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Tamara L. Roehling Nova Southeastern University

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Are Finger Width Palpation, Tape Measure, and Caliper Reliable, Valid and Accurate to Diagnose Diastasis Recti Abdominis (DRA)?

By

Tamara L. Roehling, PT, DPT

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

Nova Southeastern University

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### Approval/Signature Page

We hereby certify that this dissertation, submitted by Tamara L. Roehling, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the dissertation requirement for the degree of Doctor of Philosophy in Physical Therapy.

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## Abstract

Purpose: Diastasis recti abdominis (DRA) is a condition where the medial rectus bellies separate at the linea alba. A DRA can negatively impact posture, trunk and pelvic stability, pelvic floor muscular control, respiration, trunk movement, and abdominal viscera support. The purpose of this research is to determine whether tools used in the clinic effectively screen for DRA. Specifically, this study compared the reliability, validity, and diagnostic accuracy of finger width, tape measure, and caliper measurements to the clinical best standard, ultrasound imaging. Additionally, the study investigates whether there is a correlation between DRA and low back pain and pelvic floor dysfunction. Participants: A sample of convenience of 49 men and women ranging from 18 to 64 years and female parity ranging from nulliparous to multiparous. Methods: This is a clinimetric, test-retest study. Two examiners measured the distance between the rectus bellies (interrecti distance or IRD) via finger width palpation, tape measure, and caliper under two conditions: at rest and during an abdominal crunch. Measurements were taken at two locations, above and at the umbilicus. A sonographer measured the IRD using ultrasound imaging under the same conditions and at the same locations. Participants returned within 7 days and the clinical measures were repeated. Examiners were blinded to measurements taken by the different examiners during the two measurement days. Results. Measurements taken with the tape measure had the strongest interrater reliability (moderate), followed by caliper (fair to moderate), then finger width palpation (poor to moderate). Tape measure also exhibited the strongest intrarater reliability ranging from good to very good (ICC=0.77-0.83). Finger width palpation followed with good intrarater reliability (ICC=0.63-0.76) and the caliper ranged from moderate to good (ICC=0.53-0.61). Concurrent validity was fair to moderate for finger width palpation (ICC=0.36-0.56) while the other measurement tools were deemed fair (ICC=0.21-0.39). All three measurement tools had excellent specificity (96.3-100%) but low sensitivity (<25%). Urinary incontinence and DRA were correlated with a moderate effect size and 4.9 odds ratio. Conclusions. Methods commonly used to screen for DRA have moderate interrater reliability, good to very good intrarater reliability, fair to moderate concurrent validity, and excellent specificity with low sensitivity. DRA and urinary incontinence are correlated.

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## **Chapter 1: Introduction**

#### Introduction

This dissertation was developed to determine whether measurement tools used in the clinic effectively screen for diastasis recti abdominis (DRA), so proper diagnosis and treatment can be implemented. Specifically, finger width palpation, tape measure, and caliper measurement were compared to the clinical best standard, ultrasound imaging.

In the first chapter, the statement of the problem is introduced, along with the relevance, significance, and need for the study. The four research questions, along with hypotheses, are discussed. Lastly, operational definitions for 12 terms used in the dissertation report are included.

#### Statement of the Problem

Diastasis recti abdominis is a condition where the medial rectus muscle bellies separate at the linea alba (Figure 1).<sup>1</sup> DRA is often seen during the childbearing year; between 66%-100% of women during the third trimester have a DRA and up to 53% during the immediate postpartum period.<sup>2</sup> Incidence of DRA declines during the first 8 weeks after childbirth, but does not always resolve.<sup>3</sup> Mota et al<sup>4</sup> report the incidence of DRA in older, parous women undergoing hysterectomy at 38.7% and 52% for urogynecological menopausal women. Risk factors for DRA include routinely lifting heavy objects,<sup>4,5</sup> chronic obstructive pulmonary disorder,<sup>4</sup> obesity,<sup>4</sup> multiparity,<sup>6</sup> and lack of activity during pregnancy.<sup>7,8</sup>

Figure 1. DRA Schematic



Illustration courtesy of Kristen Roehling

DRA is not only prevalent in women, but can also occur in men<sup>9</sup>; however, there have been no published studies reporting the incidence of DRA in men in the general population. Risk factors for men include increasing age, weight fluctuations, weightlifting, full sit-ups, genetic weakness of the abdominal muscles, chronic or intermittent abdominal distention, and frequent intraabdominal pressure.<sup>10</sup> McPhail et al<sup>11</sup> found a significantly higher prevalence of DRA in Caucasian males with abdominal aortic aneurysms (66.7%) compared to Caucasian males with peripheral arterial disease (16.7%). However, this study only compared the two cardiovascular groups and did not compare to the general population. If a DRA goes untreated, poor posture,<sup>3</sup> low back pain,<sup>3</sup> poor cosmetic appearance,<sup>12</sup> stress urinary incontinence,<sup>13</sup> fecal incontinence,<sup>13</sup> pelvic organ prolapse,<sup>13</sup> low back pain,<sup>1,6,12,14</sup> and decreased quality of life<sup>1</sup> may result. There have been no published studies examining the costs associated with DRA; however, the costs associated with conditions correlated with DRA are high. Chronic back pain costs \$50 billion per year in healthcare costs, disability, and productivity loss.<sup>15</sup> Women with stress urinary incontinence spend on average \$750 annually to manage this condition.<sup>16</sup> If physical therapists use accurate methods to screen for DRA, a diagnosis can be made and a proper surgical referral or physical therapy treatment can be initiated to mitigate the risk of developing these conditions.

The presence of a DRA is assessed by measuring the interrecti distance (IRD). To measure IRD, ultrasound imaging is the best standard for clinical practice<sup>1</sup>; however, equipment is expensive and extensive training is required. Therefore, most physical therapists utilize finger-width measurement, a tape measure, or a caliper to measure IRD.<sup>9</sup> For these measurements, clinimetric properties have not been well established. Therefore, the current study compares the reliability, validity, and diagnostic accuracy of finger width, tape measure, and caliper measurements to the clinical best standard, ultrasound imaging.

#### Relevance, Significance, and Need for Study

Computer tomography (CT) and magnetic resonance imaging (MRI) are the gold standards for diagnosing DRA; however, neither are practical given the high cost plus the radiation exposure associated with CT.<sup>1</sup> Therefore, ultrasound imaging, which is more cost effective, has become the clinical best standard for diagnosing DRA. Mendes et al<sup>17</sup> compared the accuracy of IRD measurements with ultrasound imaging to IRD measurements taken during abdominoplasty. There were no differences between ultrasound imaging and surgical measurements at the umbilicus and above the umbilicus, but ultrasound imaging measurements were smaller below the umbilicus. This difference may have been due to the presence of fibrosis from cesarean section scarring, since 19 of the 20 participants in the study had undergone a previous cesarean section. Also, good intrarater reliability has been established for experienced clinicians trained in ultrasound imaging<sup>18</sup>; however, reliability ranges from low to high for a newly trained clinician with only eight hours of instruction, consisting of three hours of lecture, three hours of practical instruction, and two hours of supervised one-on-one practice.<sup>19</sup> Therefore, clinicians using ultrasound imaging should be adequately trained and demonstrate proficiency. This study utilized a physician and a physical therapist who are both accredited medical sonographers (RDMS). Ultrasound imaging has also been shown to be reliable for IRD measurements at rest, during partial sit-up, and while a subject draws-in the umbilicus when measured above the umbilicus in healthy females ranging from nulliparous to postpartum.<sup>4</sup>

Although more affordable and practical in a clinical setting compared to CT and MRI, ultrasound imaging requires costly equipment and training. Only 4.4% of women's health physical therapists utilize ultrasound imaging.<sup>9</sup> The majority of women's health physical therapists utilize finger width palpation (96.6%), tape measure (17%) and caliper (1.7%). Therefore, the current study examined the clinimetric properties of these three clinical measurement tools compared to ultrasound imaging.

Palpation and measuring the number of fingers which fit between the rectus abdominis muscle separation (finger width palpation) is the most widely used technique in the clinical setting.<sup>9</sup> Mota et al<sup>20</sup> examined the criterion validity and reliability of finger width palpation compared to ultrasound imaging in healthy women. There was no difference between ultrasound

imaging and finger width palpation with the experienced clinicians; however, there was significant difference between ultrasound imaging and finger width palpation from the nonexperienced clinician. Intrarater reliability was good and interrater reliability was moderate. Bursch<sup>21</sup> examined the interrater reliability of finger width palpation in women who were 4 days postpartum vaginal delivery. There was a moderate correlation between the experienced clinicians, but overall finger width palpation was not reliable. Therefore, with inexperienced clinicians, finger width palpation has been shown to be not valid or reliable.

There has been only one published study examining the clinimetric properties measuring IRD with a tape measure; however, the Fundamentals of Pregnancy and Postpartum Physical Therapy course sponsored by the American Physical Therapy Association Section on Women's Health promotes its use and 17% of women's health physical therapists use this technique.<sup>9,22</sup>

Calipers are the least used measurement tool amongst women's health physical therapists; however, this tool has the strongest validity and reliability. Chiarello and McAuley<sup>18</sup> compared caliper measurements to ultrasound imaging in males and females. There was no difference between measurements taken above the umbilicus. Barbosa et al<sup>1</sup> examined the validity of calipers compared to ultrasound imaging in women during the immediate postpartum period. There was good agreement between the two measurement tools. A moderate correlation (r>0.5) was found for measurements taken at 3 cm, 6 cm, and 9 cm above the umbilicus and a strong correlation (r>0.75) 12 cm above the umbilicus.

The clinical best standard, ultrasound imaging, also has very high intrarater reliability<sup>18</sup> and validity when measured above the umbilicus, but not below.<sup>17</sup> DRA can occur at any level along the linea alba but the incidence is highest at the umbilicus (52%) and above the umbilicus (36%) with only 11% occurring below.<sup>3</sup> In addition, all of the subjects with a DRA below the

umbilicus had a DRA at or above the umbilicus. Therefore, the current study only screened for DRA at the umbilicus and above.

Published studies examining IRD measurement tools have focused on reliability and validity, but specificity and sensitivity have primarily not been reported. Given a tool's discrimination of whether DRA is present or absent, examining sensitivity and specificity is vital. Also, there has not been a single study comparing all four clinical IRD measurement techniques. This study examined validity, reliability, and sensitivity/specificity for finger width palpation, tape measure, and caliper measurements compared to ultrasound imaging when assessing for DRA.

#### **Research Questions Investigated**

The broad objective of this research was to determine whether measurement tools used in the clinic effectively screen for DRA, so proper diagnosis and treatment can be implemented to reduce the negative impact on quality of life. The primary aim of this study was to compare the reliability, validity, and diagnostic accuracy of finger width palpation, tape measure, and caliper measurements to the clinical best standard, ultrasound imaging. A secondary purpose was to determine whether there is a correlation between low back pain, pelvic pain, incontinence, and pelvic organ prolapse and DRA.

The research questions are as follows:

- 1. What is the intrarater and interrater reliability of finger width palpation, tape measure, and caliper measurement when measuring IRD?
  - a. Research Hypothesis (H<sub>1</sub>): There will be good intrarater and interrater reliability (ICC  $\geq 0.80$ ) of finger width palpation, tape measure, and caliper measurement when measuring IRD.

- b. Null Hypothesis (H<sub>01</sub>): There will not be good intrarater and interrater reliability (ICC  $\leq 0.79$ ) of finger width palpation, tape measure, and caliper measurement when measuring IRD.
- 2. When measuring IRD, what is the concurrent validity of finger width palpation, tape measure, and caliper measurement compared to the clinical best standard, ultrasound imaging?
  - Research Hypothesis (H<sub>2</sub>): There will be good concurrent validity (ICC ≥ 0.61) of finger width palpation, tape measure, and caliper measurement compared to the clinical best standard, ultrasound imaging, when measuring IRD.
  - b. Null hypothesis (H<sub>02</sub>): When measuring IRD, there will not be good concurrent validity (ICC  $\leq 0.60$ ) of finger width palpation, tape measure, and caliper measurement compared to the clinical best standard, ultrasound imaging.
- 3. What is the diagnostic accuracy of finger width palpation, tape measure, and caliper measurement when measuring IRD?
  - a. Research Hypothesis (H<sub>3</sub>): When measuring IRD, finger width palpation, tape measure, and caliper measurements will be accurate (p>0.05) compared to the clinical best standard, ultrasound imaging.
  - b. Null Hypothesis (H<sub>03</sub>): When measuring IRD, finger width palpation, tape measure, and caliper measurements will not be accurate (p>0.05) compared to the clinical best standard, ultrasound imaging.
- 4. What is the correlation between low back pain, pelvic pain, incontinence, and pelvic organ prolapse and DRA?

- a. Research Hypothesis (H<sub>4</sub>): There will be a strong correlation (Cramer's V ≥ 0.60)
  between low back pain, pelvic pain, incontinence, and pelvic organ prolapse and DRA.
- b. Null Hypothesis (H<sub>04</sub>): There will not be a strong correlation (Cramer's V  $\leq$  0.59) between low back pain, pelvic pain, incontinence, and pelvic organ prolapse and DRA.

#### **Operational Definitions**

<u>**Caliper Measurement**</u> – Measuring the interrecti distance by palpating the medial borders of the recti abdominis, inserting then widening the caliper tips until they snugly fit between the muscle bellies, and recording the distance in centimeters.<sup>23</sup>

**Diastasis Rectus Abdominis** – Separation of the right and left medial rectus muscle bellies at the linea alba.<sup>9</sup> A separation greater than 2 finger widths  ${}^{3,9,24}$  or 2 cm ${}^{25,26,27}$  at the linea alba is considered a DRA.

Fecal Incontinence – Inability to control flatulence and/or feces.<sup>28</sup>

**Finger Width Palpation** – Measuring the interrecti distance by recording the number of fingers that fit between the medial borders of the rectus abdominis.<sup>23</sup>

Inter-recti Distance – Distance between the two rectus abdominis muscles.<sup>29</sup>

Linea Alba – A meshwork of collagen fibers formed from the aponeuroses of the external abdominal obliques, internal abdominal obliques, and transverse abdominis. The linea alba spans from the xiphoid process to the pubic symphysis and its function is to maintain proximity of the bilateral rectus abdominis.<sup>30</sup>

**Low Back Pain** – Pain, muscle stiffness or tension experienced between the costal margin and inferior gluteal folds, and may or may not be accompanied with leg pain.<sup>31</sup>

<u>Pelvic Girdle Pain</u> – Pain located in the posterior pelvis below the lumbar spine which may or may not radiate to the groin or pubic symphysis and three positive provocation tests, including posterior pelvic pain provocation tests, active straight leg raise, and sacral compression test.<sup>32</sup>

<u>Pelvic Organ Prolapse</u> – Protrusion of pelvic organs through the urogenital diaphragm into or past the vagina.<sup>28</sup> Individuals with pelvic organ prolapse will report a feeling of heaviness in the pelvic region or a feeling that something is falling out of the vagina or rectum.

Pelvic Pain – Pain located in the lower abdomen, pelvis, or perineum.<sup>33</sup>

<u>Stress Urinary Incontinence</u> – Involuntary loss of urine occurring with sneezing, coughing, or physical exertion.<sup>28</sup>

<u>**Tape Measure Measurement**</u> – Measuring the interrecti distance by palpating the medial borders of the recti abdominis, measuring the distance between the medial borders using a tape measure, and recording the distance in centimeters.<sup>23</sup>

<u>Ultrasound Imaging Measurement</u> – The distance between the two medial recti abdominis muscle bellies captured via ultrasonography as measured using an onscreen ruler software feature.<sup>23</sup>

<u>Urgency Urinary Incontinence</u> – Involuntary loss of urine occurring with a strong urge to void.<sup>28</sup>

#### Summary

Diastasis recti abdominis is a condition which the medial rectus muscle bellies separate at the linea alba. DRA impacts males and females. If not treated, DRA has potential negative

consequences. Therefore, when screening for DRA, it is vital health care providers use reliable, valid, and accurate measurement tools.

Ultrasound imaging is the clinical best standard to screen for DRA; however, the equipment is expensive and extensive training is required. Therefore, most physical therapists use finger width palpation, tape measure, and/or caliper measurements. This study is the first to look at all three measurement tools together compared to ultrasound imaging and will provide new clinimetric information.

## Chapter 2: Review of the Literature

#### Introduction

Diastasis recti abdominis (DRA) is a condition in which the medial rectus muscle bellies separate at the linea alba. This condition negatively impacts both men and women. It is vital clinicians use a measurement tool to screen for DRA that is reliable, valid, and accurate. This study is the first study to examine the three most commonly used measurement tools together and compare to the clinical best standard to determine their reliability, validity, and accuracy.

This chapter focuses on the historical overview of the research literature, including what has been studied regarding the linea alba, prevalence of DRA, possible risk factors in women and men, possible consequences of DRA, and current treatment. The chapter then focuses on published literature specific to the clinimetric properties of ultrasound imaging, finger width palpation, tape measure, and caliper measurement.

#### Historical Overview of the Research Literature

#### The Linea Alba

The linea alba is comprised of collagen fibers formed by the aponeuroses of three abdominal muscles: the external and internal abdominal obliques and the transverse abdominis, and spans from the xiphoid process down to the pubic symphysis.<sup>30</sup> Its function is to keep the right and left rectus abdominis muscles in close proximity to each other.<sup>34</sup> The linea alba widens under chronic increased intra-abdominal pressure, which often occurs with pregnancy, consistent cough, weight gain and certain exercises, such as full sit-ups.

One hundred fifty nulliparous women whose body mass index was less than  $30 \text{ kg/m}^2$  were studied to determine the normal width of the linea alba.<sup>34</sup> The linea alba was considered

nonpathological with a width of 1.5 cm at the xiphoid, 2.2 cm measured 3.0 cm above the umbilicus, or 1.6 cm measured 2 cm below the umbilicus (Table 1). However, these measurements pertain to women who have not been pregnant and who are not obese.

Rath et al<sup>35</sup> defined pathological interrecti distance (IRD), the space between the two rectus muscle bellies at the linea alba, in men and women with suspected intraabdominal disease. Forty male and female participants with a mean age of 51.5 years  $\pm$  19.6 years participated in the study. For participants younger than 45 years, an IRD greater than 1.0 cm measured above the umbilicus, 2.7 cm at the umbilicus, or 0.9 cm below the umbilicus were considered pathological. For participants older than 45 years, an IRD greater than 1.5 cm measured above the umbilicus, 2.7 cm at the umbilicus, or 1.4 cm below the umbilicus were classified pathological. However, even though male participants exhibited a statistically significant wider IRD (p=0.01) than female participants, these measurement guidelines are the same for males and females.

Also, sex differences in linea alba composition have been found.<sup>30</sup> A greater number of transverse fibers, which counteract intraabdominal pressures commonly seen in pregnancy, were present in female cadavers, whereas male cadavers presented with more oblique fibers. Oblique fibers are primarily involved in trunk movement. Female cadavers presented with 60% transverse fibers compared to 37.5% in males. Also, increased stiffness has been noted in transverse linea alba collagen fibers. Another cadaver study<sup>36</sup> found female cadavers had increased stiffness in the infraumbilical region, compared to male cadavers; this could be expected as increased stiffness is needed to decrease linea alba deformity during pregnancy. Therefore, should normal IRD be the same for both sexes, as suggested by Rath et al<sup>35</sup>?

	Population	IRD	IRD	IRD
		above	at	below
		umbilicus	umbilicus	umbilicus
Beer et al <sup>34</sup>	Nulliparous women	> 2.2 cm	Not defined	>1.6 cm
(2009)	Aged $20 - 45$ years			
	BMI <30			
Rath et al <sup>35</sup>	Male and females <45 years	>1.0 cm	>2.7 cm	>0.9 cm
(1996)	Male and females >45 years	>1.5 cm	>2.7 cm	>1.4 cm

Table 1. Pathological IRD Based on Cadaver Studies

#### Prevalence of DRA

The prevalence of DRA is unknown in the general population. Only two studies have examined prevalence in both males and females, both being cadaver studies. Chiarello et al<sup>29</sup> examined 34 cadavers (18 male and 16 female) between the ages of 47 and 99 years. The only exclusion criteria were tearing of the linea alba during the postmortem dissection. The study found 74% of the cadavers had a DRA; however, this percentage seems high compared to published studies examining prevalence in high risk populations, such as postpartum, whose incidence is less than 74%.

Chiarello et al<sup>37</sup> examined 30 cadavers (22 male and 8 female) with a mean age of  $82\pm7.5$  years. Eight cadavers had a DRA, for an overall prevalence of 26.7%, with 23% male and 38% female exhibiting DRA. This prevalence is significantly less than the previous study<sup>29</sup> which may be due to cadavers with surgical abdominal scars were excluded but were not excluded in the previous study. Chiarello et al<sup>29</sup> found surgical abdominal scarring significantly predicted DRA above the umbilicus (p=.0222) and at the umbilicus (p=.0131). Given this study excluded a potential risk factor for DRA, prevalence may be lower. A retrospective chart review of women who visited a urogynecology practice for treatment of pelvic pain, urinary incontinence, fecal incontinence, and/or pelvic organ prolapse was conducted.<sup>13</sup> A total of 547 charts were reviewed

and 52% of the women (mean age of 52 years) had DRA. However, Spitznagle et al<sup>13</sup>defined DRA as an IRD of 0.5 fingerbreadths or greater, whereas DRA is typically defined as greater than 2 fingerbreadths, commonly referred to as the Noble criteria.<sup>3,5,21</sup> Using the more commonly accepted DRA definition, only 12.6% of the women would have DRA.

The prevalence of DRA during pregnancy has been reported to range from 66% to 100% during the third trimester<sup>3,38</sup> and between 34.9% to 68% during the postpartum period (Table 2).

	Number of	Time Frame when	Prevalence of	Definition
	Participants	IRD Measured	DRA	of DRA
Rett et $al^{39}$ (2009)	467	6 hours	68.0%	> 2 cm
Candido et al <sup>12</sup> (2005)	208	48 hours	34.9%	> 2.5 cm
Bursch <sup>21</sup> (1987)	40	< 4  days	62.5%	> 2 fingers
Boissonnault and Blaschak <sup>3</sup> (1988)	71	5 - 12 weeks	52.0%	> 2 fingers
Sperstad et $al^5$ (2016)	300	6 weeks	60.0%	> 2 fingers
Mota et al <sup>38</sup> (2015)	84	6-8 weeks	52.4%	> 1.6 cm
Parker et $al^{40}$ (2009)	53	$\geq$ 3 months	50.9%	> 2 cm
Mota et al $^{38}$ (2015)	84	12 – 14 weeks	53.6%	> 1.6 cm
Mota et al <sup>38</sup> (2015)	84	6 months	39.3%	> 1.6 cm
Sperstad et $al^5$ (2016)	300	6 months	45.4%	> 2 fingers
Sperstad et $al^5$	300	12 months	32.6%	>2 fingers
Gitta et $al^{41}$ (2016)	200	Not given	46.5%	Not given

Table 2. Prevalence of DRA During the Postpartum Period	b
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#### Possible Risk Factors in Women

Several studies have identified potential risk factors for DRA in women, with some risk factors being more supported by the literature than others. These possible risk factors include

pregnancy, ethnicity, multiparity, childcare responsibilities, not engaged in regular exercise before or during pregnancy, cesarean section, multiple gestation, advanced age, weak pelvic floor muscle strength, maternal age, greater weight gain during pregnancy, and larger birth weight.

#### Pregnancy

Due to the hormonal influence on the linea alba connective tissue and the mechanical stresses placed on the abdominal wall by an expanding uterus, a DRA typically develops during the second trimester and is most severe by the end of the third trimester.<sup>3</sup> By the end of the third trimester, the waist circumference can increase up to 50 cm and the recti abdominis muscles can stretch up to 20 cm.<sup>42</sup> Coldron et al<sup>43</sup> studied 115 postpartum women (72 primiparous, 43 multiparous) and 69 age-matched nulliparous women. Across the first year, IRD was significantly larger than controls (p<0.0001). Within the postpartum group, IRD decreased the most during the first two months after delivery (p<0.0001) but remained larger than the control group at 12 months. Typically, the greatest natural recovery of DRA occurs during the first eight weeks after delivery; then, after eight weeks, recovery plateaus.<sup>14</sup>

#### Ethnicity

Two studies have found Caucasian and Asian ethnicities increase the risk for developing a DRA.<sup>12,13</sup> Racial differences in connective tissue may be a contributing factor.

#### Multiparity

Multiple studies have found multiparity, giving birth two or more times, increases a woman's risk for DRA.<sup>6,8,13,41,44</sup> Previous pregnancies may further weaken the abdominal musculature, or a previous DRA may not have completely recovered. If there's a separation of

the abdominal muscles, however mild, the mechanical stresses on the abdominal wall and hormonal changes during pregnancy can exacerbate a DRA.

A positive correlation between parity and DRA (p<0.001) was found in 95 participants, aged 19 to 24 years, who visited a Turkish gynecology practice with the primary complaint of a vaginal infection.<sup>44</sup> There was no incidence of DRA in nulliparous participants, while 2% primiparous and 59% multiparous women had a DRA. The mean IRD measured in nulliparous, primiparous, and multiparous groups were  $0.15\pm0.4$  cm,  $0.98\pm0.35$  cm, and  $2.35\pm1.01$  cm, respectively.

Lo et al<sup>8</sup> discovered women with a DRA were more likely to be multiparous versus primiparous, 67.3% versus 50% (p=0.01). Dalal et al<sup>6</sup> found 60% of postpartum multiparous women compared to 40% primiparous women who were being treated for lumbopelvic or pelvic floor dysfunction exhibited a DRA. Gitta et al<sup>41</sup> found a significant correlation (p<0.001), as well as Spitznagle et al<sup>13</sup>. Only one study did not find a correlation (p=0.10) between multiparity and DRA.<sup>12</sup>

#### Childcare Responsibilities

Two studies have found providing childcare involving frequent lifting and carrying young children increases the risk for DRA.<sup>5,12</sup> Frequent lifting and carrying can cause strain and further weakening of the abdominal wall. Also, women who do not lift properly, and perform a Valsalva maneuver when lifting, also places them at greater risk. Candido et al<sup>12</sup> found multiparous women were almost 12 times more likely to have a DRA if they provided the childcare (p<0.001). Sperstad et al<sup>5</sup> found women performing heavy lifting more than 20 times each week were 20 times more likely to develop a DRA (OR 2.18, 95% CI 1.05-4.52).

#### Not Engaged in Regular Exercise Before or During Pregnancy

Multiple studies have shown exercise before or during pregnancy decreases the risk of developing DRA<sup>2,7,12</sup>; however, two studies did not show exercise has a protective response.<sup>5,38</sup> Chiarello et al<sup>7</sup> examined the effects of exercise during pregnancy. Ninety percent of women who did not exercise developed a DRA compared to only 12.5% who participated in an exercise program consisting of pelvic tilts, pelvic floor and transverse abdominis strengthening, and education on prenatal body mechanics.

Candido et al<sup>12</sup> found women who either had no DRA or a mild DRA exercised at least two times each week compared to women with a moderate or severe DRA. Over 19% of women with either no or mild DRA were vigorous exercisers compared to 11.8% with moderate to severe DRA.

A systematic review pooled the data from three studies (n=228) and found exercise performed during pregnancy reduced the incidence of DRA by 35% (RR 0.65, 95% CI 0.46-0.92).<sup>2</sup> Therefore, for every three women who exercise, exercise would prevent DRA in one woman. Also, data pooled from two studies found a 6-week antenatal abdominal strengthening program significantly decreased IRD. Mean IRD in the exercising group was 1.14 cm (0.38 cm) compared to 5.95 cm (2.36 cm) in the non-exercising group.

#### Delivery via Cesarean Section

Two studies found cesarean section increases risk<sup>8,44</sup> and three studies did not show cesarean section to be a risk factor.<sup>5,12,45</sup> Lo et al<sup>8</sup> discovered 47.5% participants with DRA delivered via cesarean section versus 24% vaginal delivery (p=0.003) and hypothesized damage to the aponeuroses and nerves during abdominal surgery decreases the integrity and strength of the abdominal wall. Volkan et al<sup>44</sup> reports the incidence of DRA increased significantly after a

second cesarean section (p=0.004). Spitznagle et al<sup>13</sup> and Chiarello et al<sup>29</sup> did not examine cesarean section specifically but found an abdominal surgical history increased the risk for DRA (p<0.001 and p=0.0131, respectively).

#### Multiple Gestation

Multiple gestation, carrying two or more fetuses at one time, increases a woman's risk for DRA.<sup>46</sup> Multiple gestation is often associated with a wider abdominal circumference and increased stretching of the abdominal wall. Lo et al<sup>8</sup> found 27.3% of DRA cases where multiple gestation versus 1.7% in the control group (p<0.0001). Candido et al<sup>12</sup> did not find multiple gestation to be a risk factor; however, there were only 10 participants who carried multiple gestation, so a limited sample size may not have been adequate to delineate this risk factor.

#### Advanced Age

Only one study looked at women in the more advanced age group and found women who were post-menopausal (p<0.001) and are using hormone replacement therapy (p<0.001) are at greater risk for DRA.<sup>13</sup> The authors did not have an explanation for the increased incidence of DRA with hormone replacement therapy since this was the first study to examine the relationship between hormone replacement therapy and DRA. The age-related changes to connective tissue elasticity, especially if a separation did not get resolved during a woman's younger years, may explain the increased incidence. Previous studies examining risk factors included women either in the postpartum period<sup>8,12,38,41</sup> or between the ages of 19 to 24 years<sup>44</sup>, too young for hormone replacement therapy. Chiarello<sup>29</sup> examined risk factors in cadavers but whether the cadavers took HRT was not known.

#### Weak Pelvic Floor Muscle Strength

Spitznagle et al<sup>13</sup> discovered a higher percentage of women with DRA had weak pelvic floors compared to women without DRA (p<0.01).

#### Maternal Age

One study found maternal age to be a risk factor<sup>8</sup>, and four studies did not find maternal age correlated with DRA.<sup>5,12,38,39</sup> Lo et al<sup>8</sup> found women whose mean age was 34 years versus 30.4 years had a higher risk for developing DRA (p<0.001) and proposed age-related muscle weakness could be a contributing factor. However, do muscles weaken that much over a 3.6-year span for women in their thirties? Given four other studies did not find maternal age to be a risk factor, it is questionable whether women giving birth at a later age plays a role in developing DRA.

#### Greater Weight Gain during Pregnancy

Only one study found greater weight gain during pregnancy increases the risk of developing DRA<sup>8</sup> and three studies did not reach the same conclusion.<sup>5,12,38</sup> Lo et al<sup>8</sup> found women who had DRA gained on average 35.3 pounds during pregnancy, whereas women who did not have DRA gained an average of 30.7 pounds (p=0.02). A possible explanation given was greater weight gain may lead to increased stretching of the abdominal wall, but would weight gain less than 5 pounds lead to significantly more stretching? A limitation of this study is how DRA diagnosis was made. DRA was diagnosed if the IRD exceeded 2.5 cm or if a visible bulge was detected during physical activity. Observing a bulge is not a validated or reliable method to diagnose.

#### Larger Birth Weight

Only one study found giving birth to a larger baby increases the risk for DRA<sup>8</sup> and two studies did not reach the same conclusion.<sup>5,38</sup> Lo et al<sup>8</sup> found women who had DRA gave birth to a baby with a mean birthweight of 3637.0 g (8.0 pounds) compared to women without DRA, whose baby's average birthweight was 3263.5 g (7.2 pounds) (p<0.001). A possible rationale is increased stretching of the abdominal wall as a result of a larger birth weight. However, a non-validated or reliable method, a visible bulge during physical activity, was used to diagnose DRA.

#### Possible Risk Factors in Men

Risk factors for DRA in males have not been studied in as much depth as female risk factors. Possible risk factors include increased advanced age, weight fluctuations, congenital weakness of abdominal muscles, waist girth, and activities that increase intra-abdominal pressure, such as weight lifting, strenuous physical activity and performing full excursion sit-ups.<sup>10,29,47</sup> Rath et al<sup>35</sup> discovered increased IRD measurements in the supraumbilical linea alba (p=0.005) and in the infraumbilical linea alba (p=0.003) in the older participants. No difference was noted at the level of the umbilicus. Chiarello et al<sup>29</sup> discovered abdominal girth greater than 102 cm (40 inches) increases the risk for DRA (p=0.0016). A stepwise regression analysis showed for every centimeter above 102 cm, there was an IRD increase of 0.14 cm.

Also, McPhail<sup>11</sup> found a correlation between DRA and abdominal aortic aneurysm (AAA). In the study, 42 Caucasian males with either an AAA (n=18) or atherosclerotic peripheral arterial disease (PAD) in the lower extremities (n=24) were evaluated for DRA via visual observation. Diastasis rectus abdominis was present in 66.7% men with AAA versus 16.7% with PAD (p=.001), indicating a four times higher risk in older males with AAA than PAD. However, a limitation of this study is diagnosis was made if a visible bulge in the linea

alba above the umbilicus was seen during a sit-up, which is not a validated or reliable method to diagnose.

However, Moesbergen et al<sup>48</sup> did not find a correlation between AAA requiring surgical repair and DRA. The prevalence of DRA in men seeking AAA repair was 67% compared to 63% in the control group.

#### Possible Consequences of DRA

The abdominal wall plays a key functional role in posture, trunk and pelvic stability, breathing, trunk movement, and supporting the viscera.<sup>2</sup> When there is a disruption in the abdominal wall, which occurs with a DRA, these functions are altered and can lead to multiple conditions as a result of lumbopelvic instability and pelvic floor weakness.<sup>2</sup>

Typically, patients are not referred to physical therapy for the treatment of DRA. Patients are often referred for another diagnosis, which DRA is identified and may be contributing to the primary diagnosis. Keeler et al<sup>9</sup> surveyed 296 women's health physical therapists throughout the United States and asked which primary diagnoses were most common for patients who they have treated for DRA. The most common diagnoses were low back pain (80.7%), followed by pelvic floor dysfunction (62.0%), pelvic pain (59.5%), and urinary incontinence (59.4%). Only 41.6% of physical therapists stated DRA was the primary diagnosis.<sup>9</sup>

Dalal et al<sup>6</sup> found a correlation between DRA and lumbopelvic pain in women who were 3 months or more postpartum. Prevalence of DRA in 30 women seeking physical therapy treatment for pelvic pain, low back pain, SI joint dysfunction, pubic symphysis dysfunction, or incontinence was 83.3%. There was no control group examining prevalence in women seeking physical therapy treatment for other body regions as a comparison, which was a limitation of the study.

Whitaker et al<sup>49</sup> measured the IRD in 50 male and female participants with and without lumbopelvic pain. Pain correlated moderately with IRD (r=0.51, p<0.001). Also, the Oswestry Disability Index, a validated tool used to quantify disability for low back pain, correlated moderately with IRD (r=0.43, p=0.02). In addition, the participants with lumbopelvic pain displayed a wider IRD compared to those without lumbopelvic pain.

Spitznagle et al<sup>13</sup> found women with DRA were 1.79 times more likely to have one or more pelvic floor dysfunction diagnoses than women without DRA (p<0.001). In women with DRA, the chances of developing stress urinary incontinence, fecal incontinence, and pelvic organ prolapse were 1.28, 2.56, and 2.25 times greater, respectively.

Volkan et al<sup>44</sup> studied 95 Turkish women between the ages of 19 and 24 years. The incidence of cystocele, rectocele, and uterine prolapse in women with a DRA were 57%, 50%, and 52%, respectively. Despite their young age, these women with DRA were already exhibiting pelvic organ prolapse.

Gitta et al<sup>41</sup> found a significant difference between postpartum women who have a DRA versus postpartum women without DRA in many categories, including decreased quality of life (p=0.017), low back pain (p=0.039), and urinary incontinence (p=0.028).

Parker et al<sup>40</sup> compared 39 women who gave birth at least 3 months prior and were seeking physical therapy treatment for lumbopelvic pain and pelvic floor dysfunction to a control group (n=53). There was a significant difference between those with and without a DRA on the Visual Analog Scale for abdominal and pelvic area pain (p=0.023) but not for lumbopelvic pain. Also, there was no correlation seen between DRA and stress urinary incontinence, fecal incontinence, or pelvic organ prolapse, unlike the study by Spitznagle et al.<sup>13</sup> However, in the Parker et al study<sup>40</sup>, the authors noted participants who experienced incontinence or pelvic organ prolapse could have been placed in the control group if they were not receiving treatment for these symptoms, though the number of these participants was not disclosed. This is a major limitation of the study since the control group did not truly serve as a control.

Another study that did not find a correlation between DRA and urinary incontinence or pelvic organ prolapse was conducted by Bo et al<sup>24</sup>. Three hundred primiparous women were examined at 21 weeks gestation and 6 weeks, 6 months, and 12 months postpartum. There was no statistically significant difference between women with and without DRA at any assessment point, except at 6 weeks postpartum, when 15.9% of women without a DRA exhibited stage 2 (1 cm or less from the hymenal ring) pelvic organ prolapse compared to 4.1% who had DRA (p=0.001). When possible confounders, such as body mass index and general physical activity were adjusted, statistical significance remained (p=0.0002). Therefore, primiparous women with DRA were not more likely to have pelvic organ prolapse or urinary incontinence up to one year postpartum.

Additionally, Braga et al<sup>50</sup> did not find a correlation (p=0.91) between DRA and stress urinary incontinence in postpartum women. However, IRD was measured using ultrasound imaging with the participants laying in supine without contracting their abdominal musculature. Screening for DRA in the clinical setting typically involves the individual laying in hook lying position while performing a mini abdominal curl-up during exhalation. If IRD was measured using the traditional method, IRD and confirmation of DRA may have had different results.

Mota et al<sup>38</sup> did not find a correlation between lumbopelvic pain and DRA at 6 months postpartum. There was no difference in prevalence of lumbopelvic pain in women with DRA (27.3%) compared to women without DRA (27.5%). However, this study defined DRA with an IRD 1.6 cm or greater measured 2 cm below the umbilicus. This definition was derived from a

study<sup>34</sup> using nulliparous women so the cut-off point for determining a DRA may have been too narrow for the postpartum population. Also, more women experience DRA at level of the umbilicus(52%) and above the umbilicus (36%) than below the umbilicus  $(11\%)^9$  so only measuring DRA below the umbilicus is another limitation of this study. Additionally, Sperstad et al<sup>5</sup> found no correlation between lumbopelvic pain in women with a mild DRA, defined as two to three finger width separation, at 12 months postpartum (p=0.10).

Lastly, there has been no correlation found between IRD and respiratory muscle strength during pregnancy.<sup>42</sup> Intuitively, as IRD widens, the core muscle group would be placed in a less optimal position, resulting in decreased inspiratory and expiratory muscle strength. A possible explanation given for this unexpected finding was possible recti abdominis muscle hypertrophy to counteract, though recti abdominis muscle hypertrophy was not studied.

#### Treatment of DRA

If DRA remains severe during the postpartum period, abdominal hernia, incarceration, or life-threatening strangulation may occur.<sup>51</sup> Surgery to correct DRA has been shown to decrease low back pain<sup>52-54</sup>; however, not all individuals are surgical candidates, such as women who plan to get pregnant in the future.<sup>54</sup> Complications have been noted with surgical repair, including encapsulated seromas and surgical repair failure.<sup>52</sup> Other complications from DRA surgical correction include hematomas, minor skin necrosis, wound infections, wound surgical scar dehiscence, post-operative pain, nerve damage, and a recurrence rate as high as 40%.<sup>55,56</sup> Given the risks with surgery, less invasive options, such as abdominal strengthening exercise, neuromuscular retraining, and electrical stimulation have also shown to be effective.<sup>2</sup>

Physical therapy has been shown to be very effective in reducing IRD. Gitta et al<sup>41</sup> found 24 physical therapy visits over a 3-month period focusing on transverse abdominis strengthening significantly reduced IRD in six post-partum women (p=0.028). Also, a case study report described a 32-year-old women referred to physical therapy at 7 weeks postpartum with an IRD of 11.5 cm at the umbilicus, and more than 9 cm along the linea alba.<sup>57</sup> The patient participated in 18 treatment sessions over a 4-month period with treatment consisting of patient education, progressive abdominal strengthening exercises with neuromuscular retraining, and support garments. By the end of treatment, IRD decreased to 2.0 cm at the widest distance. In addition, Deering et al<sup>58</sup> incorporated an 8-week abdominal retraining program for 13 female recreational runners who had given birth within the past 24 months and had a DRA as confirmed by ultrasound imaging. The IRD decreased significantly below the umbilicus (P=0.006) but not above (P=0.711). However, this may be due to the abdominal retraining program targeted the lower abdominals. The decrease in IRD below the umbilicus was also maintained 6 weeks after the abdominal retraining program had ended.

Schlaff et al<sup>59</sup> recruited 24 women with a DRA who were 6 to 12 weeks postpartum to determine which physical therapy intervention was most effective in reducing the DRA. Participants were randomly assigned to one of four groups: exercise, kinesiotaping, exercise plus kinesiotaping, or control. The exercise group focused on transverse abdominis strengthening 3 to 4 times each week for 12 weeks. The participants in the exercise plus kinesiotaping group exhibited the greatest reduction in IRD  $(1.31\pm 0.20 \text{ cm})$ , followed by exercise  $(0.91\pm 0.41 \text{ cm})$ , kinesiotaping  $(0.19\pm 0.39 \text{ cm})$  and control  $(0.23\pm 0.60 \text{ cm})$ . Transverse abdominis strengthening was an effective intervention to decrease IRD; combining transverse abdominis strengthening with kinesiotaping resulted in even greater IRD reduction.
Sancho et al<sup>45</sup> compared three traditional DRA-reducing exercises: abdominal crunch, drawing-in, and drawing-in plus abdominal crunch exercises. Supraumbilical IRD decreased the most during an abdominal crunch exercise (0.42 cm; 95% CI 0.05 to 0.79). This suggests abdominal crunches are most effective in reducing IRD.

In women with DRA who were 3 months to 3 years postpartum ,Walton et al<sup>60</sup> compared a 6-week supine strengthening treatment program (abdominal crunch, posterior pelvic tilt, Kegels, and Russian twist) to a dynamic core stabilization program (plank, posterior pelvic tilt, Kegels, and Russian twist). Both groups displayed a significant decrease in IRD (p=0.036), but the supine strengthening treatment group showed a slightly greater decrease from pre-test to post-test. Both groups also exhibited a significant improvement on the Oswestry Disability Index and Pelvic Floor Disability Index scores, with no differences noted between groups. Therefore, either a supine or dynamic core stabilization strengthening program can be effective in reducing DRA in postpartum women.

Khandale and Hande<sup>25</sup> studied 30 women who had just given birth and participated in an abdominal strengthening exercise program, 30 minutes per day, 5 days per week for 8 weeks. IRD decreased significantly from pre-intervention to post-intervention (p<0.0001); however, a control group was not utilized so it is not known whether lower abdominal strengthening exercise caused the reduction or whether natural resolution decreased IRD given the women began the intervention immediately following delivery, though the study does not specify how many days post-delivery.

One case study described a woman with DRA who was 8 years postpartum and had associated abdominal and lumbar back pain, weakness, fatigue, and decreased quality of life.<sup>61</sup> A 6-week program focusing on core strengthening, neuromuscular education, and aerobic exercise

resulted in a 79% and 48% improvement in physical Short Form 36 (SF36) and social SF36 scores, respectively. This case study highlights even eight years postpartum, positive results can be achieved through physical therapy intervention.

Lastly, in three postpartum females at various healing stages with DRA, one case series examined the effects of neuromuscular electrical stimulation applied to the abdominal muscles 30-minutes, five days per week for 12 weeks.<sup>62</sup> All three participants displayed a reduction in IRD and a significant improvement in Patient Specific Functional Scale (PSFS), surpassing the minimal detectable change for clinical significance. Participant 1's IRD decreased from 2 finger widths to 0 finger widths and PSFS score increased from 2.25 to 5.75, with a higher score indicating less activity limitation. Participant 2's IRD decreased from 3 to 2.25 finger widths and PSFS score increased from 4.4 to 7.6. Participant 3's IRD decreased from 2 to 0.25 finger widths and PSFS score increased from 4.33 to 6.67. This case series suggests further research should be conducted to determine the effects of abdominal neuromuscular electrical stimulation on DRA.

## Research Literature Specific to the Topic

There is agreement across the literature DRA is abnormal; however, there is no consensus on which IRD measurement warrants corrective intervention.<sup>63</sup> Beer et al<sup>34</sup> published guidelines on what IRD measurement is considered pathological; however, this guideline was based on a small population sub-set, nulliparous non-obese women. Rath et al<sup>35</sup> published guidelines but both men and women followed the same cut-off point despite men in the study having significantly wider IRD. Two other studies<sup>30,36</sup> showed sex differences in linea alba composition.

Some researchers consider an IRD measurement greater than  $1.5 \text{ cm}^{37}$  pathological, whereas others consider an IRD greater than  $2.0 \text{ cm}^{6,24,32}$  or  $2.5 \text{ cm}^{3,12}$  as pathological. Many

studies measuring IRD using finger width measurement follow Nobel's criteria, more than 2 finger widths as a DRA requiring corrective intervention.<sup>5,24,25</sup> Studies have followed various IRD measurements to define DRA (Table 3). Given there is no consensus on which IRD is considered a DRA requiring corrective intervention, the proposed study will utilize the most commonly used guideline, more than 2 finger widths or more than 2cm separation.

	IRD	IRD	IRD
	above umbilicus	at	below
		umbilicus	umbilicus
IR	D Measured in Fing	ger Widths	
Bo et $al^{24}$ (2016)	>2 fingers	>2 fingers	>2 fingers
Boissonnault & Blaschak <sup>3</sup> (1988)	>2 fingers	>2 fingers	>2 fingers
Bursch <sup>21</sup> (1987)	>2 fingers	N/A	N/A
Keshwani et al <sup>64</sup> (2015)	>2 fingers	>2 fingers	>2 fingers
Khandale & Hande <sup>25</sup> (2016)	>2 fingers	N/A	>2 fingers
Sperstad et al <sup>5</sup> (2016)	>2 fingers	>2 fingers	>2 fingers
Spitznagle et al <sup>13</sup> (2007)	>2 fingers	N/A	>2 fingers
Zachovajevas et al <sup>65</sup> (2012)	N/A	>2 fingers	N/A
II	RD Measured in Ce	ntimeters	
Candido et al <sup>12</sup> (2005)	>2.5 cm	>2.5 cm	>2.5 cm
Chiarello et al <sup>7</sup> (2005)	>2 cm	>2 cm	>1 cm
Chiarello et al <sup>37</sup> (2009)	>1.5 cm	>2.7 cm	>1.5 cm
Chiarello et al <sup>32</sup> (2017)	>2 cm	>2 cm	>2 cm
Dalal et al <sup>6</sup> (2014)	>2 cm	N/A	>2 cm
Lo et al <sup>8</sup> (1999)	>2 cm	N/A	>2 cm
Mota et al <sup>38</sup> (2015)	N/A	N/A	>1.6 cm

Table 3. IRD Criteria Used to Define DRA

Parker et $al^{40}$ (2009)	>2 cm	>2 cm	>2 cm
Rett et al <sup>39</sup> (2009)	>2 cm	N/A	>2 cm
Volkan et al <sup>44</sup> (2011)	>2 cm	N/A	N/A

Also, there is no international consensus on the best measurement location (Table 4).<sup>46</sup> Twenty-one studies measured the IRD at the superior border of the umbilicus, above the umbilicus and below. Eleven studies measured above and below the umbilicus but not at the superior umbilical border. Two studies measured above and at the level of the umbilicus, four studies measured above the umbilicus only, and four studies measured at the umbilicus only.

### Table 4. Location for IRD Measurements

Umbilicus, Above,	Above and Below	Umbilicus and	Above the	Umbilicus
and Below	the Umbilicus	Above	Umbilicus	
Boissonnault &	Mota et $al^4$ (2012)	Lee &	Barbosa et al <sup>1</sup>	Whittaker et al49
Blaschak <sup>3</sup> (1988)		Hodges <sup>67</sup> (2015)	(2013)	(2013)
Sperstad et al <sup>5</sup>	Dalal et $al^6$ (2014)	Lee &	Bursch <sup>21</sup>	Sclaff et al <sup>59</sup>
(2016)		Hodges <sup>68</sup> (2016)	(1987)	(2017)
Chiarello et al <sup>7</sup>	Lo et al <sup>8</sup> (1999)		Volkan et al <sup>44</sup>	Zachovajevas et
(2005)			(2011)	al <sup>65</sup> (2012)
Candido et al <sup>12</sup>	Spitznagle et al <sup>13</sup>		Pascoal et al <sup>69</sup>	Boxer & Jones <sup>66</sup>
(2005)	(2007)		(2014)	(1997)
Mendes et al <sup>17</sup>	Acharry &			
(2007)	Kutty <sup>14</sup> (2015)			
Bo et al <sup>24</sup> (2016)	Chiarello &			
	McAuley <sup>18</sup> (2013)			
Chiarello et al <sup>29</sup>	Mota et al <sup>20</sup>			
(2012)	(2013)			
Chiarello <sup>32</sup> (2017)	Khaneale &			
	Hande <sup>25</sup> (2016)			
Beer et al <sup>34</sup> (2009)	Chiarello et al <sup>27</sup>			
	(2016)			
Rath et $al^{35}$ (1996)	Ret et al <sup>39</sup> (2009)			

Chiarello et al <sup>37</sup>	Sancho et al <sup>45</sup>
(2009)	(2015)
Mota et al <sup>38</sup>	
(2015a)	
Parker et al <sup>40</sup>	
(2009)	
Lemos et al <sup>42</sup>	
(2011)	
Walton et al <sup>60</sup>	
(2016)	
Keshwani &	
McLean <sup>64</sup> (2015)	
Elliott-Burke &	
Kirk <sup>70</sup> (2017)	
Gillard et al <sup>71</sup>	
(2015)	
Mota et al <sup>72</sup>	
(2015b)	
Ponmathi et al <sup>73</sup>	
(2016)	
Rodrigues et al <sup>74</sup>	
(2015)	

This study measured above and at the level of the umbilicus, but not below. Ultrasound imaging served as the clinical best standard the other clinical measurement tools were compared. Measurements were taken below the umbilicus, since good reliability and validity have not been established for ultrasound imaging at the infraumbilical level.<sup>4,17,23</sup> Additionally, Boissonnault and Blaschak<sup>3</sup> discovered the majority, 52% of DRA occurred at the umbilicus, 36% above the umbilicus, and only 11% below. Also, all participants who displayed DRA below the umbilicus also had DRA either at the umbilicus or above. This further justifies not measuring IRD below the umbilicus, even though most studies do measure below.

There have been numerous studies not focused on establishing psychometric properties measuring IRD using various measurement methods, including computed tomography (CT),

ultrasound imaging, finger width palpation, tape measure, and caliper measurement. Studies using CT have focused on DRA surgical correction, with the exception of only one study which focused on physical therapy outcome.<sup>75</sup> Not only is it vital to utilize measurement tools with strong clinimetric properties in the clinical environment, it is also important to utilize measurement tools in research. Three studies not listed in Table 5 diagnosed DRA based on photograph<sup>76</sup>, visual inspection<sup>11</sup>, or plain abdominal radiograph.<sup>77</sup> Therefore, this study not only measures the reliability, validity, and diagnostic accuracy of tools physical therapists use in the clinical environment<sup>9</sup>, but also the tools used in research studies: finger width palpation, tape measure, and calipers compared to the clinical best standard, ultrasound imaging.

CT Scan	Ultrasound	Finger Width	Tape Measure	Calipers
	Imaging	Palpation		
Collie et al <sup>75</sup>	Beer et al <sup>34</sup> (2009)	Acharry et al <sup>14</sup>	Candido et al <sup>12</sup>	Boxer & Jones <sup>66</sup>
(2004)		(2015)	(2005)	(1997)
			× ,	
Emanuelsson et	Chiarello et al <sup>27</sup>	Bo et al <sup>24</sup>	Emanuelsson et	Chiarello et al <sup>7</sup>
$a1^{52}(2016)$	(2016)	(2016)	$a1^{52}$ (2016)	(2005)
ur (2010)	(2010)	(2010)	ui (2010)	(2003)
Moesbergen et	Coldron et al <sup>43</sup>	Boissonnault &	Litos <sup>57</sup>	Chiarello et $a1^{37}$
a <sup>148</sup> (2000)		Doissonnaurt $\alpha$	(2014)	
al <sup>10</sup> (2009)	(2008)	Blaschak <sup>3</sup> (1988)	(2014)	(2009)
Nahas et al <sup>78</sup>	Gillard at $a1^{71}$	Elliott Burke &	Shennard et al <sup>79</sup>	Chiarello et al <sup>29</sup>
		E = 1.70 (2017)		
(2001)	(2015)	$\mathbf{K}$ IFK <sup>++</sup> (2017)	(1996)	(2012)
Nahas et al <sup>80</sup>	Kaping et al <sup>81</sup>	Khandale &		Chiarello et al <sup>32</sup>
(2002)	(2015)	Hande <sup>25</sup> (2016)		(2017)
(2002)	(2013)	(2010)		(2017)
Nahas et al <sup>82</sup>	Lee et al <sup>68</sup>	Rett et al <sup>39</sup>		Dalal et al <sup>6</sup>
(2004)	(2016)	(2009)		(2014)
		( )		
Nahas et al <sup>83</sup>	Liaw et al <sup>26</sup>	Sperstad et al <sup>5</sup>		Gitta et al <sup>41</sup>
(2005)	(2011)	(2016)		(2016)
		<b>`</b>		×
Palanivelu et al <sup>84</sup>	Mota et al <sup>72</sup>	Spitznagle et al <sup>13</sup>		Hsia & Jones <sup>85</sup>
(2009)	(2015)	(2007)		(2000)

Table 5. Non-Psychometric	Published Studies that Measured	IRD using Specific Methods
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Rath et al <sup>35</sup> (1996)	Pascoal et al <sup>69</sup> (2014)	Volkan et al <sup>44</sup> (2011)	Khandale & Hande <sup>25</sup> (2016)
	Sancho et al <sup>45</sup> (2015)	Wade <sup>86</sup> (2005)	Lemos et al <sup>42</sup> (2011)
	Schlaff et al <sup>59</sup> (2017)	Wiley et al <sup>62</sup> (2017)	Parker et al <sup>40</sup> (2009)
	Van Uchelen et al <sup>56</sup> (2001)	Zachovajevas et al <sup>65</sup> (2012)	Ponmathi et al <sup>73</sup> (2016)
	Walton et al <sup>60</sup> (2016)		Walton et al <sup>60</sup> (2016)
	Whittaker et al <sup>49</sup> (2013)		
	Wiley et al <sup>62</sup> (2017)		

## Review of the Literature on Ultrasound Imaging.

Despite ultrasound imaging being the clinical best standard to screen for DRA, only 4.4% of women's health physical therapists utilize this tool.<sup>9</sup> The equipment is cost-prohibitive to many clinicians and extensive training is required. Hides et al<sup>19</sup> examined the intrarater reliability of a physical therapist who had received only 8 hours of ultrasound imaging training, classifying as a novice examiner. The training consisted of three hours of lecture, three hours of practical instruction, and two hours of supervised one-on-one practice. Reliability was examined across three measurements of the same ultrasound image, across three separate ultrasound images, and across two separate days on 19 male and female subjects. Reliability ranged from very high with the same image (ICC<sub>3,1</sub>>0.97) to low across images (ICC<sub>3,4</sub>=0.44) and images taken over two

separate days (ICC<sub>3,6</sub>=0.36). Therefore, if ultrasound imaging is used, the examiner must be experienced, and reliability must be assessed.

Ultrasound imaging has been shown to be a reliable and valid tool to screen for DRA above and at the level of the umbilicus, but not below. Mendes et al<sup>17</sup> compared IRD measurements taken with ultrasound imaging prior to surgery to measurements taken during open abdominoplasty. There were no differences between ultrasound imaging and measurements taken intraoperatively with a surgical compass at the umbilicus and above the umbilicus, but ultrasound imaging measurements were smaller below the umbilicus. The difference may have been due to the presence of fibrosis from cesarean section scarring, since 19 of the 20 subjects in the study had undergone a previous cesarean section. Also, images of the rectus abdominal muscles below the umbilicus lack definition, making it more difficult to take precise measurements.

Keshwani et al<sup>64</sup> examined the intrarater reliability measuring IRD using ultrasound imaging in postpartum women with a 2 finger width or greater IRD. Intraclass Correlation Coefficient (ICC) values were greater than 0.90 above, at, and below the umbilicus. Standard error of measurement varied between 0.11 to 0.27 cm. The minimal clinically important difference (MCID) was 0.27 to 0.46 cm at the umbilicus and above but was higher below the umbilicus, ranging from 0.52 to 0.75 cm. The higher MCID values below the umbilicus may be due to increased adipose tissue making measurement conditions more challenging. This study supports ultrasound imaging to be a reliable tool at the infraumbilical level (ICC>0.90); however, greater measurement error below the umbilicus exists.

Lower ICC values of measurements taken below the umbilicus were obtained by a study conducted by Mota et al<sup>4</sup> examining the test-retest reliability of ultrasound imaging. Twenty-four

women with different parity and time since given birth participated in this study. Reliability was assessed at rest and under two conditions which require the abdominal muscles to contract. Measurements were taken above and below the umbilicus on two separate days. Reliability for measurements taken above the umbilicus was very good at rest (ICC=0.98) and during abdominal contractions (ICC=0.83-0.90). However, only moderate reliability for measurements taken below the umbilicus during an abdominal crunch (ICC=0.50).

A systematic review<sup>23</sup> pooled the ICCs for intrarater reliability from three studies<sup>4,26,87</sup> and intrarater reliability was between 0.95 and 0.97 for measurements taken at different locations along the linea alba, as well as for resting and abdominal contraction measurements. Test-retest reliability had pooled ICCs of 0.81 to 0.94 for resting measurements and 0.68 to 0.86 for abdominal contraction measurements. Reliability was lower for measurements taken below the umbilicus, during an abdominal crunch, and for the novice sonographers.

A limitation of ultrasound imaging is the interrecti distance must fit within the width of the ultrasound transducer, which more severe DRA do not fit. For measuring the more severe DRA, utilizing other methods, such as an acoustic standoff pad (15 cm x 10 cm x 2 cm pad placed in between the skin and transducer) or panoramic technology (software that combines successive images to create one image), both considered extended field of view (FOV) methods, is necessary.<sup>88</sup> Keshwani et al<sup>88</sup> examined the criterion validity and reliability of using extended FOV technique when measuring IRD of three finger widths or less. Results found measurements using extended FOV were not different than standard ultrasound imaging (P=.441) and were highly correlated to measurements taken using standard ultrasound imaging (r>0.95, p<.00001). Standard error of measurement of each extended FOV technique was small, 0.17-0.18 cm. High reliability was also noted with ICC<sub>3,1</sub>>0.90 for all three techniques. In conclusion, extended FOV

technique is valid and reliable when measuring IRD. The proposed study would have utilized panoramic technology if needed.

### Review of the Literature on Finger Width Palpation.

Only two studies have been published examining the psychometric properties of finger width palpation, which is a method 96.6% of women's health physical therapists use to screen for DRA.<sup>9</sup>

Bursch<sup>21</sup> examined the interrater reliability of finger width palpation in 40 women who were less than four days postpartum. There were four examiners measuring DRA: two experienced and two non-experienced. The two experienced clinicians had the highest reliability with a correlation of 0.75; however, there was a statistically significant difference between the raters' measurements (p<0.0005). It was postulated the difference in measurements may be due to different widths of the examiners' fingers and the variability in pressure applied to the abdomen which would affect the depth of measurement. The study concluded finger width measurement is not a reliable method to screen for DRA.

Mota et al<sup>20</sup> examined intrarater and interrater reliability of finger width palpation in 20 healthy women, 12 being post-partum. One physical therapist had 31 years of experience measuring IRD and the other had 7 years of experience. Intrarater reliability was good (weighted Kappa greater than 0.7) for both physical therapists and interrater reliability was moderate (weighted Kappa =0.534) with a percentage agreement of 62.5%. The lower interrater reliability may have been due to differences in amount of experience between the two physical therapists, though both had significant experience, differences in finger width, and/or differences in amount of pressure applied to the soft tissue while measuring.

Review of the Literature on Tape Measure.

When screening for DRA, 17% of women's health physical therapists measure IRD using a tape measure.<sup>9</sup> The American Physical Therapy Association Section on Women's Health Fundamental Topics of Pregnancy and Postpartum Physical Therapy course teaches participants to use tape measurement when screening for DRA.<sup>22</sup>

Only one published study has examined the psychometric properties of tape measurement. Emanuelsson et al<sup>89</sup> compared tape measurements taken in the clinic office, as well as intraoperatively, to computer tomography in 55 male and female participants undergoing DRA surgical repair. Clinical tape measurement overestimated IRD by more than 0.5 cm in 35% of participants when compared to intraoperative measurements. Concordance Correlation Coefficients of 0.37-0.48 were calculated between clinical and intraoperative measurements indicating poor agreement.

### Review of the Literature on Calipers.

Despite the supporting research, low cost, and no extensive training required, only 1.7% of women's health physical therapists utilize calipers when screening for DRA.<sup>9</sup>

In a study with 106 postpartum women who delivered both by cesarean section (62%) and vaginally (38%), there was no significant difference between calipers and ultrasound imaging measurements above the umbilicus. The mean differences in the caliper versus ultrasound measurements were less than 0.1 cm.<sup>23</sup> Sensitivity and specificity were 89.7% and 75%, respectively. The positive predictive value was 82.5%. This study supports caliper measurement to screen for DRA.

When measuring IRD above and below the umbilicus in men and women participants, Chiarello et al<sup>18</sup> examined the concurrent validity of calipers compared to ultrasound imaging. When measurements were taken above the umbilicus, there was no statistically significant difference in IRD measurements between the caliper and ultrasound imaging. Intraclass correlation coefficient with abdominal muscles at rest and while contracting were 0.79 and 0.71, respectively. Caliper measurements were 0.03 cm greater when measuring at rest and 0.03 cm smaller during the abdominal contractions. Standard error of measurement (SEM) ranged from 0.01 cm to 0.17 cm for above-umbilical measurements, but the SEM was higher when measuring below the umbilicus, 0.74 cm to 1.43 cm. Caliper measurements taken below the umbilicus were significantly larger (p<0.0001). The overestimated caliper measurements below the umbilicus may be due to increased subcutaneous fat in this region, causing more difficulty palpating the inner edge of the rectus abdominis muscle. Also, based on a previous ultrasound imaging study<sup>17</sup>, the validity of ultrasound imaging below the umbilicus has not been demonstrated.

A systematic review<sup>23</sup> found Pearson's correlations of r=0.66-0.79 for calipers and ultrasound measurements. ICCs for interrater and intrarater reliability were good to very good, ranging from 0.78 to 0.97. Comparing calipers to ultrasound, low measurement error was found above the umbilicus with good agreement for discriminative purposes (83%; weighted Kappa=0.66).

Boxer and Jones<sup>66</sup> examined the intrarater reliability caliper measurements from an examiner with minimal experience using calipers at the umbilicus on 30 participants ranging from 1.5weeks to 22 weeks postpartum. High reliability was found at rest (ICC=0.93) and during an abdominal crunch (ICC=0.95). Standard error of measurement was also small, 0.31 cm

and 0.16 cm for measurements taken at rest and during an abdominal crunch, respectively. Therefore, for novice examiners, caliper measurements are a reliable DRA screening method.

## The Contribution the Study Makes to the Field

This research study is unique since it is the first study to look at all three measurement tools together compared to ultrasound imaging. There has only been one published study that has examined the sensitivity and specificity of caliper measurement and none addressing the diagnostic accuracy of finger width or tape measure. Only one published study has examined clinimetric properties of IRD measured with a tape measure. This study provides new clinimetric information on the three clinical tools often used to assess for DRA.

It is vital that physical therapists assess DRA with reliable, valid, and accurate measurement tools. At this time, 97% of women's health physical therapists are using tools that are not well supported in the literature.<sup>9</sup> Further examination is warranted so DRA can be accurately diagnosed and proper treatment initiated.

## Summary

There is no universally accepted IRD measurement to define DRA; however, the majority of research studies define DRA as an IRD greater than 2 finger widths or 2.0 cm. DRA is a condition which affects both men and women. Nearly 100% of women in their third trimester will develop DRA and DRA often persists during the postpartum period and beyond. If DRA is not identified and treated, multiple ailments can occur. Therefore, it is vital healthcare clinicians use reliable, valid, and accurate screening methods so a proper referral can be made, if necessary.

Ultrasound imaging is the clinical best standard; however, equipment can be costprohibitive and extensive training is required. Research studies have shown caliper measurements to be reliable and valid; however, less than 2% of women's health physical therapists use calipers to screen for DRA. The majority of physical therapists use finger width palpation or a tape measure to screen for DRA, which is supported by limited research with only three published studies examining the clinimetric properties. Therefore, this study is needed to compare reliability, validity, and accuracy of finger width palpation, tape measure, and caliper measurements to the clinical best standard, ultrasound imaging. The study also examined the prevalence of DRA in men and women.

# Chapter 3: Methodology

## Introduction

The aim of this study was to compare the reliability, validity, and diagnostic accuracy of finger width palpation, tape measure, and caliper measurements to the clinical best standard, ultrasound imaging. This chapter outlines the methodology used in this dissertation. Research design and sampling, including recruitment, inclusion and exclusion criteria, and how the number of subjects needed for recruitment was determined, is justified. Also, approvals and research methods, including how data was collected, is presented. Data analysis for each of the four research questions is discussed. Lastly, resources needed to complete this study are outlined.

## **Research Design**

This was a clinimetric, test-retest study to evaluate the reliability, criterion validity, and diagnostic accuracy of three measurement tools compared to a clinical best practice standard. Also, a demographic survey was administered to determine if there is a correlation between low back pain, pelvic pain, incontinence, and pelvic organ prolapse and diastasis recti abdominis (DRA).

### Sampling

Participants were recruited via convenience sampling from employees and students at A.T. Still University; patients being treated for low back pain and pelvic floor dysfunction from local physical therapy outpatient private practices; obstetricians; women attending Mothers of Multiples support groups; local gyms; and among colleagues and friends. Participants ranged from 18 to 64 years and included males and females with various size of interrecti distance

(IRD), and female parity ranging from nulliparous to multiparous. All participants were Englishspeaking.

Potential participants were excluded from the study for any of the following conditions:

- Pregnancy, due to changes in IRD as pregnancy progresses and risk of supine hypotensive syndrome with hook-lying position;
- Previous abdominal surgery, since scarring may cause the linea alba or umbilicus to have visual deformity;
- Rheumatologic or connective tissue disease, since the linea alba is connective tissue;
- Body mass index greater than 35, due to excessive adipose tissue may decrease accuracy of ultrasonography measurements;
- History of an inguinal, femoral, or umbilical hernia;
- Spinal surgery within the past 6 months; or
- Low back pain that limits the participant's ability to perform an abdominal contraction.

Fifty-one participants enrolled in this study. Sample size was calculated based on the assumption that an intraclass correlation coefficient (ICC) of 0.60 would indicate reliability (null hypothesis), and that an ICC of at least 0.80 would be adequate (alternative hypothesis). Including an estimated 10% drop-out rate between the two days of measurement, 51 participants were required to provide 90% power to detect a one-tailed difference (p=0.05) between an ICC=0.60 and ICC=0.80. The research question addressing diagnostic accuracy was exploratory, not confirmatory, due to the sample size not being adequate for power.

### Approvals and Research Methods

The proposed study took place at A.T. Still University in Mesa, Arizona after receiving Institutional Review Board approval by Nova Southeastern University and A.T. Still University. The approval letters can be found in Appendix A. To ensure adherence to a standard protocol by all examiners collecting data, a training session was provided by the principal investigator. The training session included proper procedures, informed consent, and data collection sheets.

Participants completed a personal data questionnaire on the first visit at the beginning of the session. The questionnaire was administered by the primary investigator. The questionnaire included age, parity, number of fetuses, weight, height, body mass index, mode of delivery, ethnicity and presence of low back pain, pelvic pain, urinary incontinence (stress, urge, and mixed), fecal incontinence, and pelvic organ prolapse. Responses were self-reported and not confirmed by medical diagnosis/medical history review. The questionnaire was written in lay language so respondents could understand the questions. For example, for urinary incontinence, language describing stress urinary incontinence is, "Do you leak urine when you cough, sneeze, or exercise?" Language describing urge urinary incontinence is, "Do you leak urine when you get a strong and uncomfortable need to urinate?" These types of questions have been validated by the Questionnaire for Urinary Incontinence Diagnosis (QUID). 90,91 For other conditions, participants were asked if they experience common symptoms associated with each condition. For example, for pelvic organ prolapse participants were asked if they have a feeling of pressure/fullness in the pelvic region or a feeling that something is falling out of the vagina/rectum. For pelvic pain, participants were asked if they have pain in the pelvic region or in the lower abdominal region. For fecal incontinence, participants were asked if they have difficulty controlling flatulence (gas) or have involuntary loss of stool/feces. Lastly, participants were asked if they have low back pain.

Two examiners, including the principal investigator, measured IRD via finger width palpation, tape measure, and caliper at rest and during an abdominal crunch. The sonographer

measured IRD via ultrasound imaging. The order of the examiner and the measurement tool was randomized using a 3x3 Latin square. Additionally, the examiners were blinded to the other examiners' measurements and the measurements taken by ultrasonography.

The two therapists performing the measurements had 21- and 22-years' experience as a physical therapist. One therapist had 5 years' experience measuring IRD via finger width palpation but had not used tape measure or a caliper. The second therapist had 5 years' experience measuring IRD using finger width palpation and tape measure, but had no experience using a caliper. The ultrasonographer who captured all ultrasound images has been a credentialed musculoskeletal sonographer through the American Registry for Diagnostic Medical Sonography for 6 years. The ultrasonographer who oversaw the ultrasonography aspect of the study and verified all measurements offline has been a credentialed medical sonographer through the American Registry for Diagnostic Medical Sonography for 22 years. He also has over 20 peer-reviewed publications in ultrasonography. A research assistant with experience in the ultrasonography lab measured interrecti distance offline. All IRDs were measured by three different individuals to ensure accuracy.

Participants lay in the hook-lying position on an examination table with one pillow behind their head. Measurements were taken at two locations along the linea alba: at the superior ring of the umbilicus and 4.5 cm above the umbilicus. These locations were marked with a dermographic water-soluble marker. The examiner stood at the participant's side facing them. Each examiner measured IRD with each measurement tool at rest and while the participant performed an abdominal contraction. Both conditions were demonstrated for the participant. Resting measurements were taken while the participant gently raised their head off the pillow to enable the examiner to identify the space between the two recti muscle bellies. To perform an

abdominal contraction, the participant contracted their abdominal muscles by tucking their chin into the chest and lifting their head and shoulders off the examination table, with arms extended at their side until the inferior angle of the scapula lifted off the table, as palpated by the examiner's left index finger. This position was held for 5-10 seconds while the measurement was taken. To avoid muscle fatigue, the subject was given a 1-minute rest break before the next measurement was taken. Each measurement location and condition were repeated three times by the examiners.

Finger width palpation was conducted by the examiner inserting their second, third, and fourth fingers of their dominant hand into the participant's abdomen across the linea alba at the umbilicus. The number of fingers that fit into the space between the medial borders of the recti abdominal muscles at rest and during an abdominal contraction were recorded. Three measurements were taken for each condition at each location and the average for each was recorded for data analysis.

A flexible tape measure was used to measure IRD with the examiner measuring the space in centimeters between the two recti abdominal muscles palpated by the examiner. Measurements were taken at rest and during an abdominal contraction. This measurement was recorded. Three measurements were taken for each condition at each location and the average for each was recorded for data analysis.

A caliper was used to measure IRD with the examiner placing the inside caliper jaws in the space between and perpendicular to the two muscles. The distance measured between the two recti muscles at rest and during an abdominal contraction was recorded. Three measurements were taken for each condition at each location and the average for each was recorded for data analysis.

A high-resolution ultrasound imaging system (GE Logiq P6, with a 25 mm aperture matrix array, ML 6-15), was used for acquiring images of the linea alba. The wide 50-mm aperture of the transducer enabled the localization of the medial borders of the recti within the same image frame. The high frequency of the transducer (up to 15 MHz) enabled appropriate resolution of the superficially located linea alba.

Ultrasound imaging was performed by placing the transducer transversely across the linea alba until the medial borders of the muscle bellies were visualized. Rather than freehand scanning by the operating sonographer, a custom transducer template (Figure 2) was created to ensure that image frames could be acquired at fixed discrete ranges with respect to the umbilicus. The sonographer thereby placed the transducer within these slots and acquired a fixed B-mode image frame. This approach helped minimize the operator dependence of acquiring images of the region of interest. From the B-mode images, the sonographer measured the distance between the medial borders of the recti abdominis at each discrete location from the umbilicus. Images were captured and the sonographer measured the IRD online using the device's measuring feature (Figure 3). After data collection was completed, a trained research assistant measured IRD off-line (Figure 4). IRD was measured off-line to allow more time, optimal lighting, no distractions, and attention to detail when taking the measurements. A second ultrasound sonographer verified the accuracy of these off-line measurements and these measurements were used for data analysis.



# Figure 2. Ultrasound Transducer Placement Template

IM: September 7,2018

b= 1.2 cm, a= 1.5 cm, c= 2.0 cm All slots are 2.2 cm x 6.6 cm

## Figure 3. Ultrasound Image with IRD Measured Online





Figure 4. Ultrasound Image with IRD Measured Offline

The first visit took approximately 60 minutes. Participants returned in 7 days for a second and final visit, which took approximately 30 minutes since ultrasound imaging measurements were not taken. Finger width palpation, tape measure, and caliper measurements were repeated, with the order of examiner and measurement tool randomized using a 2x2 Latin square. The examiners were blinded to previous and other examiners' measurements. Ultrasound measurements were not repeated since interrater reliability and intrarater reliability were calculated for finger width palpation, tape measure, and caliper.

This study does not utilize an intervention. However, if a participant was identified to have a DRA, proper treatment was initiated. After data collection was completed, if a DRA was diagnosed by ultrasound imaging, a phone call or in-person discussion was made by the principal investigator to inform the participant, advise them to contact their primary care physician, and the participant was given a list of local physical therapists who treat DRA, with whom they could choose to schedule an appointment.

#### Data Analysis

Statistical calculations were performed using SPSS Version 26. Level of significance was set at p<.05. The mean and standard deviation of demographic data were calculated for age (years), parity, number of fetuses, weight (kg), height (cm), BMI (kg/m<sup>2</sup>), and number of Cesarean sections and vaginal deliveries. Ethnicity was reported as percentages.

#### Analysis Research Question 1

Intra-rater and inter-rater reliability were calculated using intraclass correlation coefficients (ICC) for level of agreement for each condition (rest and abdominal contraction), location, and measurement tool. A Bland-Altman plot was constructed to compare the difference between each measurement in each examination.

#### Analysis Research Question 2

Concurrent validity of each measurement tool compared to ultrasound imaging was calculated using ICC and standard error of measurement (SEM). ICC values less than or equal to 0.20 was considered poor, 0.21 to 0.40 fair, 0.41 to 0.60 moderate, 0.61 to 0.80 good, and 0.81 to 1.00 very good. <sup>92</sup> In previous studies, SEM has been calculated to be 0.05 to 0.20 cm for ultrasound imaging and 0.01 to 0.41cm for calipers. <sup>2</sup> To determine whether a difference in IRD is beyond measurement error, minimal detectable change was calculated at the 95% confidence interval.

### Analysis Research Question 3

Based on the precedent established by previous research, any IRD greater than 2 finger widths or 2 cm was considered positive for a DRA. <sup>3,4</sup> A 2x2 contingency table was constructed for each measurement tool and compared to ultrasound imaging. The McNemar test determined

whether a diagnosis of DRA from each measurement tool was confirmed by ultrasound imaging. Sensitivity, specificity, and positive and negative predictive values were calculated.

#### Analysis Research Question 4

Cramer's V coefficient was computed to determine if there was a correlation between low back pain, pelvic pain, incontinence, and pelvic organ prolapse and DRA. A value of 0.20 to 0.40 is moderate association, 0.40 to 0.60 is a relatively strong association, 0.60 to 0.80 is a strong association, and 0.8 to 1.0 is a very strong association. <sup>93</sup> Relative risk ratios and 95% confidence intervals were calculated to determine the magnitude of association between DRA and each of the pelvic floor dysfunction and low back pain diagnoses.

#### Resources

Data collection occurred in the Interdisciplinary Neuromuscular Research Laboratory at A.T. Still University, Mesa campus. The laboratory is a 3,000 square foot facility dedicated to faculty research. The facility is located on the border of two cities, Mesa and Gilbert, and within two miles of two freeways providing convenient access to participants.

The ultrasound imaging device is the property of A.T. Still University. Dr. Makin oversaw the ultrasonography images captured by Jeanne Noble, PT, RMSK and measured offline by Shreya Ramkumar. Assistance with statistics was provided by statistician, Dr. Curt Bay, PhD, who is on faculty at A.T. Still University.

The primary resources required for this project were payment of the ultrasonographer (\$45/hour), second physical therapist rater (\$50/hour), and the research assistant who measured IRD offline (\$20/hour). Under a previous grant Dr. Makin received, A.T. Still University had purchased an ultrasound imaging device which was utilized for this study. This dissertation was

primarily funded by the A.T. Still University Warner Grant and the ATSU PT Department Grant in the amount of \$4200 and \$1005.13, respectively. Total expenditure and funding are listed in Table 6.

Expenditure	Cost	Total
Ultrasonographer	\$45/hour x 33.25 hours	\$1,496.25
2 <sup>nd</sup> PT rater	\$50/hour x 60 hours	\$3,000.00
Research assistant	\$20/hour x 40 hours	\$800.00
Ultrasound transducer placement template design and fabrication	\$150	\$150.00
Calipers	\$9.07 each x 2	\$18.14
Tape measures	\$6.87 each x 2	\$13.74
Miscellaneous supplies (disposable sheets; hand gel; dermographic pens; alcohol wipes; clipboards)		\$77.27
		Total: \$5,555.40
Funding		Total
A.T. Still University Warner Grant		\$4,200.00
A.T. Still University PT Department Grant		\$1,005.13
Primary investigator private funding		\$350.27
		Total: \$5,555.40

Table 6. Research Study Expenditures and Funding

## Summary

This chapter presented the research design to evaluate the reliability, criterion validity, and diagnostic accuracy of three measurement tools compared to the clinical best standard, as well as investigating whether there is a correlation between DRA and other pelvic floor and low back dysfunction was discussed. Justification for inclusion and exclusion criteria, along with how sample size was determined was presented. Data analysis for the four research questions and resources available was also discussed.

# Chapter 4: Results

### Introduction

The purpose of this dissertation was to determine the reliability, validity, and diagnostic accuracy of three tools used to screen for diastasis rectus abdominis (DRA) compared to the clinical gold standard. Another aim of this study was to determine if low back pain and pelvic floor dysfunction correlate with DRA. In this chapter, the results from each of the four research questions are presented.

## Participants

Participants were recruited between October 2018 and April 2019 through convenience sampling. Fifty-one participants initially enrolled; however, two participants did not return for the second visit, thus they were excluded. One participant did not return due to car mechanical issues and the second participant did not state a reason. Fifty-one participants were required to provide 90% power with an estimated 10% dropout rate; therefore, 46 participants were necessary for sufficient power. The study's dropout rate was only 4%, so the study was sufficiently powered with 49 participants completing the study.

Of the 49 participants, 35 (71%) were females and 14 (29%) were males. Age ranged from 18 years to 64 years with mean age of 41 years  $\pm$  12 years. Forty-one (84%) of the participants self-identified as White, three (6%) Asian, three (6%) Black, and one (2%) American Indian or Alaska Native.

Body mass index (BMI) ranged from 18.5 kg/m<sup>2</sup> to 33.8 kg/m<sup>2</sup> with mean BMI of 26.0  $\pm$  4.0 kg/m<sup>2</sup>. According to the weight status guidelines set forth by the Centers for Disease Control and Prevention<sup>94</sup>, no participants were underweight (BMI <18.5), 20 (41%) were considered a

healthy weight (BMI between 19.5-24.9), 23 (47%) were classified as overweight (BMI between 25.0-29.9), and 6 (12%) were considered obese (BMI  $\geq$  30.0).

Of the 35 female participants, parity ranged from 0 to 7 births. Fifteen (43%) participants were nulliparous women, four (11%) were primiparous women, seven (20%) had given birth twice, six (17%) had given birth three times, one (3%) had four births, one (3%) had five births, none (0%) had six births, and one (3%) had seven births. Of the 52 births, all were singleton, except for one set of twins. Forty (77%) of the deliveries were vaginal delivery and 12 (23%) were by Cesarean delivery.

As diagnosed via ultrasound imaging, 28 (57%) participants had diastasis rectus abdominis (DRA) either at the umbilicus, above the umbilicus, or both. Location of the diagnosed DRA can be found in Figure 5. Fifty-seven percent (57%) of both males and females separately had a DRA.

At Above umbilicus 18 umbilicus 7 3

Figure 5. Location of DRA as Diagnosed by Ultrasound Imaging

Interrecti distance ranged from 0.6 cm to 4.7 cm with a mean of 1.93 cm. Of those who had DRA, 86% were classified as mild (2.01 cm to 3.5 cm), 14% as moderate (3.6 cm to 5.0 cm), and 0% as severe (greater than 5.0 cm.

The percentages of participants self-reporting low back pain and/or pelvic floor dysfunction are reported in Table 7. Of those who experienced urinary incontinence, nine (47%) reported stress incontinence symptoms, five (26%) reported urge, and five (26%) reported mixed (both stress and urge) incontinence symptoms.

	All Participants	Females	Males
Urinary incontinence	39%	54%	0%
Low back pain	37%	37%	36%
Pelvic pain	16%	23%	0%
Pelvic organ prolapse	8%	11%	0%
Fecal incontinence	8%	11%	0%

Table 7. Prevalence of Low Back Pain and Pelvic Floor Dysfunction

## Research Question 1: Intrarater and Interrater Reliability

Intraclass correlation coefficient (ICC) average measures estimates and their 95% confident intervals were calculated using SPSS Version 25 based on the ICC (3,1) consistency model (Table 8). Interrater reliability for finger width palpation ranged from poor to moderate, tape measure was moderate, and caliper measurements ranged from fair to moderate interrater reliability. The ICC did not exceed 0.80; therefore, the null hypothesis cannot be rejected.

Measurement Tool	IC	ICC		Bland-Altman Plot	
Location, Condition	ICC	95% CI	Mean	LOA	p-
	coefficient		Difference		value
Finger Width Palpation					
Umbilicus, Rest	0.54	0.31 - 0.71	0.20	0.07 to 0.34	.004*
Umbilicus, Crunch	0.42	0.16 - 0.63	0.31	0.17 to 0.44	<.001*
Above, Rest	0.32	0.04 - 0.55	0.69	0.55 to 0.84	<.001*
Above, Crunch	0.18	010 - 0.44	0.67	0.53 to 0.82	<.001*
Tape Measure					
Umbilicus, Rest	0.49	0.25 - 0.68	-0.14	-0.30 to 0.02	.078
Umbilicus, Crunch	0.53	0.30 - 0.71	-0.27	-0.44 to -0.11	.006*
Above, Rest	0.46	0.20 - 0.65	0.40	0.24 to 0.57	<.001*
Above, Crunch	0.53	0.30 - 0.71	0.37	0.20 to 0.53	<.001*
Caliper					
Umbilicus, Rest	0.35	0.08 - 0.58	-1.35	-2.78 to 0.07	.062
Umbilicus, Crunch	0.35	0.08 - 0.57	-1.35	-2.90 to 0.20	.087

Table 8. Interrater Reliability of Finger Width Palpation, Tape Measure, and Caliper Measurement When Measuring IRD

Above, Rest	0.46	0.20 - 0.65	-1.11	-2.38 to 0.15	.083
Above, Crunch	0.40	0.14 - 0.61	-0.25	-1.73 to 1.23	.732

Abbreviations: ICC=Intraclass correlation coefficient; CI=Confidence interval; LOA=Limits of agreement

\* p < 0.05 indicating statistically significant difference between raters

For intrarater reliability, the ICC exceeded 0.80 for measurements taken with a tape

measure during an abdominal crunch; therefore, the null hypothesis was rejected (Table 9).

Intrarater reliability for finger width palpation was good, and ranged between moderate to good

for caliper measurements, but the ICC did not meet the threshold to reject the null hypothesis for

these two instruments.

Table 9. Intrarater Reliability of Finger Width Palpa	ation, Tape Measure, and Caliper
Measurement When Measuring IRD	

Measurement Tool	ICC		<b>Bland-Altman Plot</b>		
Location,	ICC	95% CI	Mean	95%	p-
Condition	coefficient		Diff	LOA	value
Finger Width Palpation					
Umbilicus, Rest	0.63	0.49 - 0.74	0.09	0.00 to 0.17	.043**
Umbilicus, Crunch	0.68	0.55 - 0.77	0.08	0.00 to 0.15	.035**
Above, Rest	0.71	0.60 - 0.80	0.04	-0.04 to 0.11	.320
Above, Crunch	0.76	0.66 - 0.83	0.04	-0.04 to 0.11	.320
Tape Measure					
Umbilicus, Rest	0.77	0.68 - 0.84	0.01	-0.07 to 0.09	.755
Umbilicus, Crunch	0.83*	0.75 - 0.88	0.00	-0.07 to 0.07	.978
Above, Rest	0.78	0.69 - 0.85	0.04	-0.12 to 0.05	.389
Above, Crunch	0.83*	0.75 - 0.88	0.03	-0.03 to 0.11	.345
Caliper					
Umbilicus, Rest	0.59	0.44 - 0.70	0.20	-0.58 to 0.98	.611
Umbilicus, Crunch	0.61	0.47 - 0.72	0.44	-0.34 to 1.21	.265
Above, Rest	0.53	0.37 - 0.66	0.22	-0.63 to 1.06	.613
Above, Crunch	0.54	0.38 - 0.66	0.04	-0.91 to 0.83	.922

Abbreviations: ICC=Intraclass correlation coefficient; CI=Confidence interval; LOA=Limits of agreement

\* ICC  $\geq$  0.80; Null hypotheses rejected

\*\* p <0.05 indicating statistically significant difference between raters

## **Research Question 2: Concurrent Validity**

ICC average measures estimates and their 95% confident intervals were calculated based on the ICC (3,1) consistency agreement model (Table 10). Standard error of measurement was calculated using Microsoft Excel 365. Concurrent validity compared to ultrasound imaging was fair for all measurements taken with the tape measure and caliper. Validity was fair for finger width measurements taken above the umbilicus, but moderate when taken at the umbilicus. The ICC did not exceed 0.60 so the null hypothesis cannot be rejected.

Measurement Tool	IC	Standard Error of	
Location, Condition	ICC coefficient	95% CI	Measurement (cm)
Finger Width Palpation			
Umbilicus, Rest	0.56	0.12 to 0.77	0.39
Umbilicus, Crunch	0.55	-0.02 to 0.78	0.40
Above, Rest	0.36	-0.09 to 0.63	0.38
Above, Crunch	0.38	-0.06 to 0.65	0.37
Tape Measure			
Umbilicus, Rest	0.39	-0.16 to 0.68	0.37
Umbilicus, Crunch	0.30	-0.20 to 0.63	0.37
Above, Rest	0.35	-0.18 to 0.65	0.28
Above, Crunch	0.31	-0.16 to 0.61	0.38
Caliper			
Umbilicus, Rest	0.29	-0.18 to 0.60	0.30
Umbilicus, Crunch	0.27	-0.18 to 0.58	0.33
Above, Rest	0.32	-0.17 to 0.62	0.30
Above, Crunch	0.21	-0.17 to 0.51	0.35

Table 10. Concurrent Validity of Finger Width Palpation, Tape Measure, and Caliper Measurement When Measuring IRD

Abbreviations: ICC=Intraclass correlation coefficient; CI=Confidence interval

## Research Question 3: Diagnostic Accuracy

A 2x2 contingency table was constructed and the McNemar test confirmed there was a statistically significant difference between the number of diagnosed DRA with ultrasound imaging compared to each measurement tool (Table 11). Sensitivity, specificity, positive predictive value, and negative predictive value were also calculated. Finger width, tape measure,

and the caliper had excellent specificity ranging from 96.3% to 100%, but sensitivity was low at 0% to 23.8%. Positive predictive value was either near or at 100% when measured using a tape measure, caliper, or finger width at the umbilicus at rest. Positive predictive value was 0% when measured with finger width palpation above the umbilicus or at the umbilicus during a crunch since neither rater identified a DRA under these locations and/or conditions. Negative predictive value was equally distributed across all three measurement tools ranging from 56% to 70%.

Measurement Tool		Present	Absent	Total	Combinatio	on Values
Location, Condition						
Finger Width Palpation						
Umbilicus, Rest	Present	1	0	1	Sensitivity:	4.5%
	Absent	21	27	48	Specificity:	100%
	Total	22	27	49	PPV:	100%
					NPV	56%
					p-value:	<.001
Umbilicus, Crunch	Present	0	0	0	Sensitivity:	0%
	Absent	21	28	49	Specificity:	100%
	Total	21	28	49	PPV:	0%
					NPV:	57%
					p-value:	<.001
Above, Rest	Present	0	0	0	Sensitivity.	0%
	Absent	17	32	49	Specificity:	100%
	Total	17	32	49	PPV:	0%
				.,	NPV:	65%
					p-value:	<.001
Above, Crunch	Present	0	0	0	Sensitivity:	0%
	Absent	18	31	49	Specificity:	100%
	Total	18	31	49	PPV·	0%
	Total	10	51	12	NPV.	63%
					p-value:	<.001
Tape Measure					•	
Umbilicus, Rest	Present	3	1	4	Sensitivity:	13.6%
	Absent	19	26	45	Specificity:	96.3%
	Total	22	27	49	PPV:	75%
					NPV:	57.8%
					p-value:	<.001

Table 11. Sensitivity, Specificity, PPV and NPV of Finger Width Palpation, Tape Measure, and Caliper Measurement When Measuring IRD

	Umbilicus, Crunch	Present Absent Total	5 16 21	0 28 28	5 44 49	Sensitivity: Specificity: PPV: NPV: p-value:	23.8% 100% 100% 63.6% <.001
	Above, Rest	Present Absent Total	2 15 17	0 32 32	2 47 49	Sensitivity: Specificity: PPV: NPV: p-value:	11.8% 100% 100% 68.1% <.001
	Above, Crunch	Present Absent Total	2 16 18	0 31 31	2 47 49	Sensitivity: Specificity: PPV: NPV: p-value:	11.1% 100% 100% 66% <.001
Caliper	Umbilicus, Rest	Present Absent Total	2 20 22	0 27 27	2 47 49	Sensitivity: Specificity: PPV: NPV: p-value:	9.1% 100% 100% 57.4% <.001
	Umbilicus, Crunch	Present Absent Total	3 18 21	0 28 28	3 46 49	Sensitivity: Specificity: PPV: NPV: p-value:	14.3% 100% 100% 60.9% <.001
	Above, Rest	Present Absent Total	3 14 17	0 32 32	3 46 49	Sensitivity: Specificity: PPV: NPV: p-value:	17.6% 100% 100% 69.6% <.001
	Above, Crunch	Present Absent Total	2 16 18	0 31 31	2 47 49	Sensitivity: Specificity: PPV: NPV: p-value:	11.1% 100% 100% 66% <.001

Abbreviations: PPV=Positive predictive value; NPV=Negative predictive value

Given the tape measure had the most favorable clinimetric properties overall, but

underestimated the IRD, a receiver operating characteristic (ROC) curve analysis was conducted

a posteriori for measurements taken during an abdominal crunch (Table 12). Only the abdominal

crunch condition was analyzed since abdominal crunch measurements are typically used for

DRA screening.

Table 12. Receiver Operating Characteristic (ROC) Curve Analysis of the Tape Measure When Measuring IRD

Location	AUC	<b>Standard Error</b>	95% CI	p-value
Umbilicus	0.736	0.07	0.60 - 0.87	0.005*
Above	0.711	0.08	0.56 - 0.87	0.014*

Abbreviations: AUC=Area under the curve; CI=Confidence interval \*p<0.05

For measurements taken with the tape measure during an abdominal crunch at the umbilicus, an IRD measurement of 0.95 cm indicating DRA would yield 0.905 sensitivity and 0.464 1-specificity (Figure 6). This translates to 90.5% true positive rate and a 46.4% false positive rate.

Figure 6. Receiver Operating Characteristic (ROC) Curve for the Tape Measure at the Umbilicus



For measurements taken with the tape measure during an abdominal crunch above the umbilicus, an IRD measurement of 1.15 cm indicating DRA would yield 0.722 sensitivity and

0.290 1-specificity (Figure 7). This translates to a 72.2% true positive rate and a 29% false positive rate.

Figure 7. Receiver Operating Characteristic (ROC) Curve for the Tape Measure Above the Umbilicus



Research Question 4: Correlation between DRA and Low Back Pain and Pelvic Floor Dysfunction

To determine the correlation between DRA and low back pain, pelvic pain, fecal and urinary incontinence, and pelvic organ prolapse, Cramer's V was performed (Table 13). The only condition that showed statistical significance was urinary incontinence, which had a moderate effect size and a 4.9 odds ratio of presenting along with DRA.

Condition	Value	Significance	Odds Ratio	95% Confidence Intervals
Low back pain	.02	.864	0.9	0.28 - 2.91
Pelvic pain	.16	.265	2.6	0.47 - 14.38
Fecal incontinence	.19	.175	0.2	0.02 - 2.31
Urinary incontinence	.35	.014*	4.9	1.31 – 18.33
Pelvic organ prolapse	.19	.175	0.2	0.02 - 2.31

Table 13 Correlation between Low Back Pain, Pelvic Floor Dysfunction and DRA among All Particinants

p<0.05

Given that female participants were the only participants who reported pelvic pain, incontinence, and pelvic organ prolapse, a Cramer's V analysis was conducted posteriori among female participants (Table 14). Urinary incontinence was the only condition which showed statistical significance with a moderate effect size and 8.3 odds ratio of presenting along with DRA.

Table 14. Correlation between Low Back Pain, Pelvic Floor Dysfunction and DRA among Female Participants

Condition	Value	Significance	<b>Odds Ratio</b>	95% Confidence
				Intervals
Low back pain	.07	.686	1.3	0.33 - 5.39
Pelvic pain	.20	.245	2.8	0.48 - 16.35
Fecal	.23	.167	0.2	0.02 - 2.27
incontinence				
Urinary	.48	.014*	8.3	1.79 - 38.01
incontinence				
Pelvic organ	.23	.167	0.2	0.02 - 2.27
prolapse				
prolapse				

\*p<0.05

### Summary of Results

Tape measure measurements exhibited moderate interrater reliability whereas caliper measurements range from fair to moderate and tape measure was poor to moderate interrater reliability. Tape measure measurements exhibited good to very good intrarater reliability, while the intrarater reliability of finger width palpation was good and caliper measurements ranged from moderate to good. Concurrent validity was the best for finger width palpation when measuring at the umbilicus and was considered moderate, while finger width palpation above the umbilicus, tape measure, and caliper was deemed fair. All three measurements tools had excellent specificity but low sensitivity. One hundred percent (100%) positive predictive value was calculated for tape measure and caliper while all three tools displayed 56%-70% negative
predictive value. Lastly, the only condition correlated with DRA was urinary incontinence with a moderate effect size and 4.9 odds ratio when factoring all participants, and an 8.3 odds ratio of presenting along with DRA among only female participants.

## Chapter 5: Discussion

## Introduction

The purpose of this chapter is to discuss the key findings in relation to the current evidence and its implications to physical therapy practice. Limitations and recommendations for further research are also discussed. A summary concludes this chapter.

## Discussion

In this study, 57% of the participants were diagnosed via ultrasound imaging with diastasis rectus abdominis (DRA). Only two studies have been published examining the prevalence of DRA, both being cadaver studies, and found the prevalence to be 74% in one study<sup>29</sup> and 26.7% (23% male and 38% female) in another study.<sup>37</sup> Unfortunately Chiarello et al<sup>29</sup> only reported prevalence among all cadavers and did not report male versus female prevalence. The age of the cadavers were much older than the participants in this study, with the age range between 47 – 99 years of age<sup>29</sup> or mean age of 82 years<sup>37</sup> compared to an age range of 18 years to 64 years and a mean age of 41 years. Equal number (57% of the females and 57% of the males) were diagnosed with DRA. Many individuals correlate DRA with pregnancy; however, this study found men and women were just as likely to have DRA. The male participants in this study were physically active and routinely engaged in exercise. Given that activities increasing intra-abdominal pressure are risk factors for males developing DRA,<sup>10</sup> different results may have been seen if a more male sedentary population had been studied.

A retrospective chart review of women who visited a urogynecology clinic for treatment of pelvic floor dysfunction found a DRA prevalence rate of 52% in women with a mean age of 52 years<sup>13</sup>, which is more aligned with the present study. A different study examined DRA in women between the ages of 19 to 24 years who visited a gynecology practice with vaginal infection symptoms. They found a prevalence of DRA in multiparous women to be 59%, which is similar to what the present study found.<sup>44</sup>

Self-reported incidence of urinary incontinence was 54.3% females and 0% males. The study's prevalence of urinary incontinence in females resembles the national average of 53.4%, but the male average is significantly lower than the national average of 15.1%.<sup>95</sup> The mean age of male participants in this study was younger at 33.5 years. The younger age group may account for the significantly lower prevalence rate since male urinary incontinence typically affects older males.

Females reported a 37% incidence of low back pain compared to 36% of males. Both are higher than the 26.4% national average for US workers.<sup>96</sup> The higher prevalence may be due to the occupations of the participants. Sixty-five percent of the participants were either a physical therapist, student physical therapist, physician assistant, occupational therapist, nurse, or an athletic trainer. These occupations are physically demanding, which can lead to low back pain.

Eight female participants (16%) self-reported pelvic pain. The national average for women during their reproductive years is 39%.<sup>97</sup> The lower prevalence may be due to the questionnaire. Participants were only asked if they experience pain in the pelvic region or lower abdominal area. If a validated pelvic pain questionnaire had been utilized, the self-reported prevalence may have been different.

Four participants (8%) reported pelvic organ prolapse, which is slightly higher than the national average self-report rate of 3%-6%.<sup>98</sup> However, if a pelvic examination was conducted to

screen for pelvic organ prolapse, a higher incidence rate may have been found since the prevalence of pelvic organ prolapse diagnosed through a pelvic examination is 50%.<sup>98</sup>

Four individuals (8%) self-reported fecal incontinence. The prevalence of fecal incontinence in noninstitutionalized American adults is 8.3%.<sup>99</sup> Therefore the prevalence in this study matches the national average.

## Research Question 1: Interrater and Intrarater Reliability

Previous studies<sup>20,21</sup> found interrater reliability for finger width palpation to be moderate, whereas this study found interrater reliability for finger width palpation to range from poor to moderate, with statistically significant difference found between the different raters' measurements. The difference in measurements may have been due to different widths of the examiners' fingers and the variability in pressure applied to the abdomen which would affect the depth of the measurement. Intrarater reliability for finger width palpation was good, consistent with Mota et al.<sup>20</sup>

Measurements taken with the tape measure were more reliable than finger width palpation. Interrater reliability was moderate and intrarater reliability was very good. There have been no published studies examining reliability for these results to be compared; however, these results are not surprising. Finger width palpation relies on the size of the examiner's fingers, and the finger size of the examiners were different. Also, measurements with the tape measure are more specific when rounded to the nearest 0.1 cm. With finger width palpation, IRD is rounded to the nearest half-finger, and as a result, precision is lost. Also, finger width palpation uses the pads of the fingers; whereas, measuring using a tape measure uses the fingertips, which allows the examiner to have more palpatory discernment.

Calipers have been studied more extensively compared to the other two measurement tools. A systematic review found interrater and intrarater reliability to range from good (ICC=0.78) to very good (ICC=0.97).<sup>23</sup> However in this study, the interrater and intrarater reliabilities were lower, ranging from fair to good. Both raters in this study had never used calipers to measure IRD before, which may account for the lower reliability; though, Boxer and Jones<sup>66</sup> found the intrarater reliability with a novice examiner to be 0.93 to 0.95. Another possible contributing factor to the lower reliability is the raters may not have been applying enough pressure through the caliper onto the participant's abdomen. Before this study began, the raters practiced using calipers on one another. The caliper's lower jaw was very uncomfortable and left scratch marks on the skin. Multiple calipers of different material, including stainless steel and plastic, were tested. To ensure participants' comfort, a Dremel was used to soften the caliper's lower jaw. As a result, the examiner had to recalibrate the caliper before each measurement. No participants reported discomfort or had scratch marks throughout the study. Despite the adaptations to the calipers, the examiners may have been fearful to place enough pressure to accurately detect the edges of the rectus abdominis muscles. In spite of the lower correlation, there was no statistically significant difference between both raters' measurements using a caliper.

### Research Question 2: Concurrent Validity

Concurrent validity compared to ultrasound imaging was strongest for finger width palpation when measurements were taken at the umbilicus. The interclass correlation coefficient was moderate (ICC=0.55) for these measurements. Measurements taken with finger width palpation above the umbilicus or any measurement with the tape measure or caliper only

displayed a fair correlation coefficient. These are much lower correlation coefficients compared to the literature.

A systematic review found correlation coefficients of 0.66 to 0.79 for calipers and ultrasound imaging<sup>23</sup>, whereas this study found significantly lower correlations of 0.21 to 0.32. Barbosa et al<sup>1</sup> found a moderate correlation between caliper measurements and ultrasound imaging. Van de Water and Benjamin<sup>23</sup> found mean differences less than 0.1 cm difference between caliper versus ultrasound measurements. In this study, the standard error of measurement ranged between 0.30 cm to 0.35 cm. The lower correlation coefficients and higher standard of error measurement may have been due to the inexperienced raters using calipers, as they may not have applied enough pressure against the abdomen for fear of hurting the participants.

There is only one published study that has investigated the concurrent validity of the tape measure compared to intraoperative measurements in patients who are undergoing DRA repair. Emanuelsson et al<sup>52</sup> compared IRD measured with a tape measure in the office to computer tomography and intraoperative measurements. The ICC was 0.37 to 0.48 indicating fair to moderate correlation, and the tape measure overestimated IRD more than 0.5 cm in 35% of the cases. In this study, the tape measure underestimated IRD by more than 0.5 cm in 59% of the cases when IRD was measured at rest. However, Emanuelsson et al<sup>52</sup> measured IRD greater than 3.0 cm and required surgical repair, whereas this study measured IRD in the general population which may account for the difference. A receiver operating characteristic (ROC) curve was analyzed to examine whether a different threshold than 2.0 cm should be implemented when using the tape measure. When measuring at the umbilicus during a crunch, a threshold of 0.95 cm yielded a 90.5% true positive rate and 46.4% false positive rate. Sensitivity is greatly

improved from 0.238, when using 2.0 cm as the threshold, to 0.905. A threshold of 1.15 cm when measuring above the umbilicus during an abdominal crunch gave a 72.2% true positive rate and 29% false positive rate. Sensitivity significantly increased from 0.111 to 0.722 when using 1.15 cm, versus 2.0 cm, as the threshold.

### Research Question 3: Diagnostic Accuracy

None of the three measurement tools displayed diagnostic accuracy (p>0.05) when compared to ultrasound imaging. All three had excellent specificity, meaning someone who does not have DRA will test negative for the DRA, with specificity ranging from 96.3% to 100%. Sensitivity, the ability of the measurement tool to correctly identify who has DRA, was low at 0% to 23.8%. The probability of having DRA for someone with a positive screening test, or positive predictive value, was 75% to 100% for all measurements taken with a tape measure, caliper, or finger width palpation measured at the umbilicus at rest. All other finger width measurements displayed 0% positive predictive value since the raters failed to identify any participants with DRA. The negative predictive value, someone with a negative screening test who does not have DRA, ranged between 56% and 70%.

The only published study that has calculated diagnostic accuracy found calipers had 89.7% sensitivity, 75% specificity, and an 82.5% positive predictive value.<sup>23</sup> Sensitivity was much lower in this study, ranging from 9.1% to 17.6% and indicating that the raters were only able to identify few of the participants who were diagnosed with DRA on ultrasound imaging. Barbosa et al<sup>1</sup> examined women who had delivered a baby within 72 hours. Screening for DRA is much easier during the postpartum period since the linea alba is significantly less taunt, thereby making it is easier to discern the linea alba from the abdominal recti muscles. This study examined participants who were not in the postpartum period. Specificity was higher at 100%

since nobody was incorrectly identified to have DRA based on caliper measurements.

Additionally, the positive predictive value of 100% also exceeded the published study because all subjects who were diagnosed with DRA based on caliper measurements were also diagnosed through ultrasound imaging. Measurements from the tape measure also displayed high specificity and positive predictive value; this indicates that when either tool identifies someone as having DRA, they are more than likely to have DRA. However, finger width palpation, tape measure, and calipers failed to recognize DRA in many cases.

## Research Question 4: Correlation between DRA and Low Back Pain and Pelvic Floor Dysfunction

In Chapter 1, to reject the null hypothesis, the a-priori threshold for a strong correlation was a Cramer's V value greater than or equal to 0.60. However, the literature supports Cramer's V being greater than or equal to 0.30 for a moderate effect.<sup>100</sup> Therefore, a Cramer's V value greater than or equal to 0.30 was considered a moderate correlation in the analysis.

There has been no consensus whether DRA is correlated with low back pain or pelvic floor dysfunction. This study investigated the correlation between DRA and low back pain, pelvic pain, urinary incontinence, fecal incontinence, and pelvic organ prolapse. The only condition which showed a statistically significant correlation (Cramer's V=0.35; p=0.014) was urinary incontinence, which had a moderate effect size. Participants who were diagnosed with DRA had 4.9 times the odds of having urinary incontinence; however, when only female participants were examined, the odds ratio increased to 8.3. These correlations are higher than previous studies which showed women with DRA had a 1.28 odds ratio of having urinary incontinence. <sup>13</sup> Spitznagle et al<sup>13</sup> also found odd ratios of 2.56 and 2.25 for fecal incontinence and pelvic organ prolapse, respectively. The current study found a lower odds ratio of 0.2 for

both diagnoses. A factor which may account for the differing odds ratio for pelvic organ prolapse is how this condition was diagnosed. Spitznagle et al<sup>13</sup> diagnosed pelvic organ prolapse through a urogynecological examination, whereas the current study asked participants to self-report common prolapse symptoms, including a feeling of pressure/fullness in the pelvic region or a feeling that something is falling out of the vagina/rectum. Only 8% of the participants in this study self-reported at least one of the two common symptoms. If a pelvic floor examination had been conducted, the number of participants classified as having pelvic organ prolapse may have been higher. However, Bo et al<sup>24</sup> incorporated a gynecological examination and found no increased risk of pelvic organ prolapse or urinary incontinence in women who were within the first postpartum year.

Gitta et al<sup>41</sup> found a correlation between DRA and urinary incontinence (p=0.028) and also DRA and low back pain (p=0.039) in postpartum women. Whittaker et al<sup>49</sup> studied men and women and found a correlation between DRA, lumbopelvic pain, and the Oswestry Disability Index, a validated questionnaire used to quantify disability as a result of low back pain. In contrast, this study did not find a correlation between DRA and low back pain (p=0.864) in the male and female participants. Similarly, Sperstad et al<sup>5</sup> found no correlation between lumbopelvic pain and mild DRA in women who were 12-months postpartum.

## **Clinical Implications**

There are many individuals in the general population who have DRA. The participants in this study were men and women between the ages of 18 and 64 years of age and 57% presented with DRA at the umbilicus and/or above. DRA is not limited to females only. An equal percentage of men and women, 57% each, were diagnosed with DRA. It is important for

clinicians to screen all patients for DRA, not just women, especially if the patient is at risk for DRA due to being physically active.

Ultrasound imaging is the clinical best standard to diagnose DRA. Given the equipment cost and extensive training required to use ultrasound imaging, most healthcare providers use finger width palpation, tape measure, or calipers to screen for DRA. These three measurement instruments are not as reliable between clinicians, nor valid when compared to the clinical best standard, nor able to identify most individuals who have DRA. Despite these poor clinimetric properties, some clinimetric properties were favorable. For example, if the same clinician wanted to monitor IRD across time, a tape measure would be the most reliable instrument with good to very good intrarater reliability. Calipers are also an acceptable measurement tool showing no statistically significant difference in measurements taken from two different clinicians. Additionally, if a clinician identifies DRA with any of the three commonly used tools, it is highly probable the individual does have DRA.

Individuals who have DRA should also be screened for urinary incontinence since there is a 4.9 odds ratio between the two conditions. Women who suffer from urinary incontinence are less likely to inform their healthcare provider of their symptoms due to embarrassment. Only 14%-38% seek help for this condition.<sup>101</sup> Once urinary incontinence symptoms begin, 74% of women wait at least one year before seeking help and 46% wait up to 3 years. Given women are less likely to initiate conversation concerning their symptoms, it is important to identify women who have a risk factor. If clinicians screen for DRA and find a positive test, urinary incontinence screening should be initiated. Likewise, if a health provider is treating a patient for urinary incontinence, they should also screen for DRA so treatment to reduce the DRA can be initiated, if needed.

### Limitations

Several limitations were recognized, including symptoms for low back pain and pelvic floor dysfunction were self-reported. Since pelvic organ prolapse can be asymptomatic, a pelvic examination would likely identify more individuals with the condition. The correlation between pelvic organ prolapse and DRA may be different under this condition. Although a validated tool was used to screen for urinary incontinence, a validated tool was not used for low back pain or the other pelvic floor dysfunctions.

Another limitation of this study is 86% of DRA were classified as mild (20.1mm to 35mm), 14% as moderate (36mm to 50mm) and 0% as severe (greater than 50mm).<sup>12</sup> If a greater number of participants with moderate to severe DRA had participated, the raters may have been able to identify more individuals with DRA. This would impact the diagnostic accuracy results.

A third limitation is neither raters had used calipers before this study. Both raters had extensive experience using finger width palpation and one rater had used a tape measure on multiple occasions. If the raters had comparable experience with the calipers, different results may have occurred.

Additionally, while learning how to use the calipers, both raters had personal adverse experiences with the instrument causing pain and scratch marks. Even though the calipers' inside lower jaws were softened with a Dremel tool and patients did not experience pain or scratch marks, the raters were hesitant to apply as much pressure as they did with their fingers or tape measure. Without the same amount of pressure applied, the inside jaw of the calipers may not have been positioned correctly against the two rectus muscles which would affect the measurements.

Lastly, the study's generalizability is restricted to adults aged 18 years to 64 years. If more older adults participated in the study, the results could be applied to a greater population.

## Recommendations

Canadian physiotherapists who are national experts in women's health participated in a Delphi consensus study.<sup>102</sup> The panel recommended to not solely rely on interrecti distance to diagnose and assess for DRA, but to also assess the integrity and tension of the linea alba at rest as well as during an abdominal contraction. Further research addressing linea alba integrity and tension is needed. During this study, the thickness of the linea alba was recorded from the ultrasound images at six different points along the linea alba at rest and during a contraction. The data collected during this study can be used to further investigate the role of tension and integrity with interrecti distance. Additionally, from the ultrasound images, thicknesses of the subcutaneous tissue and rectus abdominis muscles were also collected, so further examination of surrounding morphology and DRA can be examined.

## Summary

DRA is not a condition seen solely during pregnancy. Over half of the general adult population have DRA, with an equal percentage of men and women having this condition. Finger width palpation, tape measure, and caliper, methods commonly used to screen for DRA, have moderate interrater reliability, good to very good intrarater reliability, fair to moderate validity, and excellent specificity with low sensitivity. Additionally, individuals with DRA have a 4.9 odds ratio for experiencing urinary incontinence.

## Appendices

## Appendix 1: Initial Institutional Review Board Approval Letters from Nova Southeastern University and A.T. Still University



- To: Tamara Roehling College of Health Care Sciences From: Nurit Sheinberg, Ed.D. Chair, Institutional Review Board
- Date: September 11, 2017
- Subject: IRB Initial Approval Memo
- TITLE: Are Finger Width Palpation, Tape Measure, and Caliper Reliable, Valid, and Accurate to Diagnose Diastasis Rectus Abdominis (DRA)?– NSU IRB Protocol Number 2017-538

Dear Principal Investigator,

Your submission has been reviewed and approved by the Institutional Review Board under Expedited review procedures on September 6, 2017. You may proceed with your study.

Please Note: Stamped copies of all consent, assent, and recruiting materials indicating approval date must be used when recruiting and consenting or assenting participants.

Level of Review: Expedited

Type of Approval: Initial Approval

Expedited Review Category: Expedited Category 4

Level of Risk: Minimal Risk

Continuing Review: Continuing Review is due for this protocol on September 5, 2018. A continuing review (progress report) must be submitted one month prior to the continuing review date.

Changes: <u>Any changes</u> in the study (e.g., procedures, consent forms, investigators, etc.) must be approved by the IRB prior to implementation using the Amendment Form.

Post-Approval Monitoring: The IRB Office conducts post-approval review and monitoring of all studies involving human participants under the purview of the NSU IRB. The Post-Approval Monitor may randomly select any active study for a Not-for-Cause Evaluation. Final Report: You are required to notify the IRB Office within 30 days of the conclusion of the research that the study has ended using the IRB Closing Report Form.

Your study was approved under the following criteria:

Consent Participants according to criteria of 45 CFR 46.116 and 45 CFR 46.117

Translated Documents: Yes

Please retain this document in your IRB correspondence file.

CC: William Smith, JD Rose Colon, PhD

> Leah No<mark>f, Ph.D.</mark> Other

#### NOTICE of APPROVAL

DATE: 4-21-2017 TO: Tamara Roehling, PT, DPT PT FROM: ATSU, Arlzona IRB Committee SUBJECT: Approval, Protocol IRB Tracking (IRB #2017-98)

Thank you for the opportunity to review the research proposal, Are Finger Width Palpation, Tape Measure, and Caliper Reliable, Valid, and Accurate to Diagnose Diastasis Rectus Abdominis (DRA)? After reviewing the protocol and attachments, the ATSU, Arizona IRB committee believes that this proposal meets the minimal risk guidelines established by the A.T. Still University Institutional Review Board. Thank you for your time and attention to detail in completing the IRB proposal submission process. You may now proceed with data collection.

The informed consent and participant questionnaires also were reviewed and approved by the IRB. The approved consents are attached to this Notice of Approval. Please keep these original documents in your study documents file and use copies for consenting participants.

If any changes are made to the protocol following this approval, you must complete and submit the Review of Changes Form located on the IRB website prior to implementing any changes. A Continuing Review Form reporting study progress is due in the IRB office four weeks prior to the anniversary of protocol approval (date 4 weeks prior to one year renewal date). A Final Report Form is due within 30 days of study completion. The Continuing Review, Final Report and Review of Changes forms are located on the IRB web site.

If you have any questions, please feel free to call or write.

Respectfully,

R Custo Bay

Curt Bay, PhD Chair, ATSU, Arizona Institutional Review Board A.T. Still University 5850 East Still Circle Mesa, AZ 85206 Main: (480) 219-6000 Office: (480) 219-6037 MesaIRB@atsu.edu

Attachments: Signed consents 1 and 2



#### MEMORANDUM

To:	Tamara Roehling Dr. Pallavi Patel College of Health Care Sciences
From:	Nurit Sheinberg, Ed.D. Chair, Institutional Review Board
Date:	July 27, 2018

Subject: IRB Amendment Approval Memo

TITLE: Are Finger Width Palpation, Tape Measure, and Caliper Reliable, Valid, and Accurate to Diagnose Diastasis Rectus Abdominis (DRA)?– NSU IRB Protocol Number 2017-538

Dear Principal Investigator,

Your submission has been reviewed and approved by the Institutional Review Board under Expedited review procedures on . You may proceed with your study.

Please Note: Stamped copies of all consent, assent, and recruiting materials indicating approval date must be used when recruiting and consenting or assenting participants.

Level of Review: Expedited

Type of Approval: Amendment

Level of Risk: Minimal Risk

Continuing Review: Continuing Review is due for this protocol on September 5, 2018. A continuing review (progress report) must be submitted one month prior to the continuing review date.

Changes: <u>Any changes</u> in the study (e.g., procedures, consent forms, investigators, etc.) must be approved by the IRB prior to implementation using the Amendment Form.

Page 1 of 2

3301 College Avenue • Fort Lauderdale, Florida 33314-7796 (954) 262-5369 • 866-499-0790 • Fax: (954) 262-3977 • Email: inb@nova.edu • Web site: www.nova.edu/inb Post-Approval Monitoring: The IRB Office conducts post-approval review and monitoring of all studies involving human participants under the purview of the NSU IRB. The Post-Approval Monitor may randomly select any active study for a Not-for-Cause Evaluation.

Final Report: You are required to notify the IRB Office within 30 days of the conclusion of the research that the study has ended using the IRB Closing Report Form.

The following modifications were approved:

Addition of/change in research personnel

The IRB made the following specific regulatory determinations:

None

Translated Documents: No

Please retain this document in your IRB correspondence file.

CC: Rose M Colon, PhD

Leah Nof, Ph.D. Funding Not Administered Through NSU

Page 2 of 2

#### A. T. Still University, Arizona Institutional Review Board **Request for Review of Changes to Research**

Study Title: Are Finger Width Palpation, Tape Measure, and Caliper Reliable, Valid, and Accurate to Diagnose Diastasis Rectus Abdominis (DRA)?

Principal Investigator: Tamara Roehling, PT, DPT

request is	for review of changes to:	
$\boxtimes$	Investigator(s)	
	Protocol	
$\boxtimes$	Consent Form (Adult Consent, Parent Permission	, Child or Teen Assent)
	Recruitment Materials	
	Other: (enter)	

Joining the study will be Athena Turnage, PT, MPT. Athena is a licensed physical therapist who works locally. Athena will serve as the second examiner in the reliability study.

Section B: Protocol - Does this Change to Research include a protocol change?

	Yes, Attach protocol amendment summary of changes with explanatory reasons for amendment	
1000	$\times$	No

Section C: Informed Consent - Are the research protocol changes sufficient to require changes to the informed consent form(s)?

Yes, revised consent(s) attached. Added investigator to the informed consent form.

No, protocol changes do not require a change in consent language

No, consent changes not required because the study is closed to participant activities.

No, the IRB granted a waiver of informed consent when the study was approved, and the proposed changes do not necessitate the addition of an informed consent process.

Section D: Recruitment Materials - Attach new or revised recruitment or participant information documents requiring IRB review.

Section E: Signatures	$\cap$
Principal Investigator Signature	anat
If Principal Investigator is a student,	$\sim$

Date: 02/19/2018

Faculty Advisor Signature:

IRB Chair/Vice Char/Coordinator Signature: \_

Date: \_\_\_\_

**IRB Decision:** Approved Not Approved, Reason:

Denise Level Date: 2-20-2018 Revision Date: 3-1-2011

Page 1 of 1

Appendix 2: Consent Forms

	NSU IRB APPROVED: Approved: September 6, 2017 Expired: September 5, 2018 IRB#: 2017-538-Non-NSU Health	
A.T. STILL UNIVERSITY AT	SU	
Institutional Review Board - Arizo	na	
Adult Informed Consent Form for Minimal	Risk Studies	
Form 1: Study Information	l.	
General Information	÷	
Study Title: Are finger width palpation, tape measure, and caliper re diagnose diastasis rectus abdominis (DRA)?	liable, valid, and accurate to	
Principal Investigator:		
Tamara Roehling, PT, DPT Director, Post-Professional DPT Program and Assistant Professor, Ph 5850 E. Still Circle, Mesa, AZ 85206 480-219-6187	nysical Therapy	
Other Investigators:		
Leah Nof, PhD, MS, PT Alicia Fernandez-Fernandez, PT, DPT, PhD Karen Abraham, PT, PhD Inder Makin, MD, PhD Athena Turnage, PT, MPT		
Research Location: A.T. Still University (480-219-6000)	3	
You are invited to be in a study titled: Are Finger Width Palpation, Ta Reliable, Valid, and Accurate to Diagnose Diastasis Rectus Abdomin	ape Measure, and Caliper is (DRA)?	
Page 1 of 4		
	5	

NSU IRB APPROVED: Approved: September 6, 2017 Expired: September 5, 2018 IRB#: 2017-538-Non-NSU Health

This form provides information about the study and contact information. This study is being conducted by A. T. Still University and Nova Southeastern University. The purpose of this study is to increase understanding of how accurate the clinical tools we use to screen for diastasis recti abdominis (separation of the abdominal muscle) are. Any questions you may have about being in the study will be answered by a study team member.

<u>Voluntary Participation</u>: Research studies include only people who volunteer. Before you decide if you want to be in this study, it is important that you understand why the study is being done and what will be involved. If you do not want to be in the study, you will not lose any current medical benefits. You may drop out of the study at any time without losing any current benefits. The study team may decide to end your participation early, if they think ending the study is in your best interest. If you want to end the study early, you should talk to the study team. You may be asked to complete some tests before ending the study.

Study Procedures: 51 people will take part in this study.

If you agree to take part in this study, your involvement will last approximately 90 minutes. You will be asked to return to the research laboratory one time. The first research visit will take approximately 60 minutes and the second visit will take approximately 30 minutes.

During the study, you will have the distance measured between the two abdominal muscles using the following measurement techniques:

 Ultrasound imaging. The ultrasound examination will be conducted by a registered medical sonographer. Ultrasound gel will be applied to the abdominal region and ultrasound images will be taken at rest and while performing a partial sit-up.



 Finger width palpation. Examiners' fingers will be placed on the abdominal muscles, near the belly button region, and the number of fingers that fit between the two muscles while performing a partial sit-up will be recorded.

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NSU IRB APPROVED: Approved: September 6, 2017 Expired: September 5, 2018 IRB#: 2017-538-Non-NSU Health



• Caliper. A caliper will be used while performing a partial sit-up.



· Tape measure. A tape measure will be used while performing a partial sit-up.

Additionally, you will be given a questionnaire regarding age, sex, number of pregnancies/births, mode of delivery (vaginal or Caesarean), weight, height, ethnicity, and presence of low back pain, pelvic pain, urinary incontinence, fecal incontinence, and prolapse (organs in the pelvic region that drop from their normal position).

<u>Study Risks:</u> Some risks from participating in the study include: Loss of confidentiality: the study team will keep information about your study involvement and your study test results private and in locked filing cabinets and password protected computer files. However, confidentiality of study information cannot be guaranteed 100%.

Although unlikely, the study procedures may involve risks to you that are not known. ATSU does not have funds available to treat study related injuries.

To the best of your knowledge, you should not be participating in any other medical research study at the same time you participate in this study.

<u>Pregnancy Restrictions:</u> If you are pregnant you should not participate in the study. The procedure of laying on your back for an extended time after the first trimester may harm the developing baby. If you do become pregnant, you need to tell the study team.

Page 3 of 4

NSU IRB APPROVED: Approved: September 6, 2017 Expired: September 5, 2018 IRB#: 2017-538-Non-NSU Health

Study Benefits: The possible benefits you may experience from the study include identifying you have a diastasis rectus abdominis (splitting of the abdominal muscles) so proper treatment referral can be made. However, there is no guarantee that you will benefit from being in this study.

Other Choices If Not In This Study: This is not a treatment study. There are no alternatives to being in this study.

Study Costs: There is no charge for any of the study procedures. Neither you nor your insurance company will be billed for any charges specifically related to this study.

Study Payments: There is no payment for being in the study.

<u>Consent to be in the Study</u>: Before making the decision to be in this study, you should discuss the study with a member of the study team, review the information in this form, and have all of your questions answered. Your signature below means that you have received this information, have asked questions about the study and your questions have been answered. You will receive a copy of this form.

#### Participant

I have read the above statements and give my informed and free consent to be in this study.

Signature of Participant/Printed Name

Date

#### Study Staff Member

I, \_\_\_\_\_\_ certify that I have explained to the above individual the nature and purpose of the research study. I have provided the participant a copy of this consent document.

Signature of Person Conducting Consent Discussion

Date

Page 4 of 4

	A.T. Stil	I Unive	ersity,	Arizona
Insti	tutional	Review	V Bo	ard Approval
IRI	3 #	201	1- 9	8
Valid	2-20-	2018	to,	4.20-2610
Off	icial	dl	onde	

NSU IRB APPROVED: Approved: September 6, 2017 Expired: September 5, 2018 IRB#: 2017-538-Non-NSU Health Care Institution

## A.T. STILL UNIVERSITY ATSU

#### Institutional Review Board - Arizona

#### Form 2: A. T. Still University and U.S. Department of Health & Human Services Required General Information for Research Participants

Study Title: Are finger width palpation, tape measure, and caliper reliable, valid, and accurate to diagnose diastasis rectus abdominis (DRA)?

#### **Principal Investigator:**

Tamara Roehling, PT, DPT Director, Post-Professional DPT Program and Assistant Professor, Physical Therapy 5850 E. Still Circle, Mesa, AZ 85206 480-219-6187

You are receiving this general information because you want to participate in research conducted by A. T. Still University. The university and the federal government (Department of Health and Human Services) require that all research participants receive the following information. This is general information for you to take home and refer to, if necessary.

#### **Confidentiality of Study Participation**

While in the study, you will be providing information to the study team. Your participation in this research will be kept confidential to the extent permitted by law. Some of the research information could personally identify you. Your research records that are reviewed, stored and analyzed at *ATSU* will be kept in a locked area in Dr. Roehling's office at 5850 E. Still Circle, Mesa, AZ. To maintain your confidentiality, a number will be given to your study information. The list that matches your name with the code number will be kept in a locked file in Dr. Roehling's office at 5850 E. Still Circle, Mesa, AZ. The results of the study may be published but neither your name nor identity will be revealed. To maintain your confidentiality, a number will be given to your study information. Computerized information from the study will be kept in a password-protected file on a computer located in Dr. Roehling's office at 5850 E. Still Circle, Mesa, AZ and Dr. Makin's office at 5835 E. Still Circle, Mesa, AZ. Only the research investigators will have access to your study information.

Even the most secure computer systems can be broken into. You should understand that your study information may not stay confidential. The study team is committed to respecting your confidentiality, but there may be actions beyond their control.

#### Access to Research Records

NSU IRB APPROVED: Approved: September 6, 2017 Expired: September 5, 2018 IRB#: 2017-538-Non-NSU Health Care Institution

The following people or groups may inspect and copy study records.

· The Principal Investigator and research team

 The A. T. Still University Institutional Review Board (a committee that reviews and approves research studies) and

• The A. T. Still University Sponsored Programs Office

It is possible that some of the other people/groups who receive your health information may not be required by federal privacy laws to protect your information and may share it without your permission. The following groups or people outside ATSU may have access to your research records.

 The Office of Human Research Protections in the U.S. Department of Health and Human Services

#### **Research Participant Rights**

If you have questions about your rights as a research participant you may contact the Chairperson of the A. T. Still University, Arizona, Institutional Review Board at 480-219-6000.

#### **Research Related Injury**

If you think you have been injured or your condition aggravated while in a research study at A. T. Still University, you should contact the study team. The study team will assess your injury and determine treatment needed. A. T. Still University has not set aside any funds to provide payment for injury while in a study.

#### Signatures

I have been provided with this information on confidentiality and use or disclosure of my private health information while participating in a study conducted by A. T. Still University.

Study Participant/ Printed Name

Date

I have provided a copy of this document to the study participant.

Study Staff Member/Printed Name

Date

IRB # 2017-098 Approved

Valid 04/21/2017 to 04/20/2018

R Curtis Bay

Appendix 3: Demographic Questionnaire

- 1. Age: \_\_\_\_\_
- 2. Sex (circle one): Female Male 3. For females, number of times have given birth: Number of singleton (1 fetus) births \_\_\_\_\_\_ Number of twins (2 fetuses) births \_\_\_\_\_\_ Number of triplets (3 fetuses) births 4. For females, mode of delivery: Number of vaginal deliveries Number of Cesarean (c-section) deliveries 5. Weight: \_\_\_\_\_ Height: \_\_\_\_\_ 6. Ethnicity (circle all that apply): American Indian or Alaskan Native Asian Asian Indian Black or African American
  - Caucasian

7. Do you have the following (circle yes or no):

•	Low back pain	Yes	No
•	Pain in pelvic region:	Yes	No
•	Pain in lower abdominal region	Yes	No
•	A feeling of pressure/fullness in pelvic region	Yes	No
•	A feeling that something is falling out of the vagina/rectum	Yes	No
•	Difficulty controlling flatulence (gas)	Yes	No
•	Involuntary loss of stool/feces	Yes	No

8. The Questionnaire for Urinary Incontinence Diagnosis (QUID)

Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments...

<ul><li>when you cough or sneeze?</li></ul>	Yes	No
<ul> <li>when you bend down or lift something up?</li> </ul>	Yes	No
• when you walk quickly, jog or exercise?	Yes	No
• when you are <b>undressing</b> in order to use the toilet?	Yes	No
Do you get such a <b>strong and uncomfortable</b> <b>need</b> to urinate that you leak urine (even small drops) or wet yourself before you reach the toilet?	Yes	No
Do you have to <b>rush to the bathroom</b> because you get a <b>sudden, strong need</b> to urinate?	Yes	No

## Appendix 4: Recruitment Flyer With and Without NSU Approval Stamp

NSU IRB APPROVED: Approved: September 6, 2017 Expired: September 5, 2018 IRB#: 2017-538-Non-NSU Health



## **Research volunteers needed**

to increase the understanding of how accurate the clinical tools we use to screen for diastasis recti abdominis are.

Are you in the age of 18 to 64 years and are at risk for your abdominal muscles separating? Risk factors include having been pregnant, routinely lifting heavy objects, obesity, weight fluctuations, and performing full sit-ups. We are seeking men and women in this age group for participation in a 1 week research study.

Participation includes a questionnaire and having examiners measure the distance between your abdominal muscles using ultrasound, fingers, tape measure, and caliper. Participants will need to travel to A.T. Still University (5850 E. Still Circle, Mesa, AZ 85206) for 2 appointments. There is no cost or monetary compensation. A possible benefit from participating in this study is determining whether you have a diastasis recti abdominis. If you do, a proper treatment referral can be made.

For inquiries, please contact Tammy Roehling, PT, DPT at 480-219-6187 or troehling@atsu.edu.

Study approved by the A.T. Still University (#2017-98) and Nova Southeastern University Institutional Review Board <insert IRB number>.



# **Research volunteers needed**

to increase the understanding of how accurate the clinical tools we use to screen for diastasis recti abdominis are.

Are you in the age of 18 to 64 years and are at risk for your abdominal muscles separating? Risk factors include having been pregnant, routinely lifting heavy objects, obesity, weight fluctuations, and performing full sit-ups. We are seeking men and women in this age group for participation in a 1 week research study.

Participation includes a questionnaire and having examiners measure the distance between your abdominal muscles using ultrasound, fingers, tape measure, and caliper. Participants will need to travel to A.T. Still University (5850 E. Still Circle, Mesa, AZ 85206) for 2 appointments. There is no cost or monetary compensation. A possible benefit from participating in this study is determining whether you have a diastasis recti abdominis. If you do, a proper treatment referral can be made.

For inquiries, please contact Tammy Roehling, PT, DPT at 480-219-6187 or troehling@atsu.edu.

Study approved by the A.T. Still University (#2017-98) and Nova Southeastern University Institutional Review Board (#2017-538).

Appendix 5: Site Approval Letter

# A.T. STILL UNIVERSITY FIRST IN WHOLE PERSON HEALTHCARE ATSU

Nova Southeastern University 3301 College Avenue Fort Lauderdale, FL 33314-7796

Subject: Site Approval Letter

To whom it may concern:

This letter acknowledges that I have received and reviewed a request by Tamara Roehling, PT, DPT to conduct a research project entitled "*Are Finger Width Palpation, Tape Measure, and Caliper Reliable, Valid, and Accurate to Diagnose Diastasis Rectus Abdominis (DRA)?*" at the A.T. Still University Interdisciplinary Research Lab located at 5845 E. Still Circle. Mesa, AZ 85206. I approve of this research to be conducted at our facility.

When the researcher receives approval for his/her research project from the Nova Southeastern University's Institutional Review Board/NSU IRB, I agree to provide access for the approved research project. If we have any concerns or need additional information, we will contact the Nova Southeastern University's IRB at (954) 262-5369 or irb@nova.edu.

Sincerely,

Alli Bi

Kellie C. Huxel Bliven, PhD, ATC Associate Professor, Human Anatomy Director, Interdisciplinary Research Laboratory <u>kbliven@atsu.edu</u> 480-219-6191

## References

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