick, MA) script, we determined the maximal IAPs that were at least 1 second apart, maximal accelerometer vector magnitudes that were at least 1 second apart, and the IAP area under the curve (AUC) for each activity and participant according to methods established by Hamad et al. [15] We computed the highest 10 maximal IAPs and accelerometer vector magnitudes for each walking stage and the highest 5 maximal IAPs and accelerometer vector magnitudes for every other activity. In order to calculate the accelerometer vector magnitude, we took

Table 1: Descriptive measures for baseline activities and exercise activities

Activity	**Time (minutes)/ Repetitions (bpm)**	**Mean maximal IAP (SD) cm H_2O**	**Range maximal IAP (max-min)**	**Mean AUC (SD) cm H_2O s**	**Range AUC (max-min)**	**Mean maximal acceleration (SD) g-force**	**Range maximal acceleration (max-min)**
Laying Baseline	0.5/-	16.7 (4.8)	27.2-4.6	459.8 (136.0)	639.5-117.7	1.00 (0.03)	1.17-0.94
Standing Baseline	0.5/-	36.7 (7.3)	52.4-21.6	1021.0 (202.0)	1471.7-606.2	1.04 (0.03)	1.22-0.98
Walking stage 1 1.7 mph 10% grade	3/-	47.3 (7.5)	65.9-30.3	6200.6 (1090.9)	8441.4-3912.4	1.71 (0.14)	2.21-1.44
Walking stage 2 2.5 mph 12% grade	3/-	54.5 (7.6)	76.9-35.7	6212.2 (976.2)	7989.9-3840.3	1.91 (0.18)	2.72-1.60
Walking stage 3 3.4 mph 14% grade	3/-	68.5 (11.6)	102.0-46.0	6709.5 (1169.0)	9547.8-4173.2	2.27 (0.21)	3.10-1.96
20.32 cm Step-ups	0.5/24	59.7 (11.8)	98.3-43.1	1026.0 (194.9)	1365.0-730.2	2.16 (0.14)	2.60-1.88
30.48 cm Step-ups	0.5/24	68.7 (12.7)	101.1-48.5	1040.3 (199.3)	1392.1-692.0	2.38 (0.20)	2.92-2.12
Lifting task 4.5 kg	0.5/15	48.0 (10.8)	89.6-30.3	990.4 (188.9)	1470.9-656.0	1.75 (0.26)	2.41-1.29
Plank	0.5/-	49.1 (14.0)	94.8-23.3	1081.2 (313.4)	1895.9-459.7	1.24 (0.17)	1.86-1.07
Crunches	0.5/15	27.4 (13.5)	66.2-8.9	439.1 (190.0)	968.3-180.6	1.09 (0.06)	1.26-1.01
Sit-ups	0.5/15	64.1 (23.6)	133.1-28.6	945.6 (275.8)	1553.0-468.3	1.31 (0.22)	2.84-1.09
Pushups	0.5/25	45.3 (13.3)	83.6-24.5	908.4 (230.3)	1444.5-469.3	1.72 (0.52)	3.48-1.22
Lunges	0.5/40	56.8 (11.4)	87.9-39.6	1155.4 (197.8)	1629.7-860.5	1.96 (0.22)	2.55-1.55
Weighted Lunges 4.5 kg/hand	0.5/40	57.7 (11.7)	90.8-40.9	1169.7 (193.3)	1632.6-841.3	1.95 (0.26)	2.66-1.52
Jumping Jacks	0.5/60	124.0 (23.7)	188.6-77.5	1372.7 (241.1)	1977.8-1017.8	3.17 (0.31)	3.49-2.39

the square root of the sum of the squares of the 3 axes (x, y, z) for every time point (Figure 2). The combination of data from all participants determined the mean maximal IAPs, mean maximal accelerometer vector magnitudes, and mean IAP AUCs for every activity as well as the respective standard deviations. We utilized Excel (2007, Microsoft Office, Redmond, WA) to perform linear regressions that determined the R^2 values for mean maximal accelerometer vector magnitude versus mean maximal IAP for all exercise activities and for mean maximal accelerometer vector magnitude versus mean IAP AUC for all 30-second exercise activities.



(a) (b)

Figure 2: Raw waveforms of (a) IAP and (b) acceleration for the three stages of one walking fitness test. Each walking stage lasted for 3 minutes and had an increased grade and speed. The gray square markers indicate the respective 10 maximal IAP and acceleration values for each stage, and the dashed lines indicate changing to the next stage.

RESULTS

Twenty-seven women enrolled in the study with 25 completing the entire exercise session. Two participants' data did not undergo data analysis due to the participants being unable to complete the exercise session. The average age with standard deviation (SD) of participants was 26±8 years (range 21-52), the average BMI with SD was 22.8± 2.5 kg/m^2 (range 19.5-28.4), and 88% of women were nulliparous.

All mean maximal and AUC values were compiled to determine average values for each exercise, including baselines. Table 1 shows descriptive measurements for the IAP and accelerometer data, as well as descriptions of each activity.

We first examined the relationship between mean maximal IAP and mean maximal accelerometer vector magnitude for every exercise activity (Figure 3). Jumping jacks created the highest mean maximal IAP and mean maximal accelerometer vector magnitude, while crunches created both the lowest mean maximal IAP and mean maximal accelerometer vector magnitude. When plotting mean maximal accelerometer vector magnitude versus mean maximal IAP and performing a linear regression, we found an R^2 value of 0.7405. The values for sit-ups and plank were the farthest away from the regression line, while the other exercises were within one standard deviation of the regression line.

Additionally, we compared the mean AUC for IAP with the mean maximal accelerometer vector magnitude (Figure 4). The three walking stages were not included

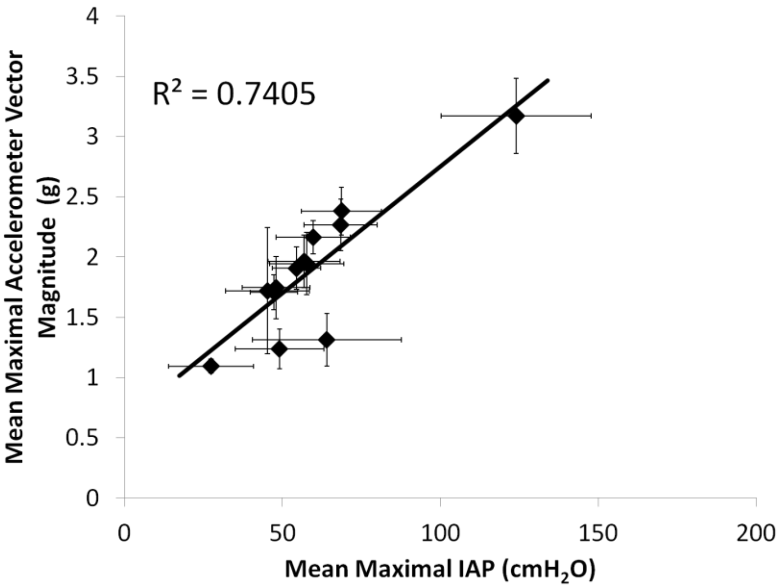


Figure 3: Linear regression and correlation between mean maximal IAP and mean maximal acceleration vector magnitude. All 13 activities were plotted and a linear regression performed to determine the R^2 value for the relationship. Each diamond datum represents one exercise and the black line is the linear regression. Error bars represent SD.

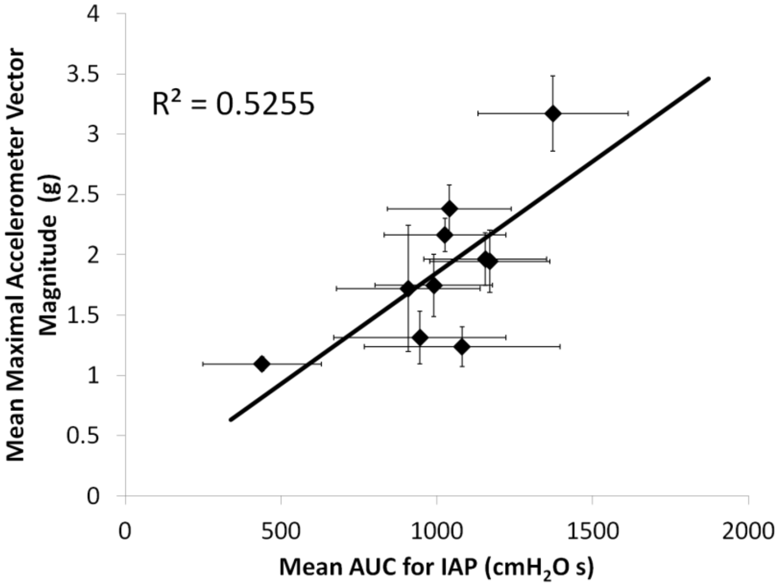
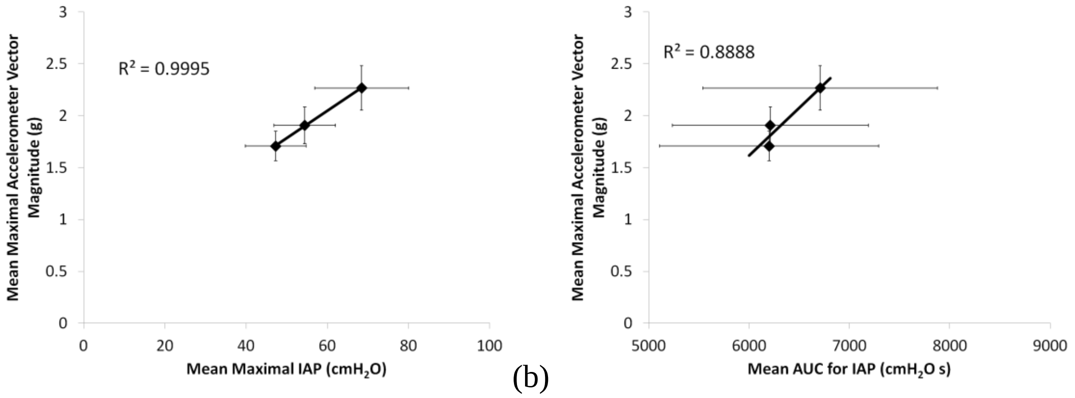


Figure 4: Linear regression and correlation between mean AUC for IAP and mean maximal acceleration vector magnitude. All 10 of the 30 second activities were plotted and a linear regression performed to determine the R^2 value for the relationship. The three walking stages were excluded because they lasted for 3 minutes each. Error bars represent SD.

in the analysis because they each lasted for 3 minutes, while all other activities lasted for 30 seconds. Examining the relationship between AUC and accelerometer vector magnitude requires the activities to occur for the same amount of time to create an accurate linear regression due to the time component involved in AUC. Once again, jumping jacks generated the highest mean AUC for IAP and the highest mean maximal accelerometer vector magnitude, and crunches generated the lowest mean AUC for IAP and the lowest mean maximal accelerometer vector magnitude. The R^2 value for the linear regression of the mean maximal accelerometer vector magnitude versus mean AUC for IAP was 0.5255. Values for three of the exercise activities were farther than one standard deviation away from the regression line, while all other values were within one standard deviation of the regression line.

Due to participants performing the walking fitness test stages for 3 minutes instead of 30 seconds, we assessed the walking stages separately (Figure 5). The mean



(a) (b)

Figure 5: Linear regression mean maximal accelerometer vector magnitude versus (a) mean maximal IAP (b) and versus mean AUC for IAP. Only the three walking stages are addressed, in which there is an increased grade and speed with progressive stages. Mean accelerometer vector magnitude and both IAP measurements increase almost linearly with an increase in grade and speed. Error bars represent SD.

maximal accelerometer vector magnitude correlated highly with the mean maximal IAP ($R^2 = 0.9995$). The mean maximal accelerometer vector magnitude also showed high correlation with mean AUC for IAP ($R^2 = 0.8888$). As the walking stage increased in speed and grade, the acceleration vector magnitude and both IAP measurements increased linearly.

DISCUSSION

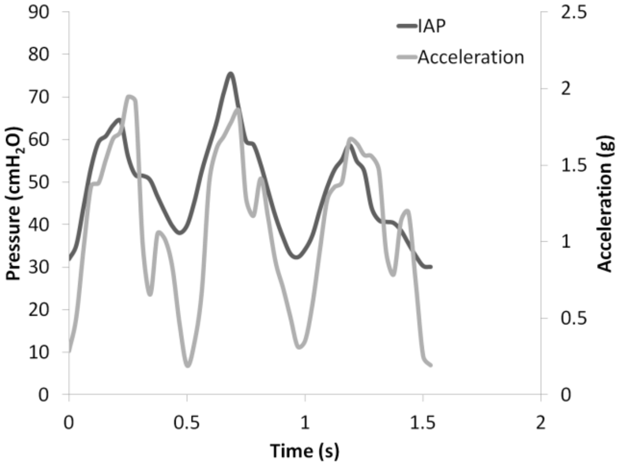
Analysis of IAP in women may be an important factor in determining the probability of women developing a PFD [2]. While the development of the WIVT enabled accurate analysis of IAP during dynamic movements without tethering a woman to a computer [4], the compliance of a woman wearing a WIVT for multiple days would most likely be limited. Accelerometers are already being used in many studies to determine physical activity levels. Our study examined the relationship between IAP measurements from the WIVT and acceleration measurements from a waist-worn accelerometer. The comparison between mean maximal IAP and mean maximal accelerometer vector magnitude showed a high R^2 value, while the comparison between mean AUC for IAP and mean maximal accelerometer vector magnitude resulted in a slightly lower R^2 value. When examining different types of walking, the R^2 values for both comparisons remained high.

Performing a linear regression for mean maximal accelerometer vector magnitude versus mean maximal IAP resulted in an R^2 value of 0.7405. The R^2 value is high when considering that acceleration and IAP are physiological measurements that normally vary from person to person and do not directly influence each other. We utilized the 1 SD distance from the linear regression line to assess whether the magnitude of the error for an activity caused the activity to not follow the linear trend. Only two of the exercises were more than one standard deviation away from the regression line, the values being for plank and sit-ups. Both plank and sit-ups highly recruit abdominal muscles, producing significant IAPs, but create static positioning for the waist-worn accelerometer. Planks employ a completely static body position, while sit-ups only move the torso with limited movement at the waist. The static positioning of the waist creates low acceleration while the high recruitment of abdominal muscles creates high IAP, which may explain the low correlation for the two activities. All other exercises, however, were within one standard deviation of the regression line, indicating that the exercises followed the linear trend and created a high correlation between acceleration and IAP. Mean maximal accelerometer vector magnitude may therefore be a strong predictor of mean maximal IAP, which indicates the sudden and forceful pressures placed on the pelvic floor muscles.

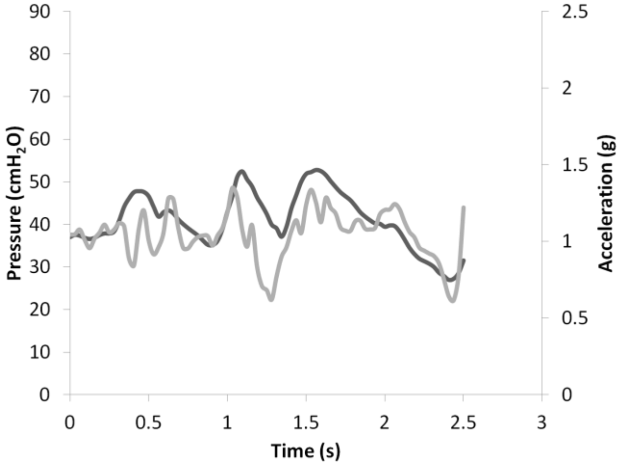
The linear regression for mean maximal accelerometer vector magnitude versus mean AUC for IAP resulted in a smaller R^2 value of 0.5255 than the R^2 value for mean maximal accelerometer vector magnitude versus mean maximal IAP. The smaller R^2 value for mean AUC for IAP indicates a weaker correlation between AUC for IAP and acceleration but is still strong when considering that the two measurements are indirectly related physiological values. Three of the ten exercises were more than one standard deviation away from the regression line: jumping jacks, 30.48 cm step-ups, and plank. The greater variability of AUC for IAP may be the result of activities that generate higher peaks in accelerometer vector magnitude, which may cause high spikes in IAP for short, sudden periods during the exercise. Activities that have lower peaks in accelerometer vector magnitude, on the other hand, may generate a higher baseline IAP and constant IAP during the entire duration of the exercise. We only included 30-second exercises in the analysis of AUC for IAP in order to eliminate the time variable associated with AUC, creating a comparison that indicates the impact of the exercises on IAP and acceleration and not the impact of the duration of the activity. The relationship between mean AUC for IAP and mean maximal accelerometer vector magnitude is not as strong as the relationship between mean maximal IAP and mean maximal accelerometer vector magnitude, showing that accelerometry is not as strong a predictor of the overall IAP generated during activities.

We additionally examined the relationship between accelerometry and IAP for the walking stages separately. The R^2 value for mean maximal accelerometer vector magnitude and mean maximal IAP was 0.9995 and 0.8888 for mean AUC for IAP. Both R^2 values are very high, particularly considering acceleration and the two measurements of IAP studied are indirectly related physiological values. The accelerometer measurements and pressure measurements both increase at similar rates when walking speed and grade increases. Our prior research found similar increases in mean maximal IAP and mean AUC for IAP with increased speed and grade [6, 7]. The high correlations are important because walking activities comprise most of women's daily physical activities. Therefore, mean maximal accelerometer vector magnitude may be an excellent predictor of a woman's IAP in real life scenarios.

Examining the raw waveforms for IAP and acceleration may provide further insight into why certain activities had higher positive correlations. Figure 6 shows descriptive IAP and acceleration waveforms for walking, the lifting task, and the sit-ups for short periods of time. The walking waveforms show three steps, where each peak in IAP is a footstep. The corresponding acceleration waveform also shows three peaks and appears to be in phase with the IAP waveform, demonstrating why walking had such a



(a)



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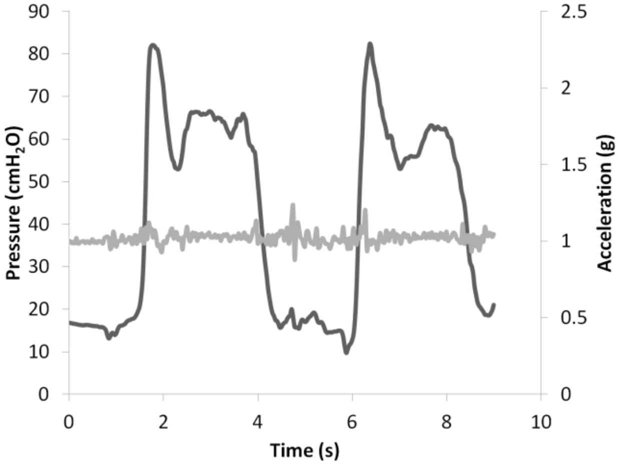

(c)

Figure 6: IAP and acceleration raw waveforms for (a) walking, (b) lifting task, and (c) sit-ups. The waveforms are in phase and similar during walking. The lifting task generated waveforms that have similar overall trends but differ in number of peaks, while sit-ups created waveforms that do not reflect each other and have a poor correlation.

high positive correlation. All three stages of walking exhibited similar waveforms. The waveforms for the lifting task do not mirror each other as well as during walking due to the presence of more peaks in the acceleration waveform, but the overall structure of the waveforms reflect each other. Sit-ups, one of the activities which had low positive correlation, have very little similarity in the waveforms for IAP and acceleration. Changes in the IAP waveform show two sit-ups occurring, while the acceleration remains around a constant value with small fluctuations. The amount of variance between the IAP and acceleration waveforms helps to account for why activities like walking had higher positive correlations than activities like sit-ups.

Some of the activities in the current study have been studied previously, and our values for IAP fall within the described ranges [16-18]. Some variations in IAP values are due to differing measurement techniques for IAP, including transrectal microtip catheters and Foley catheters connected to arterial-line pressure transducers. Cobb et al. found that lifting 5 kg generated ~57 cmH_2O when squatting and ~36 cmH_2O when lifting weights off a counter, a range consistent with our counter to floor to counter lifting task [16]. Guttormson et al. determined that IAP increased with increasing weight being lifted from a table or the floor [18]. Interestingly, we did not find a change in IAP measurements or accelerometer vector magnitude between normal lunges and weighted lunges with 9 kg, indicating that carrying up to 9 kg with an arm hang posture does not greatly affect IAP.

While the measurement techniques employed in the study have been employed previously, there are some limitations. IAP measurements taken in the upper vagina may be affected by extraneous forces from the surrounding viscera and vaginal smooth muscle contractions. However, the placement of the WIVT in the upper vagina allows the sensor to detect forces placed on the pelvic floor because the abdominal cavity is a closed system, and IAP measured in the upper vagina has been shown to approximate measurements from rectal and bladder transducers [19, 20]. Additionally, the accelerometer range in the study was ±2g, which may be too limited for more vigorous activities that women perform. The accelerometer in the IM is also not a conventionally utilized system in physical activity research. Future studies would benefit from employing commercially available waist-worn accelerometers, such as the ActiGraph GT9X Link. Lastly, the majority of participants were young, nulliparous, Caucasian females, necessitating the need to evaluate a wider range of ethnicities, ages, and parity to better understand the relationship between IAP and accelerometry.

In this study, we have evaluated the relationship between accelerometry and IAP measurements, a relationship that we do not believe has been previously explored. Mean maximal accelerometer vector magnitude is a strong predictor of mean maximal IAP and a slightly weaker predictor of mean AUC for IAP. When examining changes in walking speed and grade, representing the most common physical activity amongst women, the relationship becomes even stronger. Due to the high correlation found between IAP measurements and accelerometer measurements, waist-worn accelerometry may be a viable method for increasing wear time compliance of a sensor while collecting IAP data in real-life situations. Women would be able to wear a less invasive sensor but still be able to predict their IAP, which may lead to a better understanding of the relationship of IAP and PFDs in the future.

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