A quantitative assessment of the effects of passive upper extremity exoskeletons on sonographer's muscle activity and posture while performing transthoracic echocardiograms

by

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ABSTRACT

Sonographers assume awkward postures of the upper extremities and torso while performing scanning tasks. Upper extremity exoskeletons are a potential ergonomic intervention to support sonographers in their work. This study examined the effects of a passive upper extremity exoskeleton on objective muscle activity and posture and subjective discomfort of sonographers performing transthoracic echocardiograms (TTE). Four practicing sonographers performed TTE procedures using both the right- and left- handed scanning TECHNIQUES, with and without a passive upper extremity EXOSKELETON (2x2 design). A randomized complete block design was used with participants acting as the blocking variable. At the 50th percentile of normalized muscle activity, the exoskeleton significantly reduced the right upper trapezius ($p=0.045$), left upper trapezius ($p<0.001$), and the right medial deltoid ($p=0.034$) activation. There was also a significant interaction between EXOSKELETON and TECHNIQUE for the right anterior deltoid ($p=0.0007$) and the left medial deltoid ($p=0.006$), though simple effects analysis revealed the exoskeleton only reduced muscle activity in left-handed scanning. At every percentile level considered, the exoskeleton tended to reduce muscle activity during left-handed scanning but had little impact on right-handed scanning. Averaged across right and left-handed scanning, the 50th percentile of posture data showed the exoskeleton significantly reduced the vertical angles of the torso (14.5 vs. 21.1 degrees), left arm (15.3 vs. 21.4 degrees), and right arm (24.4 vs. 28.4 degrees) but had no impact on head angle. However, self-reported discomfort and utility did not reflect the results from the objective measures. This study provides data to support the hypotheses that upper extremity exoskeletons have positive impacts on muscle activity and posture in sonography, but the type of work and the interaction between the sonographer and patient must be considered in order for the device to provide the greatest benefit.

CHAPTER 1. **INTRODUCTION**

1.1 Ergonomic Risk in Sonography

Sonography is a medical imaging procedure where ultrasonic waves are sent out through a transducer in order to develop images of different structures in the body. This diagnostic procedure is often referred to as an ultrasound. Health care providers who perform this procedure are known as sonographers.

During a procedure, sonographers use ultrasound machines to create diagnostic imaging. Sonographers hold a transducer in one hand against the patient's body at the location of interest. The transducer must be firmly pressed into the patient's skin in order to ensure good contact. The other hand is frequently used to operate a computer in order to collect and save data (Figure 1).

Figure 1. Sonographer assumes scanning position while simulating a left-handed transthoracic echocardiogram procedure

Sonographers are exposed to many of the recognized risk factors for developing work-related musculoskeletal disorders (WRMSDs) due to the nature of the physical requirements of their work. Risks for developing WRMSDs include force, repetition, vibration, and awkward postures (Bernard, 1997; Da Costa & Vieira, 2010) of which force, repetition, and static awkward postures are present when performing ultrasonography. Sonographers must apply pressure to the transducer to maintain contact with the patient throughout the procedure (Murphey, 2017). In a review of the literature it has been found that postural risk factors for sonographers include shoulder abduction and flexion, wrist deviation and flexion, and bending/twisting of the trunk and neck (Tinetti & Thoirs, 2019). These postures arise as sonographers attempt to operate the transducer and the computer simultaneously while navigating around the patient and the bed. The sonographer often holds these static awkward postures for extended periods of time, making adjustments to the transducer location as necessary to obtain clear images. Sonographers often perform multiple exams over the course of a day, adding repetition to the work (Murphey, 2017).

As early as 1985, the medical community became aware of the ergonomic hardships faced by sonographers. Craig (1985) polled a group of 100 sonographers on health hazards they felt were associated with their job. Sonographers reported back injuries from moving patients and heavy equipment, as well as muscle strain in their upper extremities, including wrist tendinitis and carpal tunnel, due to the force and maneuvering required while operating the transducer. This study documented the “sonographer’s shoulder”, characterized by work-related pain and discomfort in the shoulder, which has been identified as a health concern in sonographers since (Alshuwaer & Gilman, 2019; Coffin, 2014; Friesen, Friesen, Quanbury, & Arpin, 2006; Pike, Russo, Berkowitz, Baker, & Lessoway, 1997; Russo, Murphy, Lessoway, &

Berkowitz, 2002). These reports have been supported by objective findings of sonographer posture and workload. When considering sonographer posture in a variety of diagnostic scanning procedures, on average, sonographers spend 66% of scanning time with a shoulder abducted more than 30 degrees (Village & Trask, 2007). This same study found that in all shoulder muscles considered (middle trapezius, supraspinatus, infraspinatus) the muscle activity was at or above 3-10% of maximum voluntary contraction during 90% of scanning time.

Pain in sonographers is wide spread and can be severe. Previous studies have noted between 80-91% of sonographers feel pain and discomfort related to their work (Burnett & Campbell-Kyureghyan, 2010; Claes, Berger, & Stassijns, 2015; Horkey & King, 2004; Muir, Hrynkow, Chase, Boyce, & McLean, 2004; Pike et al., 1997; Russo et al., 2002; Vanderpool, Friis, Smith, & Harms, 1993). Additionally, pain from sonography is not isolated to one area of the body. A survey of diagnostic medical sonographers and vascular technologists found that all respondents with shoulder pain experienced pain in at least one additional area including the neck, back, arm, elbow/ forearm, wrist, or hand/finger (Roll, Evans, Hutmire, & Baker, 2012).

In a study conducted at Mayo Clinic, where the current study takes place, sonographers were found to be a high-risk group for the development of workplace injuries and discomfort. Barros-Gomes and colleagues surveyed members of the cardiovascular medicine department and ten Mayo Clinic facilities including both sonographers and their peers (other members of the cardiovascular department including nurses, technicians, staff physicians, and administrative assistants) (Barros-Gomes et al., 2019). This study found a prevalence of work-related musculoskeletal pain in a majority of sonographers and at a much higher rate than their peers (86% vs 46%). Similar to other studies (Friesen et al., 2006; Pike et al., 1997; Russo et al., 2002; Seto & Biclar, 2008; Tinetti & Thoirs, 2019), the findings from Barros-Gomes and colleagues

(2019) report the neck, shoulder, lower back, and hand as the most common sites for sonographer discomfort. It is important to note that sonographers missed work, had work restrictions, and considered changing employment more often than their peers (Barros-Gomes et al., 2019).

Echocardiography can be an especially challenging type of sonography. In these types of procedures, there is little variation in posture compared to other types of sonography, such as vascular sonography (Simonsen & Gard, 2016). Roberts et. al (2019) provided risk factors specific to cardiac sonography including single organ scanning, small scanning windows, and the increased force to the transducer required to obtain images on obese patients. For cardiac sonographers, procedures can take a significant amount of time; Evans, Roll, Hutmire, & Baker (2010) found the majority of cardiovascular procedures to take between 15 to 45 minutes, while Russo, Murphy, Lessoway, & Berkowitz (2002) found procedures to last an average of 44 minutes. With an average of five echocardiographic exams per day (Simonsen, Axmon, Nordander, & Arvidsson, 2017), these sustained and repeated postures can have negative effects on the sonographer's musculoskeletal health. Cardiac sonographers have comparable rates of pain to their sonography peers in other specialties with 80% of cardiac sonographers reporting musculoskeletal pain (Smith, Wolf, Xie, & Smith, 1997).

In summary, there have been numerous studies surveying sonographers to assess work-related musculoskeletal disorders (Barros-Gomes et al., 2019; Claes et al., 2015; Craig, 1985; Evans et al., 2010; Friesen et al., 2006; Horkey & King, 2004; Muir et al., 2004; Pike et al., 1997; Russo et al., 2002; Smith et al., 1997; Vanderpool et al., 1993) and while these studies are important to document prevalence of the issue, they do not investigate what can be done to mitigate the problem. Clearly, sonographers are a group at high-risk for developing musculoskeletal illnesses/injuries and could benefit from ergonomic intervention.

1.2 Ergonomic Interventions in Sonography

The Australasian Society for Ultrasound in Medicine (2001) recommended sonographers think about posture “all the time” to avoid bending, twisting, sustained posture, arm abduction, and awkward postures. They recommend ergonomic considerations such as alternating scanning hand and using a support when the shoulder is abducted. Most sonographers report there is a need for ergonomic interventions and are aware of different types of interventions (Horkey & King, 2004). Despite this knowledge, patient comfort and obtaining high quality images is often prioritized over good ergonomic practices (Simonsen & Gard, 2016). Sonographers may be hesitant to implement ergonomic practices such as alternating scanning hand out of concern changes to workflow may negatively affect performance, but no difference in image quality has been found between right and left-handed scanning (Bastian et al., 2009).

A few studies have attempted to move beyond documenting musculoskeletal pain to introduce potential ergonomic interventions (Butwin, Evans, Klatt, & Sommerich, 2017; Murphey & Milkowski, 2006; Sommerich et al., 2019, 2016). Murphey & Milkowski (2006) investigated how changing the position of the scanning arm affected muscle activity. This study found that reducing the abduction angle of the scanning arm from 70 degrees (a typical working position) to 30 degrees, muscle activity was reduced by 46%. When the arm was abducted 30 degrees and the forearm supported with foam blocks, the muscle activity was reduced 78% compared to the 70 degree abduction position. Butwin et al. (2017) exposed sonographers to a combination of ergonomics education and mind-body techniques such as biofeedback through surface electromyography and yoga. Though survey data did not demonstrate significant differences in mean change scores of subjective upper extremity pain before and after the interventions across the three groups, the study did note an improvement in posture to participants exposed to biofeedback training.

Sommerich et al. (2016, 2019) worked with sonographers and vascular technicians to identify needs and provide pilot studies of intervention prototypes. In Sommerich et al. (2016), a pilot study added chair attachments to portable ultrasound machines, allowing for sonographers to sit while performing exams throughout the hospital. This intervention was given an average usability rating of 4.9 (1-5 scale, 5 is the best) and usefulness of 4.8 (1-5 scale). In the same study, an articulating arm support used to hold the transducer while scanning decreased shoulder muscle activity and reduced shoulder abduction angles by 6-11 degrees. The intervention was limited to assist with left-handed scanning and some participants found it difficult to determine the correct location to place the transducer in the prototype while scanning. Sommerich et al. (2019) investigated an inflatable pelvic support wedge to elevate and tilt the patient's pelvis during a transvaginal exam, allowing sonographers to assume more proper positioning. The prototype was well received, with diagnostic medical sonographers scoring the device 6 out of 7 (where 7 is the best) for desirability and 6.5 out of 7 for usefulness. Additionally, Sommerich et al. (2019) looked into force augmentation pumps, which provides an alternative to the vascular technologist manually compressing a patient's muscle. The augmentation pumps allowed the vascular technologists to adapt more neutral postures in both sitting and standing procedures and the two pumps used had an average usability rating of 5 (scale 1-7) and 5.5 (scale 1-7) for usefulness. Though these studies have made positive steps forward in addressing the ergonomic concerns in sonography, further research is needed to investigate the usability and effectiveness of alternative ergonomic interventions.

1.3 Exoskeletons as an Ergonomic Intervention

One potential intervention to reduce the risk of injury in sonographers is the use of exoskeletons. Perry, Rosen, & Burns (2007) defined exoskeletons as an "external structural mechanism with joints and links corresponding to those of the human body" (p. 408). An exoskeleton is designed to aid or enhance a human's physical performance. When donned, an exoskeleton attaches to the body, allowing the user to experience increased physical performance such as increased strength or performance.

There are several types of exoskeletons, each suited for a different type of activity or task. Exoskeletons can be described as 'active' or 'passive'. Active exoskeletons use an external source of energy to support human motion. This external energy may be supplied through electric motors, pneumatic muscles, or hydraulic power (Gopura & Kiguchi, 2009). Conversely, passive exoskeletons store energy in materials, such as springs or dampers, until the energy is needed to support the user's motion (de Looze, Bosch, Krause, Stadler, & O'Sullivan, 2016).

Exoskeletons can also be classified by the part of the body they are designed to support- often the upper extremities, lower extremities, or back. Lower extremity exoskeletons often focus on walking in an attempt to conserve energy to allow the user to travel great distances with less fatigue or reduced agility (Gregorczyk et al., 2010; Panizzolo et al., 2016). Other exoskeletons are designed to benefit the back during manual material handling and other lifting tasks (Toxiri et al., 2019). The third type of exoskeleton is designed to support the upper extremities. These exoskeletons provide the most benefit when use for tasks that require overhead work or other tasks where the arm is flexed or abducted for extended periods of time. Due to the nature of the sonographer's work, upper extremity exoskeletons would have the most benefit to this occupation. Sonographers work requires holding elevated and abducted arm positions for long durations of time. An upper-extremity exoskeleton could provide support to the arms and shoulders, reducing the discomfort in these areas.

Exoskeletons have been around for many years, with the military being one of the earliest adopters in the United States. US Army Research Laboratory and its predecessors have spent nearly three decades developing, studying, and identifying uses for exoskeletons (Crowell, Park, Haynes, Neugebauer, & Boynton, 2019). One application of exoskeletons of interest to the military has been on the ability of a solider to carry loads across distances. Several studies have investigated using exoskeletons to support the weight of the carried load and assist with the walking or running actions (Gregorczyk et al., 2010; Panizzolo et al., 2016). The US Army has studied both upper and lower extremity exoskeletons to assist in these tasks. In order to be functional in a military application, an exoskeleton must not support a specific task by limiting the ability to perform other related tasks. This is an important consideration in future work when adapting exoskeletons to other industries.

Research has been conducted in manufacturing industries with the use of both low-back (Hensel & Keil, 2019) and upper-extremity (Gillette & Stephenson, 2019; Smets, 2019) exoskeletons under study. Upper extremity exoskeletons were found to significantly reduce anterior deltoid EMG amplitudes during consecutive job cycles, with the exoskeleton most likely to benefit jobs with prolonged overhead movements (Gillette & Stephenson, 2019). In manufacturing settings, exoskeletons can also reduce self-reported scores of physical discomfort (Hensel & Keil, 2019; Smets, 2019). In order to obtain any benefits from the devices, workers must be willing to wear the exoskeleton. Exoskeletons must not cause discomfort to the operators during use (rubbing, chaffing, pinching) or their willingness to use the exoskeleton drops (Hensel & Keil, 2019; Smets, 2019).

Researchers have begun to consider the use of exoskeletons in health care, and not just for the patients, but for the health care providers themselves. Previous research has studied the use of exoskeletons from the patient perspective, including the use of lower limb exoskeletons for medical rehabilitation purposes (Unluhisarcikli, Pietrusinski, Weinberg, Bonato, & Mavroidis, 2011). However, little research has been done on the potential applications for the health care providers themselves. When considering the potential application for an exoskeleton in health care, members of the care delivery team have similar requirements to the adaptation of exoskeletons as workers in other industries- the exoskeleton must be easy to use, comfortable, and not interfere with the work task (Cha, Monfared, Stefanidis, Nussbaum, & Yu, 2020). If used in the operating room, an exoskeleton must also be easy to sterilize. Liu et al. (2018) conducted a study on surgeon's use of exoskeletons, focusing on surgeons who perform laparoscopic procedures. In a series of dexterity tests, there was no difference in completion times between participants with and without the exoskeleton. In the laboratory phase, participants stood three feet away from a target and focused a laparoscopic camera at it in a simulated laparoscopic surgery task. At the ten minute mark subjects reported less arm and shoulder pain with the use of the exoskeleton (3.11 vs 5.88 out of 10, $p=0.019$). In the operating room phase, participants reported experiencing less shoulder pain with the use of the exoskeleton (0.143 vs 1.143 out of 5, $p<0.0189$), and six out of seven participants would consider incorporating the device into their daily practice. Exoskeletons have great potential to reduce musculoskeletal disorders and physical discomfort in surgical team members but, there remain other health care providers who may also benefit from the use of this technology.

Exoskeletons have been shown to increase human capabilities and decrease fatigue and the risk of musculoskeletal injury. However, there are some cautions to consider when implementing exoskeletons. Safety is an important factor to consider when implementing use of an exoskeleton. Active exoskeletons often have cords or wires that power the system which may pose tripping hazards. Exposed hinges and other surfaces have the potential to pinch or snag. Many authors have highlighted the importance of proper exoskeleton fit (Crowell et al., 2019; Gillette & Stephenson, 2019; Smets, 2019) to ensure safety, user comfort, and effectiveness.

There is also the possibility that exoskeletons can transfer loads from the supported area to other areas of the body, causing higher activities in different muscles. Van Engelhoven et al. (2019) examined the impact of the level of support, or peak torque amplitude (PTA) provided by an exoskeleton. The study found decreasing levels of shoulder muscle activity with an increase in PTA provided by the exoskeleton. However, at the highest level of support, the agonist muscles reduced in activity, but the activity in the antagonist muscles increased by 22%. The authors suggest adjusting the support of an exoskeleton to fit both the user and the task, as an exoskeleton that provides high levels of support may overpower a person of smaller anthropometrics using a light tool. Another study investigated the effects of an exoskeletal vest and mechanical arm on the lumbar spine, an area of the body the exoskeleton was not designed to support. Across the two tool weights used in the study, the use of the exoskeleton increased the mean muscle forces in the left erector spinae (78.5%) and right erector spinae (120%) (Weston, Alizadeh, Knapik, Wang, & Marras, 2018). Thus, matching the exoskeleton to the body part, participant size, and task is crucial.

Exoskeletons may also be limited to a highly specific purpose and cannot address every risk factor for developing musculoskeletal illness and injury. In a study of postural assist exoskeletons, the exoskeleton reduced mean peak sagittal torso flexion by 14.2 degrees when lifting from shin height (Picchiotti, Weston, Knapik, Dufour, & Marras, 2019). However, the exoskeleton was not able to provide a benefit when compared to the control in terms of moment arms or peak spinal loads. Despite these concerns surrounding exoskeletons and user compliance with the device, the promising results from exoskeletons applied in military, automotive, agricultural, and medical sectors show that exoskeletons can be effective in reducing the amount of physical discomfort and may be a useful intervention in sonography. The introduction of an exoskeleton in sonography could support the upper extremities while allowing for the freedom of movement and the ability to perform both right and left-handed scanning. The exoskeleton may also encourage sonographers to assume a more upright posture by providing the support necessary to reach the patient simply by using their arms to reach, instead of flexing their torso.

The current study moves beyond assessing the prevalence WRMSD in sonography by examining the effectiveness of exoskeletons as a potential ergonomic intervention. In doing so, this study will explore the impact of exoskeletons in a clinical setting through objective and subjective measures.

1.4 Research Question and Hypothesis

This study aims to 1) evaluate the effectiveness of an exoskeleton in reducing muscle activity during sonography; 2) explore the impact of an upper extremity exoskeleton on the postures assumed during sonography; and 3) investigate the impact of an exoskeleton on self-reported measures of physical discomfort. It is hypothesized that the use of the exoskeleton will lower muscle activity in the upper trapezius and deltoids in sonographers performing transthoracic echocardiogram imaging procedures. This will be reflected in lower work-related physical discomfort, especially in the shoulders. Additionally, it is hypothesized that when using the exoskeleton, sonographers will have a more upright torso posture than without the exoskeleton.

CHAPTER 2. **METHODS**

2.1 Participants

Four sonographers participated in the experiment (two males, two females). All sonographers were ambidextrous in their ability to perform the procedure, but two participants (one male, one female) typically performed the procedure with their right hands and two participants typically performed the procedure with their left hands. Participants had an average (and standard deviation) stature of 179.5 (5.4) cm, body mass of 105.4 (52.2) kg. All participants had at least two years of experience working as a sonographer with a mean (standard deviation) of 5.5 (3.4) years.

2.2 Equipment

2.2.1 Electromyography

Surface electromyography (EMG) was used to collect data on the deltoid and trapezius muscles using the Delsys Trigno Wireless EMG system with Trigno Avanti sensors (Delsys Inc., MA) with a sampling frequency of 1926 Hz. Six electrodes were placed bilaterally on the upper trapezius, anterior deltoid, and medial deltoid following SENIAM standards (Figure 2).

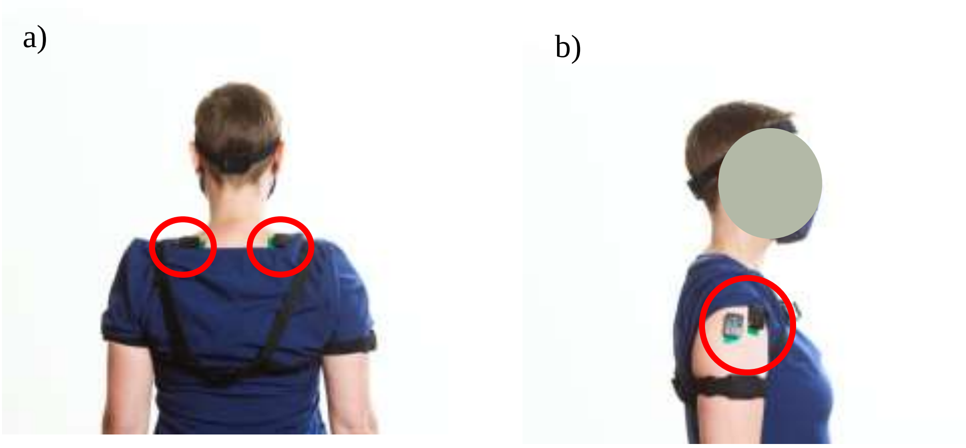


Figure 2. Placement of EMG sensors on a) the upper trapezius and b) the anterior and medial deltoid

2.2.2 Inertial Measurement Units

APDM Opal (ADPM Inc., OR) inertial measurement units (IMUs) with a sampling frequency of 128 Hz were used to continuously record posture. Sensors were fixed to elastic bands and secured at the back of the head, upper back, and right and left upper arms and wrists (Figure 3). Sensors were calibrated to body segment orientation when participants stood straight and looked forward with their arms close to the body (Figure 3).

2.2.3 Exoskeleton

In this study, the exoskeleton was the AIRFRAME ® by Levitate Technologies, Inc (San Diego, CA, USA). This exoskeleton was designed to provide increased support to the arms as arm elevation increased. Before data collection, participants were fit to the exoskeleton to determine the correct spine length, arm length, and level of support. In addition to the researchers, a representative from Levitate Technologies was present to verify proper fit for each participant. The two female participants were fit to the medium exoskeleton (Part number: 210002) and the male participants to the medium-long exoskeleton (Part number: 210004) based on stature. To ensure a comfortable fit, participants wore the exoskeleton for 1-2.5 hours on a day prior to data collection during which they performed a transthoracic echocardiogram procedure and completed computer work. After the task, any further adjustments to the exoskeleton fit were made. The task completed on this day was solely to help participants fit the exoskeleton appropriately and experience wearing the device. No data were collected during this time. Figure 4 shows a participant wearing the exoskeleton, EMG sensors, and IMU sensors.

Figure 3. IMU sensor placement and calibration pose

a)

b)

Figure 4. Participant wears the exoskeleton, EMG sensors, and IMU sensors a) Anterior view b) Side view

2.2.4 Subjective Measures

Surveys were used to obtain self-reported measures of discomfort during TTE procedures for the neck, left and right shoulder, left and right upper arm, left and right wrist/hand, upper back, and lower back (scale: 0=no discomfort, 10= significant discomfort). In the exoskeleton condition, participants were also asked to rate if the exoskeleton interfered with their work (0= no interference, 10= greatly interfered) and if the exoskeleton improved their ability to perform work (0= no improvement, 10= great improvement). These surveys were given after every TTE procedure (Appendix A-B). At the end of the day, participants were given an additional survey. On days participants wore the exoskeleton, participants were asked to rate how the exoskeleton affected their physical comfort, if they would like to use the exoskeleton in future procedures, and given space to provide open-ended comments regarding the use of the exoskeleton (Appendix C). On days without the exoskeleton, participants were given the opportunity to provide comments about their work and the study generally (Appendix D).

2.3 Description of the Task

Participants completed transthoracic echocardiogram (TTE) procedures according to normal work standards. During the TTE procedure, the sonographer used ultrasound machines to create diagnostic imaging. One hand was used to move a transducer over a patient’s torso and the other hand simultaneously operated a computer. During right handed scanning procedures, sonographers elevated their right arm to wrap around the patient’s torso in order to make contact between the transducer and the patient’s torso (Figures 5-6). When scanning with their left hand, sonographers used their left hand to operate the transducer. In this case, the sonographer did not have to reach across the patient’s torso, but used their arm to cross the distance between the edge of the patient’s bedside to the patient’s torso (Figure 5-6). In the current study, sonographers primarily completed the procedures in a seated position either on a chair next to the patient’s bedside or on the edge of the bed. Work stations had adjustable height monitors, allowing the sonographers to set the monitor in their preferred location. Occasionally, the sonographers would stand for a brief period of time in order to obtain the subcostal images for about five minutes.

Figure 6. Scanning position without exoskeleton for a) left-handed scanning and b) right-handed scanning

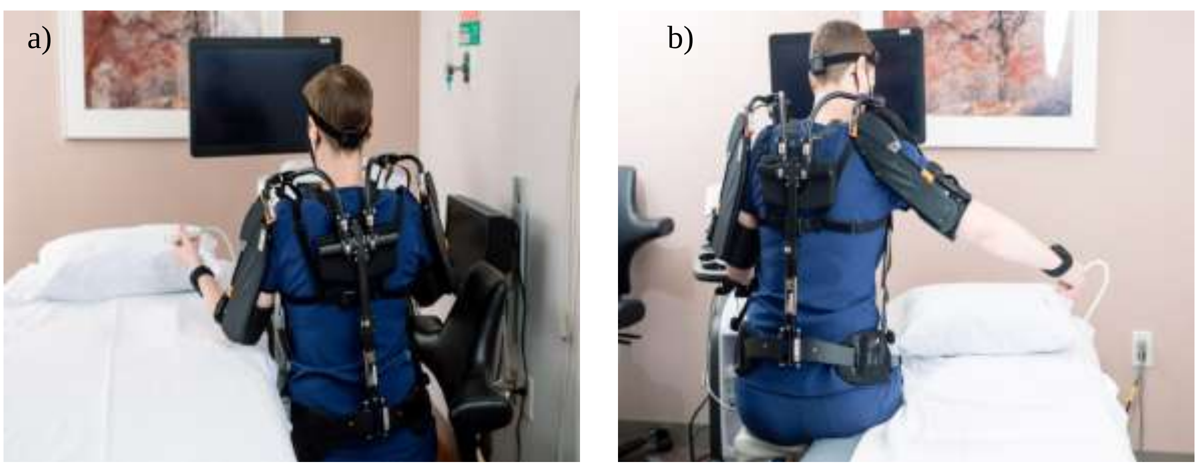


Figure 5. Scanning position with exoskeleton for a) left-handed scanning and b) right-handed scanning

2.4 Experimental Protocol

Each participant was involved in the study over the course of five days. The first day, the participants completed the informed consent document, were fit with the exoskeleton, and used the exoskeleton to become accustomed to using it in their work process as outlined in Section 2.2.3. Basic anthropometric measurements, such as stature, weight, and hand dominance were recorded. The remaining four days were reserved for data collection.

Each day of data collection, participants completed one of four conditions: exoskeleton with right-handed scanning technique, exoskeleton with left-handed scanning technique, no exoskeleton with right-handed scanning technique, no exoskeleton with left-handed scanning technique. All procedures throughout the day were completed using the assigned hand (left or right). The order in which these conditions were performed was randomized for each participant. During the exoskeleton conditions, participants wore the exoskeleton for the entirety of the work day, including each TTE procedure and the work time between procedures. Participants removed the exoskeleton over lunch.

At the start of each day, and prior to performing the scanning procedures, participants were fitted with the EMG sensors, applied bilaterally to the upper trapezius, anterior deltoid, and medial deltoid. Maximum voluntary contractions (MVC) were obtained for each muscle group. MVCs of the upper trapezius were obtained through a shoulder elevation (shrug) against a fixed resistance provided by a bar fixed to the floor through a chain. For the MVC of the deltoids, participants abducted their arm to ~85 degrees and applied an upward force against resistance applied at the elbow (elbow flexed 90 degrees). Participants were then fitted with the IMU sensors, attached to the head, wrist, arms, and upper back. IMU sensors were calibrated to body segment orientation. On the assigned days, participants donned the exoskeleton.

The participants then performed the TTE procedure as usual. After completing the procedure, participants completed a discomfort survey and workload survey (Appendix A-B). This process was repeated for each TTE procedure throughout the day. At the end of the day, participants were given the opportunity to provide comments on the study (Appendix C-D). On days participants wore the exoskeleton, they were also asked about their attitudes towards the exoskeleton.

2.5 Study Design

2.5.1 Independent Variables

There were four conditions (2x2), made from the combination of EXOSKELETON (yes or no) and scanning hand TECHNIQUE (left or right).

2.5.2 Dependent Variables

The dependent variables include posture, normalized EMG amplitude, and body segment discomfort scores. Posture was assessed through the 50th and 95th percentiles of the angle of deviation from the calibration posture of the head, torso, right arm, and left arm. Additional posture variables include the percentage of scanning time spent at head angle greater than 20 degrees, torso angle greater than 20 degrees, right arm greater than 45 degrees, and left arm greater than 45 degrees. Muscle activity measures include the 50th, 75th, 90th, 95th, and 99th percentiles of normalized EMG of the left and right upper trapezius, anterior deltoid, and medial deltoid. Discomfort was measured through subjective ratings of discomfort for the neck, left shoulder, right shoulder, left upper arm, right upper arm, left hand/wrist, right hand/wrist, upper back, and lower back.

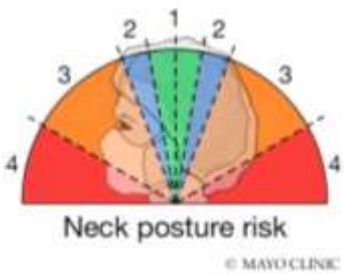
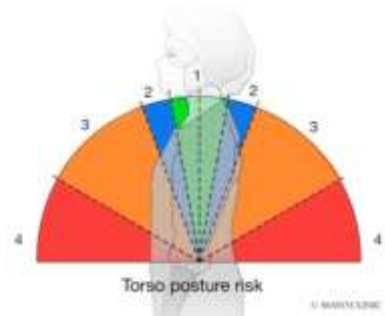
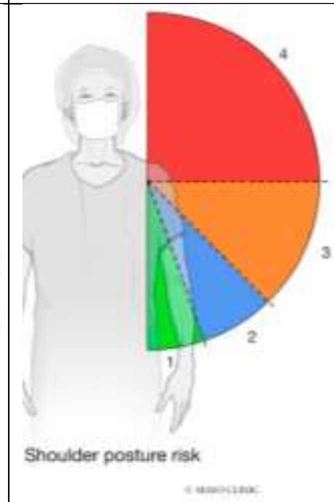
2.6 Data Analysis

2.6.1 Data Processing

IMU data were processed using MATLAB (R2019b; Mathworks Inc). Body segment angles were calculated with respect to the calibration pose for the neck, torso, left upper arm, and right upper arm relative to gravity. IMU sensors have been shown to successfully capture joint angles for these body segments (Morrow, Lowndes, Fortune, Kaufman, & Hallbeck, 2017). For each procedure, the 50th and 95th percentiles of body segment angles were calculated. Additionally, for each procedure, the percentage of time the head and torso deviated from the calibration pose more than 20 degrees and the right and left arms deviated more than 45 degrees. These threshold angles are based on the two upper levels (level three and above) for the respective body segments as determined in the Rapid Upper Limb Assessment (RULA) (McAtamney & Nigel, 1993) and through personal communication with researchers at Mayo Clinic (Table 1).

EMG data were processed using MATLAB (R2018b; Mathworks Inc). Data were bandpass filtered with a Butterworth filter from 10-400 Hz and rectified. A 60 Hz notch filter was applied. A half-second moving window average of EMG amplitude was calculated across each MVC trial. The maximum of these half-second averages was used for normalization. EMG data from each TTE procedure was filtered and rectified using the same process as the MVC data. A half-second moving window average was applied to smooth the data before it was normalized to MVC. For each procedure, the 50th, 75th, 90th, 95th, and 99th percentiles of the normalized EMG data were calculated and used for analysis. Different percentile levels were considered in order to investigate the impact of the exoskeleton at different levels of muscle activity (i.e. does the exoskeleton have a consistent impact across all levels of muscle activity, or does it impact the highest levels of muscle activity differently?).

Table 1. Joint angles and risk score cut-off levels. Reproduced by permission of Mayo Foundation for Medical Education and Research.

	Neck	Trunk	Right/Left shoulder
			
Level 1	>0˚ & <10 ˚	>0˚ & <10 ˚	>0˚ & <20˚
Level 2	>10˚ & <20˚	>10˚ & <20˚	>20˚ & <45˚
Level 3	>20˚ & <60˚	>20˚ & <60˚	>45˚ & <90˚
Level 4	>60˚	>60˚	>90˚

2.6.2 Statistical Analysis

Statistical analysis for both IMU and EMG data were performed using R version 3.5.1. A randomized complete block design was used with participants acting as the blocking variable. A MANOVA was conducted initially to test for different effects of the independent variables on the dependent variables as a group (this was done to maintain the experiment-wise error rate at 0.05). For those effects found to be significant, differences were further explored through a univariate ANOVA. For those dependent variables with both significant main effects and significant interaction, simple effects analysis was conducted on significant factors to confirm the significance of the main effects. A p-value of <0.05 was considered statistically significant.

CHAPTER 3. **RESULTS**

3.1 Overview of Sampled TTE Procedures

Data were collected on 82 procedures. Three to six cases were performed each day, with a median of five procedures a day. Procedures were between 18 and 66 minutes with an average (SD) of 36.3 (10.2) minutes. There was no statistically significant difference in procedure time with and without the exoskeleton.

3.2 Body Segment Posture Results

3.2.1 Baseline TTE Postures (No Exoskeleton)

To provide an understanding of the postures assumed during a typical TTE procedure only data from the no-exoskeleton days are provided in this section. There are differences in gross body positioning/postures between right and left-handed scanning techniques and these differences are highlighted here.

There was no significant difference in the 50th percentile head angle for right (11.9 degrees) and left-handed (10.1) technique ($p>0.05$). The average 50th percentile torso angle between right and left-handed scanning (23.4 and 18.8 degrees respectively) was significantly different ($p=0.034$). The right arm had a higher average 50th percentile angle during right-handed scanning procedures than left-handed scanning procedures (35.5 versus 21.2 degrees, $p<0.0001$). Similarly, the left arm had a higher average 50th percentile joint angle during left-handed scanning procedures (25.9 degrees) than right-handed procedures (16.9 degrees, $p=0.011$). At the 95th percentile, only the left arm angle was significantly different between the left-handed (51.7 degrees) and right-handed (40.7 degrees) scanning procedures ($p=0.003$).

Nearly one-fifth of a sonographer’s scanning time is spent with their head bent greater than 20 degrees (left-handed scanning: 17.6% of scanning time, right-handed scanning: 20.3% of scanning time, $p>0.05$). During left-handed scanning, sonographers spent on average 35.5% of scanning time with a torso angle greater than 20 degrees and during right-handed scanning the percentage of time increases to 64.4% of scanning time ($p=0.006$). Right-handed scanning required the right arm to be at an angle greater than 45 degrees for 20.9% of scanning time, while during left-handed scanning it was reduced to 8.9% ($p=0.036$). The left arm was elevated above 45 degrees for 4.4% of scanning time during right-handed scanning and for 15% of left-handed scanning ($p=0.007$).

3.2.2 Effects of EXOSKELETON and TECHNIQUE on Posture

At the 50th percentile, the MANOVA indicated there was no significant interaction between EXOSKELETON and TECHNIQUE (Table 2). With the exception of the head, the use of the exoskeleton significantly reduced the angles for all body segments considered (Averaged across scanning conditions: torso 14.5 vs. 21.1 degrees, left arm 15.3 vs 21.4 degrees, and right arm 24.4 vs. 28.4 degrees, exoskeleton vs. no exoskeleton, respectively). There was no interaction between EXOSKELETON and TECHNIQUE at the 95th percentile (Table 3). At this percentile, the exoskeleton significantly reduced the angle of the left and right arms but had no impact on the head or the torso angles. The interaction plots at the 50th and 95th percentiles are displayed in Figures 7-8.

The percentage of time body segment angles were greater than the threshold value were calculated. The threshold angle was defined as 20 degrees for the head and torso and 45 degrees for the arms (Table 1). MANOVA indicated there was not a significant interaction between the EXOSKELETON and TECHNIQUE (Table 4). Interaction plots are shown in Figure 8. The use of the exoskeleton significantly reduced the percentage of scanning time the torso and the left arm spent above their respective threshold angles.

Table 2. Results of the statistical analysis of the 50th percentile deviations from vertical postural angle of the sampled body segments

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	6.94	<0.0001	33.1	<0.0001	1.85	0.128
Head	8.74	0.461	1.44	0.235	NA*	NA
Torso	16.1	0.0001	18.3	<0.0001	NA	NA
Left Arm	9.59	0.003	5.04	0.028	NA	NA
Right Arm	6.52	0.013	89.6	<0.0001	NA	NA

*NA values were not considered because the MANOVA showed no significant interaction

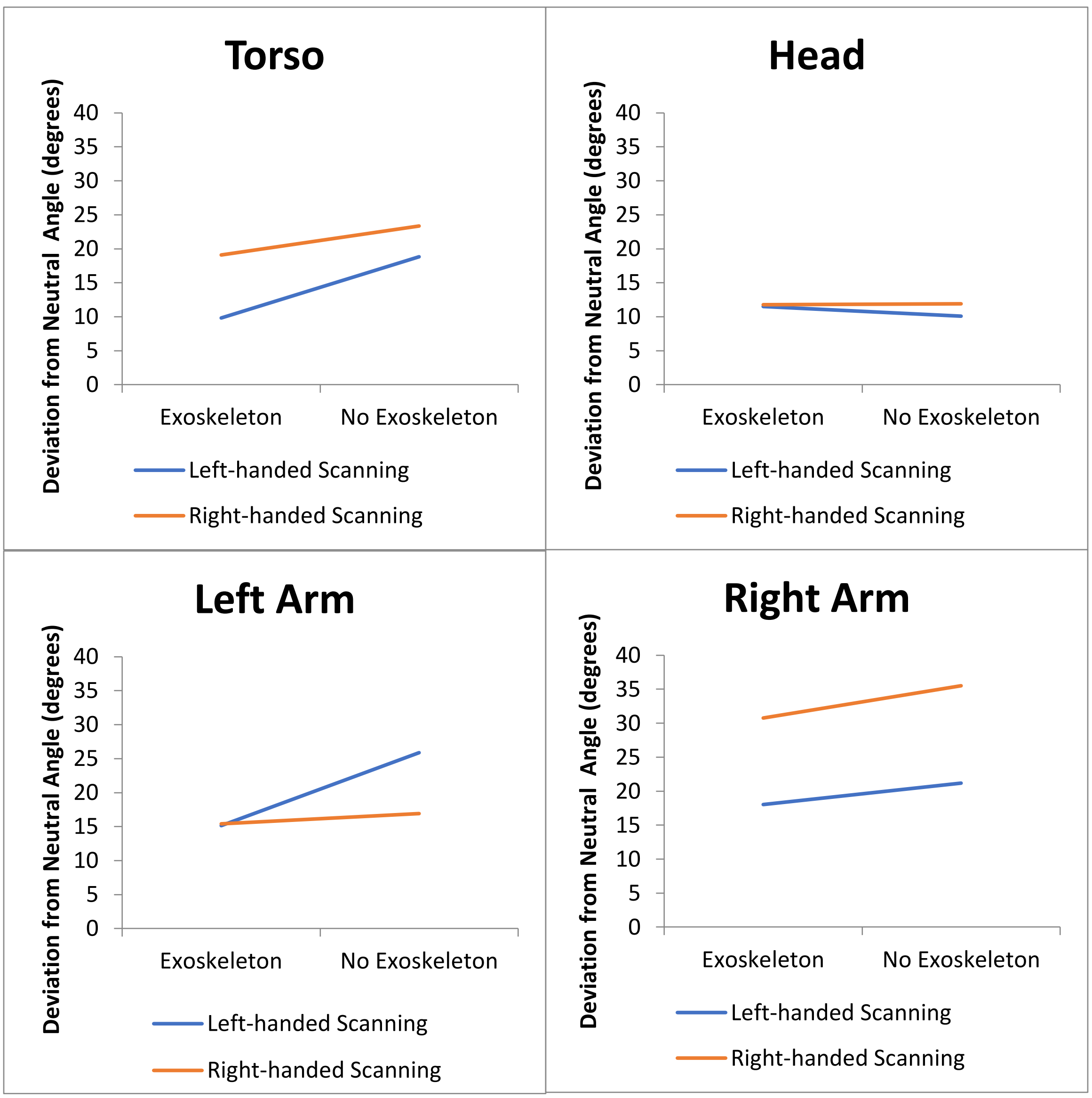


Figure 7. Interaction of TECHNIQUE and EXOSKELETON for the 50th percentile deviation from calibration postural angles of the sampled body segments

Table 3. Results of the statistical analysis of the 95th percentile deviations from vertical postural angle of the sampled body segments

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
Muscle	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	7.31	<0.0001	10.6	<0.0001	1.57	0.191
Head	0.055	0.816	0.468	0.496	NA*	NA
Torso	3.26	0.075	2.98	0.088	NA	NA
Left Arm	18.6	<0.0001	19.4	<0.0001	NA	NA
Right Arm	17.2	<0.0001	4.51	0.037	NA	NA

*NA values were not considered because the MANOVA showed no significant interaction

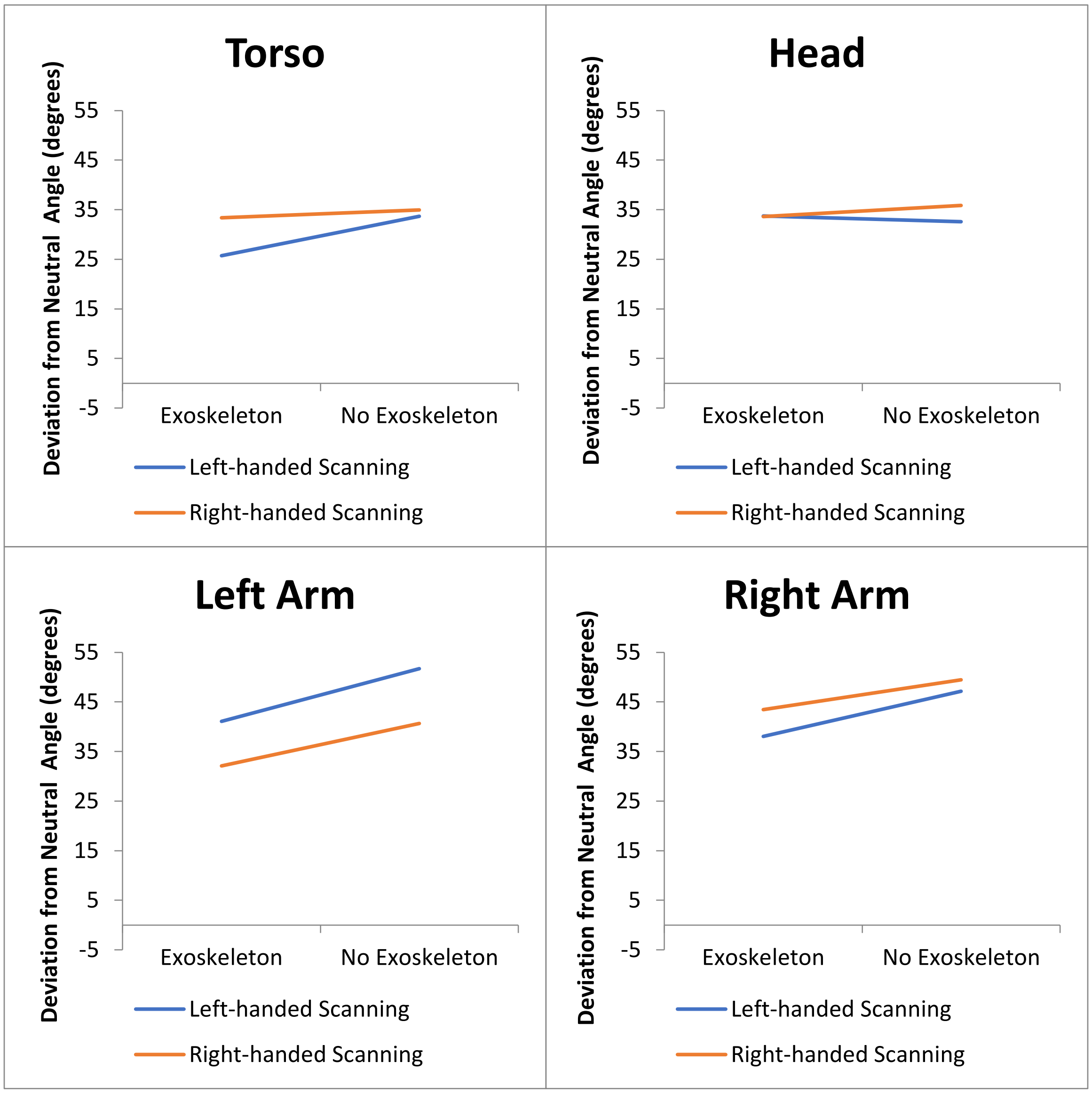


Figure 8. Interaction of TECHNIQUE and EXOSKELETON for the 95th percentile deviation from calibration postural angles of the sampled body segments

Table 4. Results of the statistical analysis of the percentage of scanning time spent above the threshold angles. (Torso and head, 20 degrees; arms, 45 degrees)

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	5.07	0.001	17.7	<0.0001	1.16	0.334
Torso	10.6	0.002	20.0	<0.0001	NA*	NA
Head	0.240	0.626	1.15	0.288	NA	NA
Left arm	11.7	0.001	15.2	0.0002	NA	NA
Right arm	3.29	0.074	7.18	0.009	NA	NA

*NA values were not considered because the MANOVA showed no significant interaction

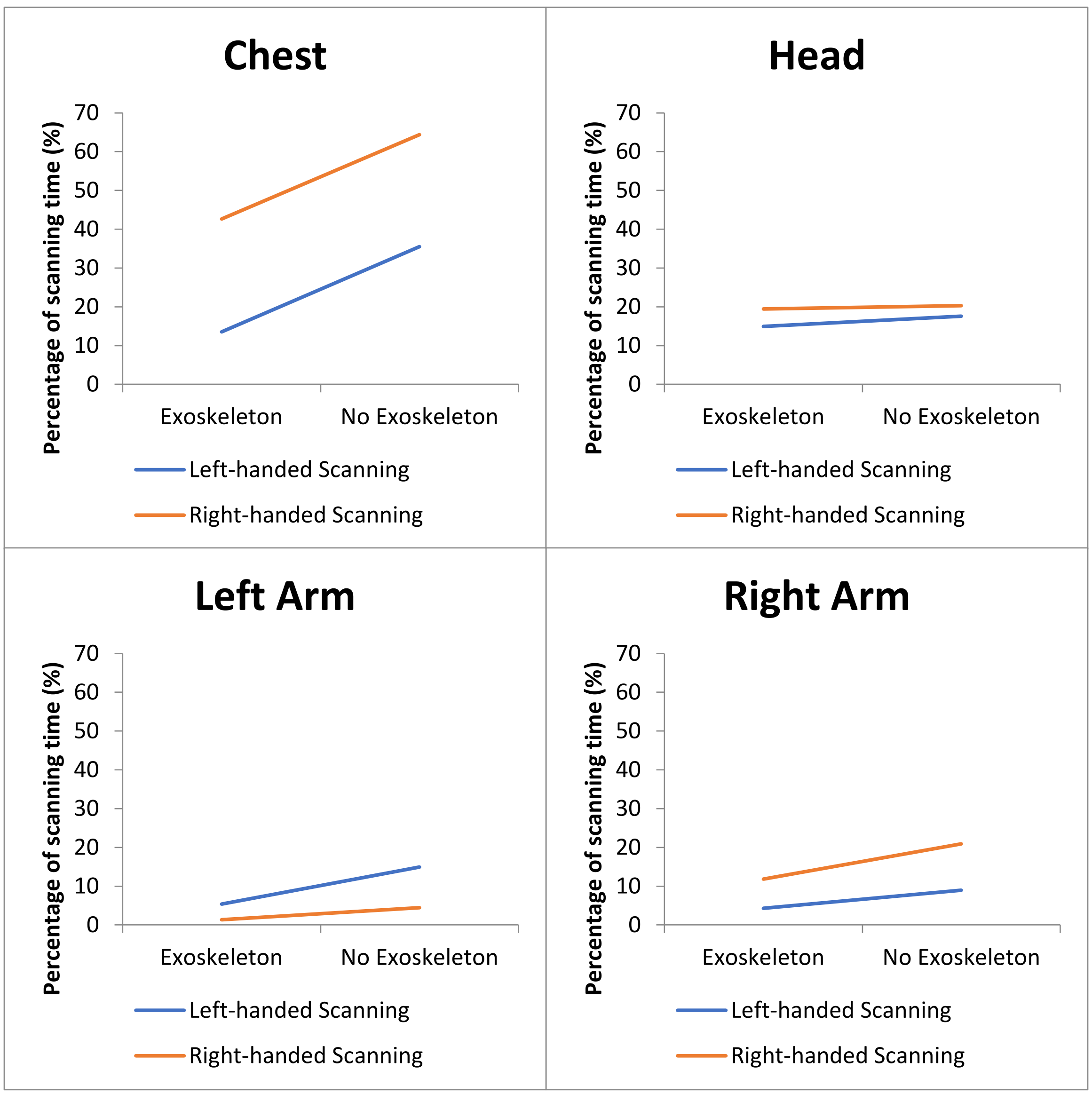


Figure 9. Interaction of TECHNIQUE and EXOSKELETON for percentage of scanning time spent above threshold angles. (Torso and head, 20 degrees; arms, 45 degrees)

3.3 Muscle Activity Results

The effects of EXOSKELETON, TECHNIQUE, and the interaction between EXOSKELETON and TECHNIQUE were considered in the analysis of the EMG data. Data were blocked on participant. EXOSKELETON, TECHNIQUE, and the interaction between EXOSKELETON and TECHNIQUE had an effect on EMG muscle activity data based on the MANOVA analysis at every percentile considered in this study.

3.3.1 Effects of EXOSKELETON and TECHNIQUE on Muscle Activity

Left Anterior Deltoid:

EXOSKELETON, TECHNIQUE, and the interaction between EXOSKELETON and TECHNIQUE were not significant at any percentile level (50^{th}, 75^{th}, 90^{th}, 95^{th}, 99th).

Right Anterior Deltoid:

At the 50th and 75th percentiles, EXOSKELETON and TECHNIQUE were not significant main effects- only the interaction between the two was significant. This can be seen through the interaction plots in Figures 10-11, where muscle activity decreased with the use of the exoskeleton in left-handed scanning but had no statistical significance for right-handed scanning (50th percentile p=0.139, 75th percentile p=0.749). At the 90th and 95th percentile, both EXOSKELETON and TECHNIQUE were significant factors while the interaction was not. At both levels, the use of the exoskeleton decreased average muscle activity. There were no significant factors at the 99th percentile level.

Left Medial Deltoid:

The interaction between EXOSKELETON and TECHNIQUE was significant at every percentile level (Table 5-9). At every percentile level, simple effects analysis showed the exoskeleton reduced muscle activity in left-handed scanning but had no impact on right-handed scanning.

Right Medial Deltoid:

The right medial deltoid was found to be significantly affected by EXOSKELETON at the 50th, 75th, and 90th percentiles. Though muscle activity was reduced in both right and left-handed scanning, simple effects analysis showed that the use of the exoskeleton significantly reduced muscle activity in left-handed scanning and had no significant difference in right-handed scanning. There was no statistically significant effect of EXOSKELETON at the 95th and 99th percentiles.

Left Upper Trapezius:

EXOSKELETON had a significant effect on the muscle activity of the left upper trapezius at every percentile level considered in the current study. The use of the exoskeleton reduced the average muscle activity in both left and right-handed scanning tasks.

Right Upper Trapezius:

At the 50th percentile, EXOSKELETON had a significant effect on the muscle activity in the right upper trapezius while the interaction between EXOSKELETON and TECHNIQUE was not significant (Table 5). However, in observing the interaction plot in Figure 10, it can be seen that the use of the exoskeleton reduced the muscle activity during the left-handed scanning condition ($p<0.0001$) but had no effect on the right-handed scanning condition ($p=0.788$). At every other percentile level (75th, 90th, 95, 99th) the interaction between EXOSKELETON and TECHNIQUE was significant. Simple effects revealed that while the use of the exoskeleton did reduce muscle activity during left-handed scanning conditions, there was no statistically significant effect on the right-handed scanning at every percentile level.

Table 5. Results of the statistical analysis of the 50th percentile of normalized EMG of the sampled muscles

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
Muscle	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	5.55	0.0001	10.3	<0.0001	4.56	0.0007
Right upper trapezius	4.17	0.045	54.3	<0.0001	3.03	0.085
Left upper trapezius	24.1	<0.0001	0.082	0.775	0.038	0.847
Right anterior deltoid	0.371	0.544	0.049	0.825	12.6	0.0007
Left anterior deltoid	0.702	0.405	2.85	0.095	0.673	0.415
Right medial deltoid	4.65	0.034	16.2	0.0001	2.89	0.093
Left medial deltoid	0.151	0.698	3.35	0.071	8.17	0.006

Table 6. Results of the statistical analysis of the 75th percentile of normalized EMG of the sampled muscles

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
Muscle	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	6.62	<0.0001	17.4	<0.0001	3.07	0.011
Right upper trapezius	3.65	0.060	61.0	<0.0001**	6.64	0.012
Left upper trapezius	33.2	<0.0001	2.12	0.150	0.487	0.487
Right anterior deltoid	4.47	0.038	5.96	0.017	8.52	0.005
Left anterior deltoid	0.004	0.948	2.14	0.148	0.544	0.463
Right medial deltoid	10.6	0.002	14.7	0.0003	3.02	0.086
Left medial deltoid	0.346	0.558	0.856	0.358	10.3	0.002

**Simple effects analysis indicated this was a significant main effect

Table 7. Results of the statistical analysis of the 90th percentile of normalized EMG of the sampled muscles

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
Muscle	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	7.25	<0.0001	33.8	<0.0001	5.41	0.0001
Right upper trapezius	4.19	0.044	108.1	<0.0001**	11.5	0.001
Left upper trapezius	41.3	<0.0001	7.00	0.010	2.74	0.102
Right anterior deltoid	8.87	0.004	11.8	0.001	2.44	0.123

**Simple effects analysis indicated this was a significant main effect

Table 7. (continued)

Left anterior deltoid	0.302	0.584	0.586	0.447	1.36	0.247
Right medial deltoid	8.65	0.004	17.2	<0.0001	3.55	0.063
Left medial deltoid	9.97	0.002	1.91	0.171	18.7	<0.0001

**Simple effects analysis indicated this was a significant main effect

Table 8. Results of the statistical analysis of the 95th percentile of normalized EMG of the sampled muscles

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
Muscle	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	7.70	<0.0001	25.9	<0.0001	5.79	<0.0001
Right upper trapezius	4.22	0.043	158.9	<0.0001**	12.5	0.0007
Left upper trapezius	40.7	<0.0001	7.44	0.008	3.57	0.063
Right anterior deltoid	8.09	0.006	4.43	0.039	1.91	0.171
Left anterior deltoid	0.0009	0.976	0.512	0.476	1.66	0.201
Right medial deltoid	2.92	0.092	10.4	0.002	2.71	0.104
Left medial deltoid	15.1	0.0002	2.84	0.096	16.3	0.0001

**Simple effects analysis indicated this was a significant main effect

Table 9. Results of the statistical analysis of the 99th percentile of normalized EMG of the sampled muscles

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
Muscle	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	7.98	<0.0001	10.5	<0.0001	3.53	0.004
Right upper trapezius	3.25	0.075	88.2	<0.0001**	4.54	0.036
Left upper trapezius	31.9	<0.0001	3.57	0.063	1.98	0.163
Right anterior deltoid	2.92	0.091	0.452	0.503	1.33	0.252
Left anterior deltoid	0.255	0.615	0.751	0.389	1.14	0.288
Right medial deltoid	0.817	0.369	4.49	0.037	2.12	0.149
Left medial deltoid	24.3	<0.0001	0.962	0.330	10.7	0.002

**Simple effects analysis indicated this was a significant main effect

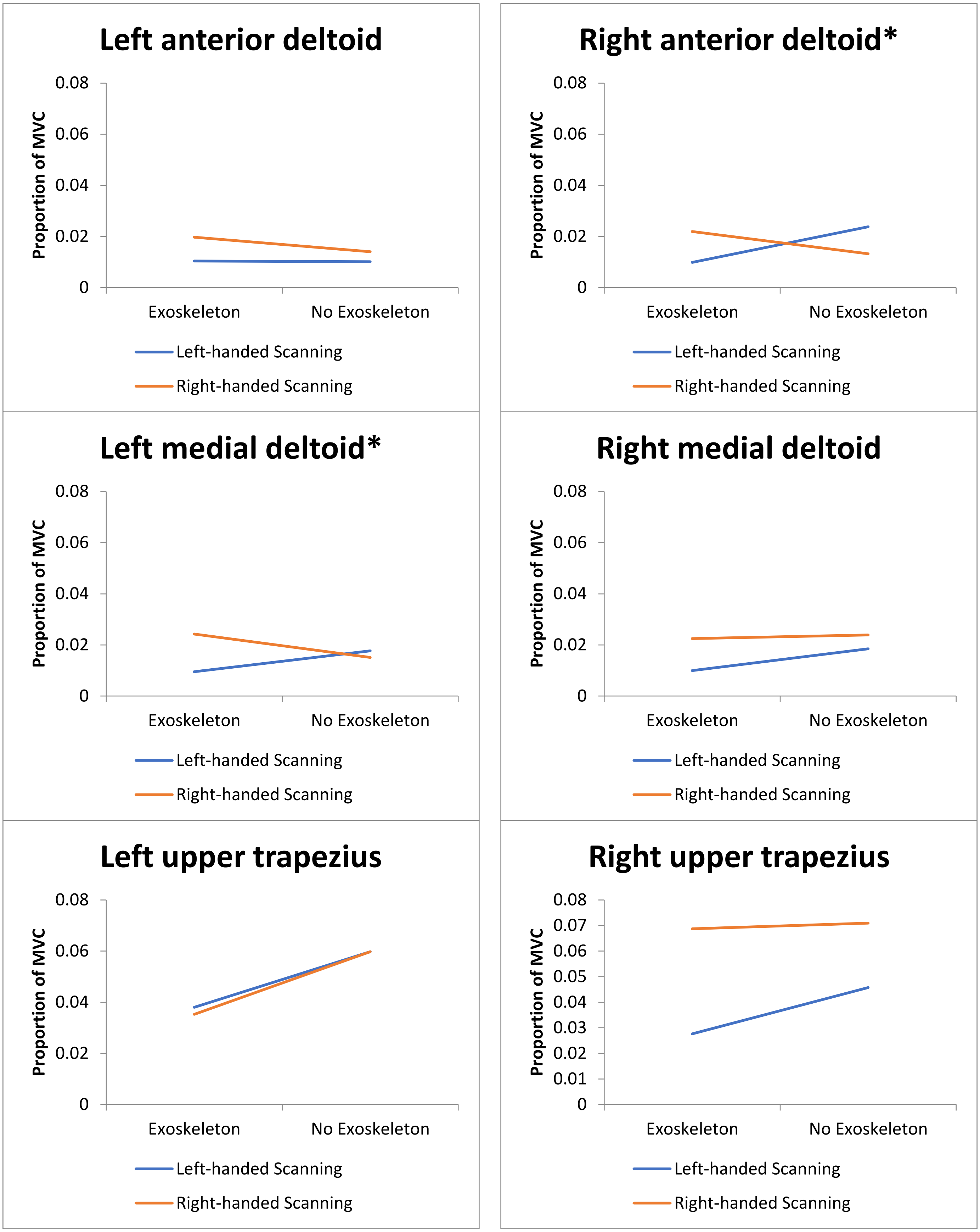


Figure 10. Interaction of TECHNIQUE and EXOSKELETON for the 50th percentile of normalized EMG of the sampled muscles. *Denotes significant interactions

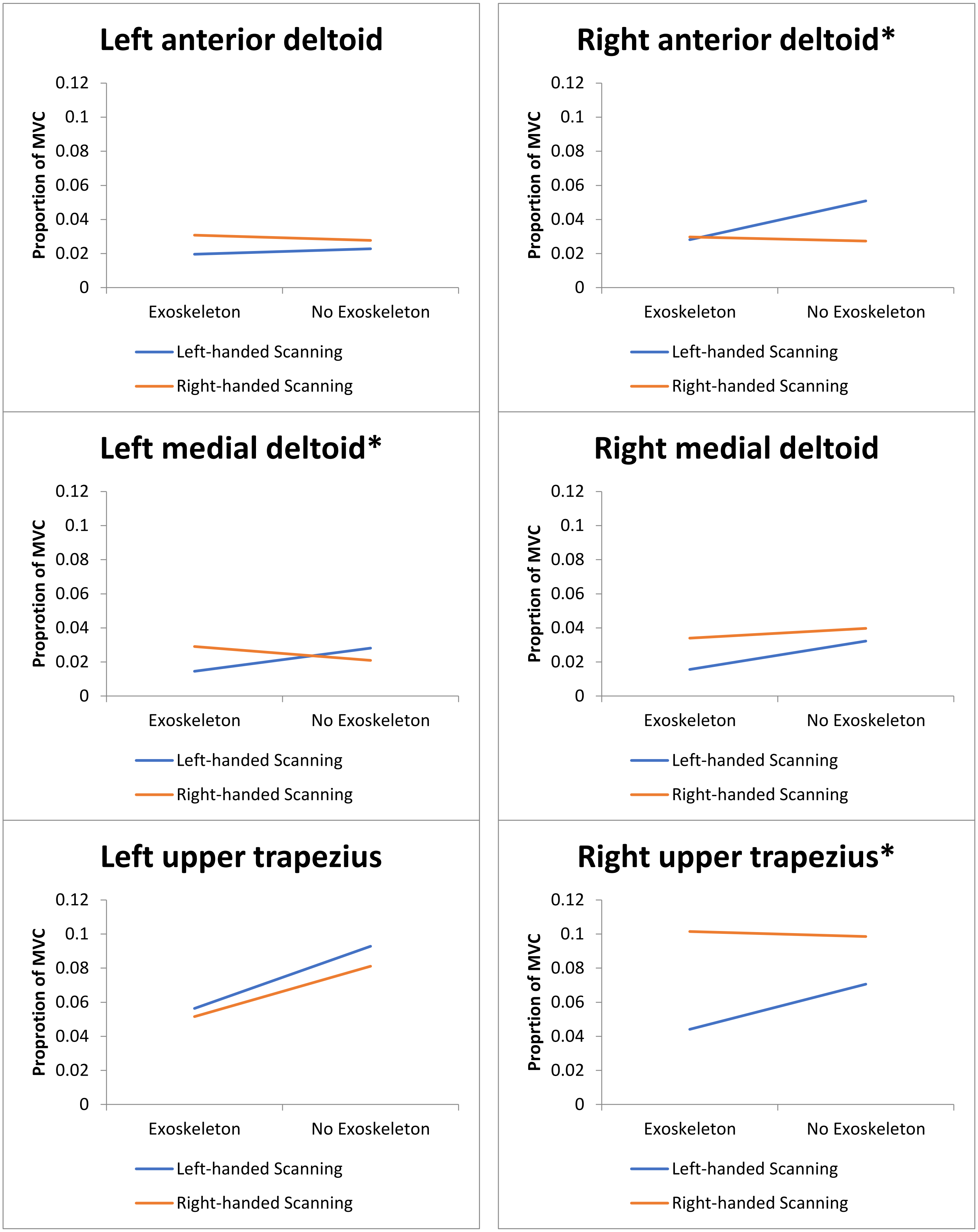


Figure 11. Interaction of TECHNIQUE and EXOSKELETON for the 75th percentile of normalized EMG of the sampled muscles. *Denotes significant interactions

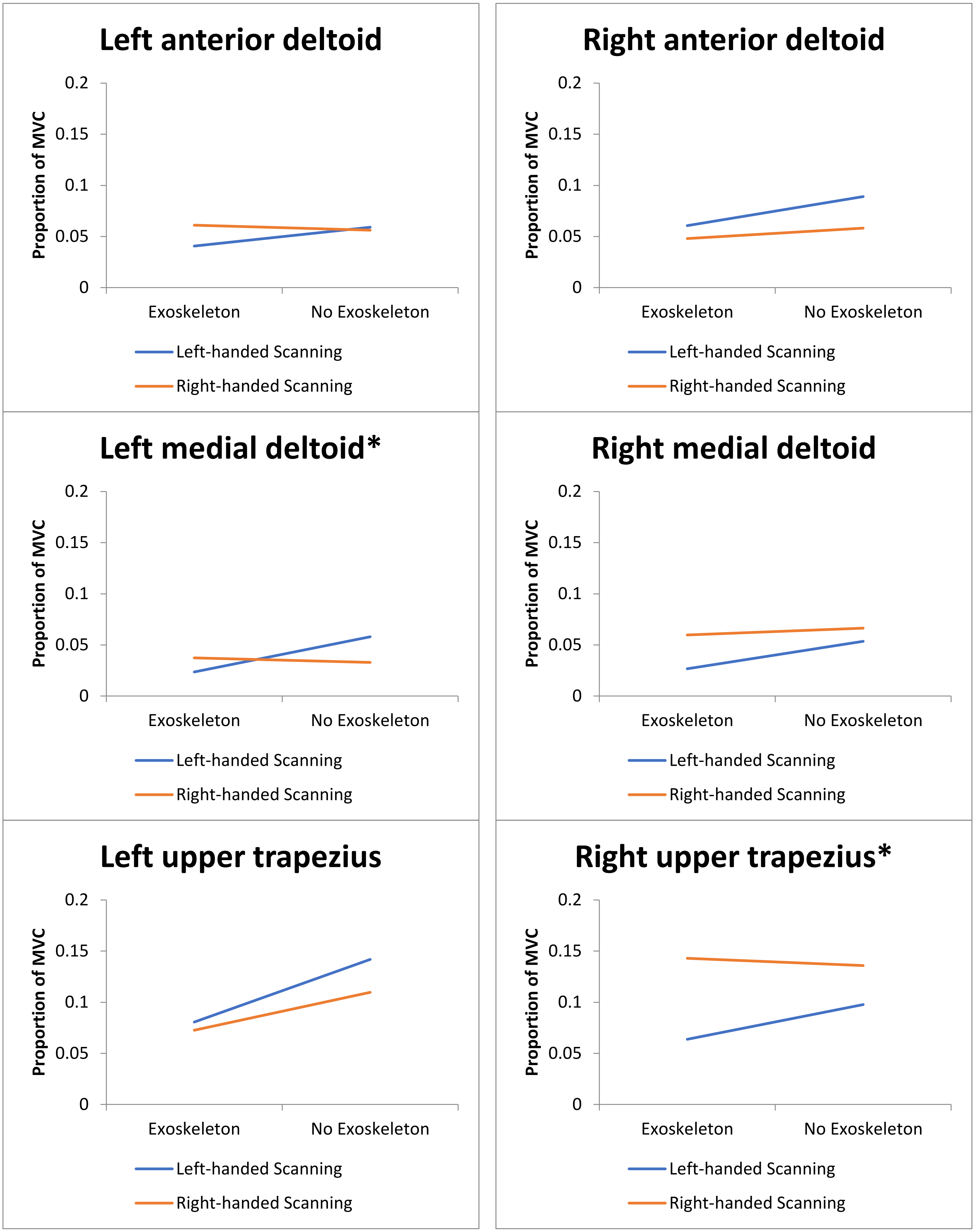


Figure 12. Interaction of TECHNIQUE and EXOSKELETON for the 90th percentile of normalized EMG of the sampled muscles. *Denotes significant interactions

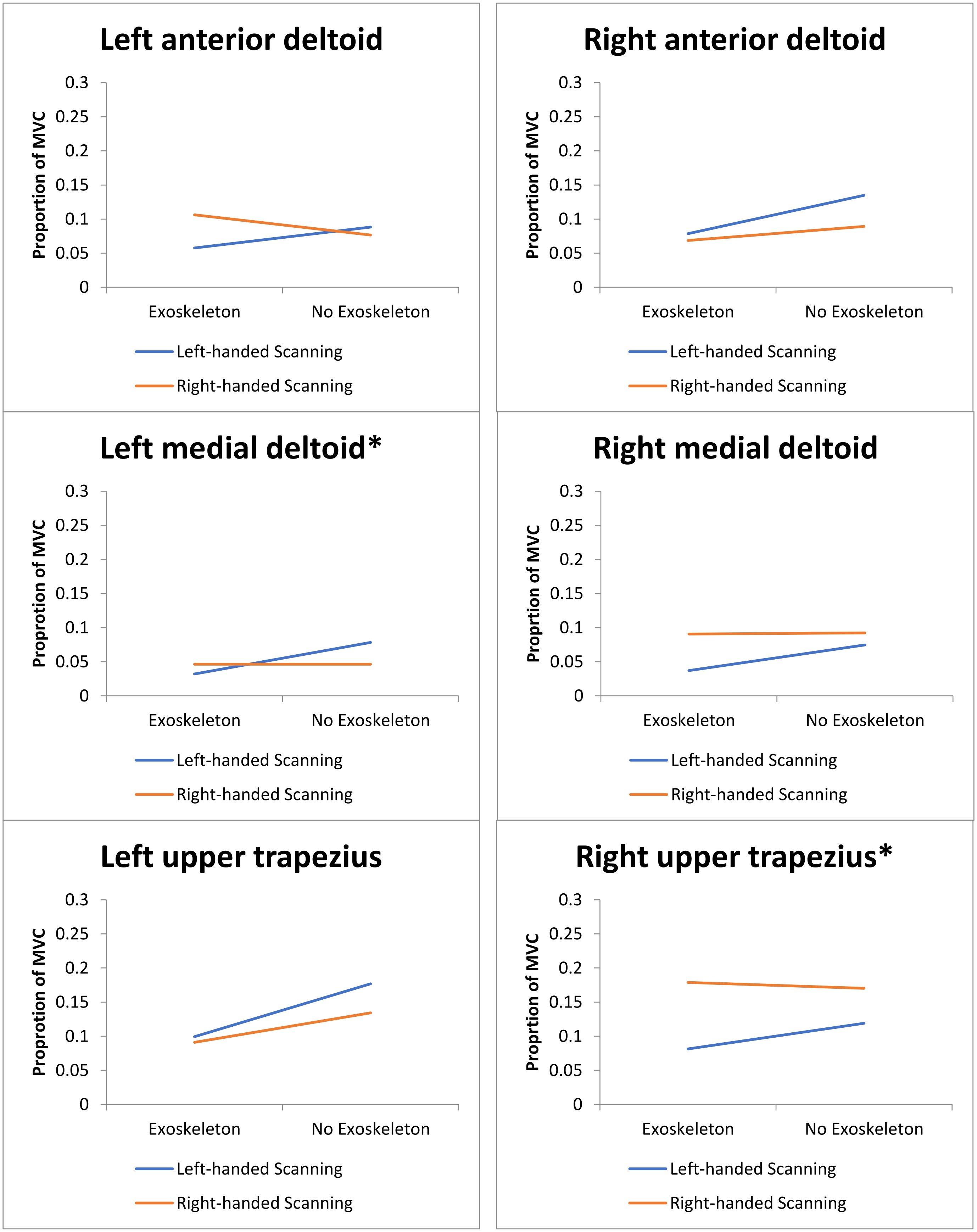


Figure 13. Interaction of TECHNIQUE and EXOSKELETON for the 95th percentile of normalized EMG of the sampled muscles. *Denotes significant interactions

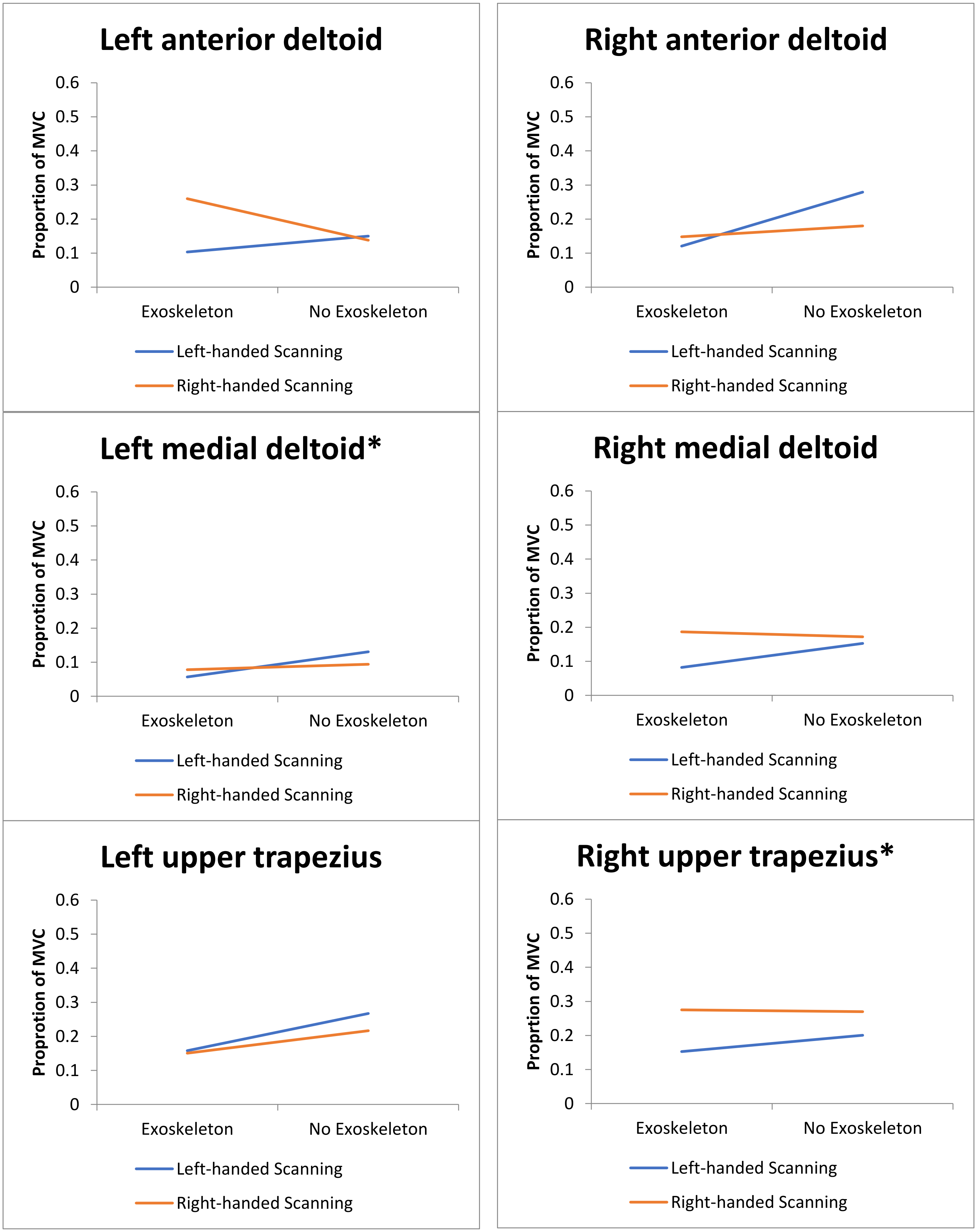


Figure 14. Interaction of TECHNIQUE and EXOSKELETON for the 99th percentile of normalized EMG of the sampled muscles. *Denotes significant interactions

3.4 Survey Results

3.4.1 After Every Procedure

Table 10 displays the responses from the subjective discomfort survey given after every TTE procedure. The statistical analysis of these results is presented in Table 11. Left shoulder discomfort was significantly higher with the use of the exoskeleton than without. Left wrist/ hand and upper back scores were reported as significantly lower with the use of the exoskeleton.

Participants self-reported low interference scores due to the exoskeleton in their scanning work, but also low benefit scores. Participants reported the exoskeleton did not provide any benefit to computer work (Table 12).

Table 10. Discomfort during TTE procedures with and without exoskeleton, reported after each TTE procedure (mean (SD)) (0=no discomfort, 10= significant discomfort)

	Exoskeleton left-hand scanning	Exoskeleton right-hand scanning	No exoskeleton left-hand scanning	No exoskeleton right-hand scanning
Neck	0.47 (0.94)	0.43 (0.79)	0.14 (0.35)	0.52 (0.79)
Left Shoulder	1.42 (1.04)	0.52 (1.01)	0.57 (1.18)	0.29 (0.70)
Right Shoulder	0.63 (0.93)	0.81 (1.18)	0 (0)	0.81 (1.14)
Left Upper Arm	0.68 (1.22)	0.14 (0.47)	0.48 (1.14)	0.10 (0.43)
Right Upper Arm	0 (0)	0.48 (1.05)	0 (0)	0.52 (1.05)
Left Wrist/Hand	0.11 (0.45)	0 (0)	0.81 (1.30)	0.29 (0.76)
Right Wrist/Hand	0 (0)	0.14 (0.64)	0.05 (0.21)	0.39 (1.00)
Upper Back	0.74 (0.91)	0.81 (1.01)	0.95 (1.21)	1.48 (1.65)
Lower Back	0.89 (1.12)	1.90 (2.37)	0.52 (0.66)	1.33 (1.61)

Table 11. Statistical analysis of discomfort survey results

	EXOSKELETON		TECHNIQUE		EXOSKELETON* TECHNIQUE	
	F statistic	p-value	F statistic	p-value	F statistic	p-value
MANOVA Results	3.15	0.003	3.58	0.001	1.70	0.107
Neck	0.654	0.421	1.44	0.233	NA*	NA
Left Shoulder	5.85	0.018	6.63	0.012	NA	NA
Right Shoulder	2.14	0.148	5.86	0.018	NA	NA
Left Upper Arm	0.448	0.505	5.89	0.018	NA	NA
Right Upper Arm	0.024	0.877	10.1	0.002	NA	NA
Left Wrist/Hand	7.45	0.008	3.43	0.068	NA	NA
Right Wrist/Hand	1.10	0.297	2.93	0.091	NA	NA
Upper Back	5.71	0.019	2.45	0.121	NA	NA
Lower Back	2.61	0.110	9.84	0.002	NA	NA

*NA values were not considered because the MANOVA showed no significant interaction

Table 12. Exoskeleton survey results

Question (Scale)	Mean (SD)
Did the exoskeleton interfere with your ability to perform the TTE? (0=no interference, 10= greatly interfered)	1.8 (2.2)
Did the exoskeleton improve your ability to perform the TTE? (0=no improvement, 10= great improvement)	1.6 (1.6)
Did the exoskeleton interfere with your ability to perform computer work? (0=no interference, 10= greatly interfered)	1.1 (1.4)
Did the exoskeleton improve your ability to perform computer work? (0=no improvement, 10= great improvement)	0 (0)

3.4.2 End of the Day Survey

When asked “Did the use of the exoskeleton increase your physical comfort when performing TTE procedures?” the average response was 3.5 (0= decreased comfort, 5=no change, 10= increased comfort), with the male participants reporting slightly higher levels of comfort (male average 4.75 versus female average 2.25). Participants reported the number of hours they would be comfortable wearing the exoskeleton to range between 3-8 hours, with an average of 4.75. When asked if they would like to use the exoskeleton for future TTE procedures, sonographers responded with “No” on seven out of eight days with the exoskeleton.

When asked what they liked about using the exoskeleton, participants reported enjoying the supported provided to the scanning arm and shoulder and several participants noted that the exoskeleton assisted during the subcostal imaging portion of the procedure. When asked what they disliked about using the exoskeleton, participants reported feeling restricted in their range of motion, making it difficult to reach around patients. Participants were concerned with navigating around the patients while wearing the exoskeleton, saying it was difficult to fit on the bed next to a patient or rest an arm on the patient as they would typically do. After wearing the exoskeleton for the day, participants also reported feeling some discomfort by the end of the day, particularly in their back. One participant noted that wearing the exoskeleton made it difficult and uncomfortable to clean the room between patients. This participant reported that the exoskeleton interfered with the ability to quickly clean surfaces and lean over to pick items off the floor.

CHAPTER 4. **DISCUSSION**

5.1 General Scanning Posture

The percentage of scanning time that the torso angle was above 20 degrees was greater during the right-handed scanning than the left-handed scanning (64.4% vs 35.5%). The IMU sensors measure the body segment deviation from the neutral calibration posture but did not contain information on the direction of this deviation. It was observed that while sonographers assumed scanning postures (Figures 5-6), torso flexion occurred not just in the sagittal plane, but in the coronal plane as well, which makes the large percentage of time the torso spends above the threshold angle during right-handed scanning tasks particularly concerning.

In right-handed scanning, sonographers often sit on the bed in order to wrap their arm around the patient. In this position, the sonographer is seated on the same surface as the patient, which causes torso flexion as the sonographer reaches towards the patient. In left-handed scanning, the sonographer is seated in a chair next to the bedside. The seat of the chair is at a lower height than the bedside, so less torso flexion is required to reach the patient. Using a chair during right-handed scanning may be ineffective, as it can be difficult to bring the seat of the chair close enough to the bedside for a sonographer to be able to reach an arm around the patient. It may be beneficial for sonographers to perform more TTE procedures with their left hand in order to keep the torso upright.

The average 50th percentile arm positions showed the arms were elevated 16.9-35.5 degrees during scanning tasks. These values for both arms in the right and left-handed scanning conditions fell within 16 degrees of the values reported by Simonsen et al. (2018) during echocardiography tasks, with the values from the current study being consistently lower. The difference in arm angle may result from the type of procedure under study. Simonsen et al.

(2018) observed echocardiography procedures, which includes but is not limited to the transthoracic echocardiogram observed in the current study. Within echocardiography, there are likely postural differences between types of procedures and TTE procedures may require less shoulder abduction than other types of echocardiography. Differences may also be related to sonographer training and work station set up at different health care institutions.

The arm used for scanning spent a greater percentage of scanning time at an angle above 45 degrees than the non-scanning arm. Averaged between the right and left-handed scans, sonographers spend 18% of scanning time with their scanning arms at an angle greater than 45 degrees and 6.7% of scanning time for the non-scanning arm. Simonsen et al. (2017) found sonographers experience more pain in the shoulder operating the transducer than the computer which suggests holding an elevated arm posture for longer periods of time likely contributes to pain in the sonographer's shoulder. Village & Trask (2007) investigated the scanning posture of sonographers performing several different types of procedures and found 45% of scanning time the shoulder was abducted more than 45 degrees, which is more than twice as high as the percentage of time for elevated arms reported in the current study. Village & Trask observed several types of sonography procedures including abdominal, leg, obstetric, and one echocardiography (the type of echocardiogram was not specified) and noted significant differences in posture depending on the type of procedure. TTE procedures may require high shoulder abduction angles for smaller percentages of scanning time than other types of sonography. Future research should clearly specify the sonography procedure considered as there is variability between types of scans, and even within the same procedure depending on the scanning hand used.

5.2 Posture

Exoskeletons are designed to reduce muscle force, but little research has investigated how the use of an exoskeleton affects posture. Exoskeletons should allow workers to complete their work tasks, without interfering with the way the task is performed. Posture should be dictated by the task with the exoskeleton used to reduce muscle force while maintaining these postures. Large differences in working posture with and without the exoskeleton would suggest that the exoskeleton has changed the behavior of the worker performing the task. Wearing a device that constantly reminds the user of their posture may encourage small changes to work posture, such as sitting up straighter. This idea is supported by the decreased torso angle in both the left and right-handed scanning conditions at the 50th percentile and the left-handed scanning torso angle at the 95th percentile. There was no change in the torso angle with the use of the exoskeleton at the 95th percentile during right-handed scanning, which is likely related to the extreme torso angle posture required for this type of scanning, as previously discussed.

The left arm angle was significantly reduced with the use of the exoskeleton for both the left and right-handed scanning at the 95th percentile and with the left-handed scanning technique at the 50th percentile. The impact of the exoskeleton on arm posture was unexpected. This result may be related to participant’s perceived discomfort while wearing the exoskeleton. During tasks with the exoskeleton, participants rated left shoulder discomfort significantly higher with the exoskeleton than without. This may be have been caused by the weight of the exoskeleton or the positioning of the exoskeleton straps over the shoulder, though it is interesting that there was no significant difference in right shoulder discomfort scores. The feeling of discomfort may have led to a smaller shoulder abduction angle to compensate. There was a greater difference in posture with and without the exoskeleton at the 95th percentile than the 50th percentile which suggests that the exoskeleton may have limited postures with a large deviation from neutral. While this may be beneficial from a WRMSD perspective, it is necessary to make sure this limitation does not interfere with sonographer's work practices. Other studies have found only small differences in posture with the exoskeleton (less than five degrees) (Iranzo, Piedrabuena, Iordanov, Martinez-Iranzo, & Belda-Lois, 2020) so the combination of exoskeleton type and task may influence what postures are required to complete the work and what range of motion the exoskeleton will support.

5.3 Muscle Activity

Different percentiles of normalized EMG were considered in order to investigate potential effects of the exoskeleton at different muscle activity levels. That is, to see if the exoskeleton reduced muscle activity at all levels equally, or if it have a greater impact at high levels of muscle activity. For example, it might be expected that the exoskeleton would have limited impact near neutral shoulder postures but have a significant impact when the shoulder postures near 90 degrees of shoulder abduction. Analysis of the normalized EMG showed that the exoskeleton had significant effect on muscles on the left side of the body (left upper trapezius, left anterior deltoid, and left medial deltoid) at every percentile level. There were less pronounced effects in the muscles on the right side of the body (right anterior deltoid had a significant interaction, a significant main effect, and no significance as percentile levels increased). Digging deeper into the data showed that at almost every percentile level there was a significant effect of exoskeleton for all the right-side muscles during left-handed scanning and no significant effect during right-handed. The only exception to this was the 99th percentile right anterior deltoid where there was no significant effect in either right or left-handed scanning.

The decrease in muscle activity due to the exoskeleton in left-handed scanning is consistent with previous research on upper extremity exoskeletons (Gillette & Stephenson, 2019;

Kim & Nussbaum, 2019; Van Engelhoven et al., 2019). The lack of effect of the exoskeleton on most muscles during right-handed scanning was unexpected. In a survey question, one participant reported the exoskeleton was "more comfortable to wear and use scanning left vs. right handed" but did not elaborate on what factors may have caused this. The effect (or lack thereof) of the exoskeleton during this task may again be related to the sonographer's posture in relation to the patient. In right-handed scanning, sonographers will often rest their arm on the patient but through both surveys and anecdotally, participants commented on their concern navigating around patients while wearing the exoskeleton. In other words, they were comfortable using the patient as a support for the right arm when not wearing the exoskeleton, but were reluctant to do so when wearing the exoskeleton. This concern likely impacted how the sonographer performed the scan, thus the exoskeleton did not provide a benefit to muscle activity in this condition. This may be related to previous findings indicating sonographers would prioritize patient comfort over their own working posture (Simonsen & Gard, 2016). This is also a behavior that might change as sonographers become more comfortable wearing the exoskeletons.

5.4 Surveys

On seven out of eight days the exoskeleton was worn, participants reported they would prefer not to use the exoskeleton for future procedures. Participants reported an overall slight decrease in physical comfort when wearing the exoskeleton, which may have influenced their willingness to wear the device for future procedures. This is consistent with the results found by Hensel & Keil (2019) who reported that user acceptance was influenced by the discomfort experienced when using the exoskeleton. Though this study found benefits in muscle activity with the use of the exoskeleton, it will only be a viable ergonomic intervention if sonographers are willing to wear it. To be effective in sonography the device must be comfortable to wear and not interfere with the sonographer's work.

5.5 Overall Results for Each Arm by Technique

During left-handed scanning, the left arm was positively impacted by the use of the exoskeleton. With the use of the exoskeleton, upper arm angle decreased by about 10 degrees (at both the 50^{th} and 95^{th} percentiles) and the muscle activity of the left medial deltoid and left upper trapezius were significantly reduced. User perceptions did not match these results as sonographers reported significantly higher discomfort in the left shoulder with the use of the exoskeleton. This may in part be due to the weight of the exoskeleton acting on the shoulder, though it is interesting that the right shoulder was not similarly affected. During left-handed scanning, all three muscles considered in the right upper extremity reduced in muscle activity with the use of the exoskeleton. There were small differences in upper arm angle and no significant difference in right upper arm or shoulder discomfort with the exoskeleton. The exoskeleton benefited both the left and right arms during left-handed scanning tasks.

With the use of the exoskeleton during right-handed scanning, there were small postural changes to the left arm (less than 2 degrees at the 50^{th} percentile, less than 9 degrees at the 95^{th} percentile) and out of the left extremity muscles considered, only the left upper trapezius showed reduction in muscle activity. There were no significant differences in left upper arm or shoulder discomfort. During right-handed scanning, there was little change to the right arm angle (less than 6 degrees at the 50^{th} and 95^{th} percentiles). Simple effects analysis showed that the exoskeleton did not significantly affect the muscle activity on the right-side muscles and there were no significant differences in right shoulder or upper arm scores with and without the exoskeleton. During right-handed scanning tasks, the exoskeleton provided limited benefits to the left arm (left upper trapezius), but had no effect on the right arm.

5.6 Limitations

There are several limitations that affect the generalizability of the results of this study. The study only considered sonographers performing TTE procedures, so the results should not be generalized to all types of sonography. Additionally, the postural and muscle activity results only represent the scanning task itself, not any other work the sonographer performs throughout the day (cleaning the room, computer work, etc.) The sonographers wore the exoskeleton over the entire workday and were asked to provide comments on the impact of the exoskeleton during all tasks performed. However, IMU and EMG data were only recorded during the TTE procedure. In addition, the participants only had a limited exposure to the exoskeleton and therefore did not have a chance to integrate the device, and its potential benefits, into their standard work practice. This is nicely illustrated in the reluctance of sonographers to rest their arm on the patient when employing the right-handed technique with the exoskeleton. Given time, sonographers might feel more comfortable in doing so, and thereby realize the positive effects of the exoskeleton in muscle force reduction.

5.7 Future Use of Exoskeletons in Sonography

In the future, several modifications could be made to improve the performance of the exoskeleton in sonography. Sonography tasks may be most benefited by an exoskeleton with a low reach adaptor. The exoskeleton use in the current study provided an increased level of support as the arm was elevated- providing the most support for tasks with high levels of arm abduction or overhead work. TTE procedures required lower arm abduction angles (the 95th percentile arm abduction angles did not exceed 55 degrees), so an exoskeleton that can provide more support at lower arm abduction angles may be beneficial for sonography. Additionally, sonographers commented that they had to tug the exoskeleton down in order for it to sit correctly. They found that the hip pads shifted as they moved between standing and seated positions which caused the exoskeleton to ride up. Changing the way the exoskeleton fastens around the hips may improve these issues.

The level of support to the right arm during right-handed scanning tasks could also be increased. Sonographers reported they were less willing to rest their arm on the patient while wearing the exoskeleton and this change in work strategy negated some of the positive effects of the exoskeleton during right-handed scanning. Increasing the level of support would allow sonographers to keep their arm above the patient, but additional support from the exoskeleton could replace the physical benefits sonographers would typically receive from resting their arms on the patient.

Further ergonomic interventions to sonography may also consider a forearm support, particularly for the right-handed scanning tasks. Adding forearm support to the exoskeleton may not be the ideal solution, as more of the exoskeleton would come in contact with the patient during procedures. Sonographers were reluctant to get too close to the patient while wearing the exoskeleton, so this addition may not be beneficial. Alternative interventions, such as a foam block that could be placed in front of the patient's torso may be considered.

For exoskeletons to be successfully used in sonography there must be buy-in from the sonographers. One potential method to increase sonographer acceptance is to shorten the total amount of time sonographers wear the exoskeleton. In the current study, sonographers wore the exoskeleton for the entire workday including while performing TTE scans, completing computer work, and cleaning the room between patients. As the participants reported the exoskeleton provided no benefit and mild interference to the computer work and was difficult to wear while cleaning the rooms, wearing the exoskeleton all day may not be the ideal solution. The exoskeleton can be used during scanning procedures and removed during other times of the workday.

Sonographers felt slightly self-conscious meeting patients while wearing the exoskeleton as it looked very “industrial”. The patients who met with sonographers wearing an exoskeleton often commented on the device, but did not express any concerns or reluctance to be treated by a sonographer wearing the exoskeleton. Designing the exoskeleton so it looked more “medical” or could sit close enough to the body to be worn under a scrub jacket may help improve sonographer’s perceptions of the device. Additionally, it will be necessary to communicate with the sonographers about their expectations regarding the exoskeleton capabilities. The exoskeleton is designed to provide support to the upper extremities so that over time sonographers experience less work related discomfort. It is not designed to completely support the arms or provide additional arm strength. As a result, sonographers may not notice immediate improvements in their work. Managing expectations can help improve sonographer perception of the device.

CHAPTER 5. **CONCLUSIONS**

This study investigated the use of exoskeletons by sonographers while performing transthoracic echocardiogram procedures. The use of the exoskeleton reduced arm deviations from natural posture (at both the 50^{th} and 95^{th} percentiles) and encouraged sonographers to adapt a more neutral torso posture (50^{th} percentile). The upper extremity exoskeletons reduced muscle activity and improved posture during left-handed scanning, but had little impact on right-handed scanning. Investigating the interaction between sonographers, the exoskeleton, and the patients will help in understanding why the exoskeleton was less effective in right-handed scanning. Though the objective measures indicated benefits to using the exoskeleton, the subjective measures did not correspond to these results. Further work needs to focus on how to incorporate exoskeletons in a way sonographers are willing to use the technology. Overall, upper extremity exoskeletons have the potential to be effective ergonomic interventions in transthoracic echocardiograms performed with the left hand and further research is necessary to provide benefit to right-handed scanning and increase sonographer acceptance.

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APPENDIX A. Discomfort Survey for Exoskeleton Conditions

Discomfort survey- After every TTE procedure
Participant ID:___________ Date: ___________ Condition:___________
Case Number: ___________

Rate your level of discomfort in the table below:

BODY PART	Before TTE	During TTE	After TTE	During Computer work
Scale	**0 = no discomfort → 10 = significant discomfort**			
Neck				
Left shoulder				
Right shoulder				
Left upper arm				
Right upper arm				
Left wrist/hand				
Right wrist/hand				
Upper back				
Lower back				

Did the exoskeleton interfere with your ability to perform the TTE? (0 no interference, 10 greatly interfered)

0 1 2 3 4 5 6 7 8 9 10

Did the exoskeleton improve your ability to perform the TTE? (0 no improvement, 10 great improvement)

0 1 2 3 4 5 6 7 8 9 10

Did the exoskeleton interfere with your ability to perform computer work? (0 no interference, 10 greatly interfered)

0 1 2 3 4 5 6 7 8 9 10

Did the exoskeleton improve your ability to perform computer work? (0 no improvement, 10 great improvement)

0 1 2 3 4 5 6 7 8 9 10

During which part(s) of the TTE procedure did you stand?

Based on <u>other</u> transthoracic echocardiogram (TTE) procedures you perform, was this procedure:

- ○ Less difficult than expected
- ○ As expected
- ○ More difficult than expected

If the procedure was more or less difficult than expected: Why was the difficulty different than you expected?

Based on <u>your expectations</u> going into this case, was this procedure:

- ○ Less difficult than expected
- ○ As expected
- ○ More difficult than expected

If the procedure was more or less difficult than expected: Why was the difficulty different than you expected?

APPENDIX B. Discomfort Survey for Non-exoskeleton Conditions

Discomfort survey- After every TTE procedure
Participant ID:____________ Date: ____________ Condition:____________
Case Number: ____________

Rate your level of discomfort in the table below:

BODY PART	Before TTE	During TTE	After TTE	During Computer work
Scale	**0 = no discomfort → 10 = significant discomfort**			
Neck				
Left shoulder				
Right shoulder				
Left upper arm				
Right upper arm				
Left wrist/hand				
Right wrist/hand				
Upper back				
Lower back				

During which part(s) of the TTE procedure did you stand?

Based on <u>other</u> transthoracic echocardiogram (TTE) procedures you perform, was this procedure:

- ○ Less difficult than expected
- ○ As expected
- ○ More difficult than expected

If the procedure was more or less difficult than expected: Why was the difficulty different than you expected?

Based on <u>your expectations</u> going into this case, was this procedure:

- ○ Less difficult than expected
- ○ As expected
- ○ More difficult than expected

If the procedure was more or less difficult than expected: Why was the difficulty different than you expected?

APPENDIX C. End of the Day Survey for Exoskeleton Conditions

Final Questionnaire - End of day

Participant ID:___________ Date: ___________ Condition:___________

Did the use of the exoskeleton increase your physical comfort when performing TTE procedures? (0= decreased comfort, 5= no change, 10= increased comfort)

0 1 2 3 4 5 6 7 8 9 10

Given the choice, would you want to use the exoskeleton in future TTE procedures?

No Yes

For what amount of time would you be comfortable wearing the exoskeleton? (Smets 2019)

___________ hours

What did you like about using the exoskeleton?

What did you dislike about using the exoskeleton?

For which tasks did the exoskeleton provide the most benefit? (Smets 2019)

Were there any tasks that were more difficult or impossible to complete due to the exoskeleton? If so, which tasks? (Smets 2019)

What would you change about the exoskeleton to make it better?

APPENDIX D. End of the Day Survey for Non-exoskeleton Conditions

Final Questionnaire - End of day

Participant ID:____________ Date: ____________ Condition:____________

Are there any comments about the study you would like to provide to the research team?

APPENDIX E. Mayo Clinic IRB Approval

MAYO CLINIC

Principal Investigator Notification:

From: Mayo Clinic IRB
To: Susan Hallbeck
CC: Merri Bremer
Joshua Finstuen
Susan Hallbeck
Karen Helfinstine
Garvan Kane
Katherine Law
Bettie Lechtenberg
Jennifer Martin
Melissa Morrow
Patricia Pellikka
Tianke Wang

Re: IRB Application # 20-001300

Application Title: Improving Ergonomics with Exoskeleton-Assisted Ultrasonography

Please note that all correspondence (modifications, continuing reviews, reportable events) related to this application must be submitted electronically in the IRBe system.

The following is an excerpt from the minutes of the Mayo Clinic Institutional Review Boards (IRB Friday) meeting dated 7/24/2020:

DECISION: The Committee received the Deferral Response Form dated, July 17, 2020, for the above referenced application. The investigator accounted for the use of the exoskeleton as a device in the IRB application and request either an NSR determination for its use or provide documentation that the device will be used as FDA indicated. The Committee determined that the concerns identified at the Committee meeting of July 17, 2020, were adequately addressed.

The Committee reviewed and approved the above referenced application and noted that all requirements for approval of research (45CFR46.111 and 21CFR56.111) were met. This approval is valid for one year unless during that time the IRB determines that it is appropriate to halt or suspend the study earlier. IRB approval will expire on July 23, 2021. The Committee approved the accrual of 4 adult subjects. The Committee approved the following site to conduct the study activities as specified in the application: Mayo Clinic in Rochester, Minnesota.

REVIEW: The Committee noted receipt of the protocol, Version 1.1, dated July 9, 2020. Funding for the study is provided by Mayo Clinic. The Committee determined that the study device, Airframe Exoskeleton, was of non-significant risk (NSR) as proposed for use in this study as it does not meet the criteria for significant risk defined under 21CFR812.3(m). As such, the Investigator and sponsor are to comply with 21CFR 812.2(b), the abbreviated FDA requirements for Investigational Device Exemption (IDE). The investigator is referred to the Mayo Clinic Office of Research Regulatory Support Quick Reference Guide, "Responsibilities of the Sponsor and/or Investigator for Non-Significant Risk Device Studies" and the Mayo Clinic IRB Policy, "Use of an Investigational Device in Human Subjects Research" for additional information. The Committee noted the receipt of Airframe Exoskeleton Is an Ergonomic Device; and Exoskeletons for Injury Prevention.

CONTACT MATERIALS: The Committee approved the questionnaires and email script as submitted.

CONSENT: The Committee approved the consent form (00) as written. The final approved consent form will be provided under the Documents tab of the main study workspace in IRBe.

REMINDERS: The Committee:

- Advises the Investigator to contact Legal Contract Administration regarding an appropriate agreement(s).
- Reminds the investigator to submit a continuing review report prior to the expiration date (reminder will be sent prior to expiration).
- Refers this application to expedited review procedures, in accordance with 45CFR46.110, categories 1(b), 4 and 7.

Attachments (if applicable):

name	version	dateCreated	dateModified
There are no items to display			

Drake, Matthew M.D., Chair
Caitlin Foss-Baumgard , Correspondent
Mayo Clinic Institutional Review Boards

IRB Friday

APPENDIX F. Iowa State IRB reliance on Mayo Clinic

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office for Responsible Research
Vice President for Research
2420 Lincoln Way, Suite 202
Ames, Iowa 50014
515 294-4566

Date: 07/30/2020

To: Gary Mirka

From: Office for Responsible Research

Title: **Improving Ergonomics with Exoskeleton-Assisted Ultrasonography**

ISU IRB ID: **20-299**

Reviewing IRB: **Mayo Clinic**

Reviewing Site PI: **Susan Hallbeck, PhD**

The ISU IRB has ceded IRB review responsibilities to the Reviewing IRB for the project identified above. To ensure protection of human subjects and compliance with regulations and policies, ISU Principal Investigators (PIs) must follow the policies and procedures of the Reviewing IRB and assume the following responsibilities:

1. Coordinate with the Reviewing-Site PI for IRB approval. Provide the reviewing-site PI with:
    a. Names of all ISU research personnel involved in the study and evidence of their human subjects protection training.
    b. Information about any applicable ISU policies (e.g., policies for participant compensation, background checks, mandatory reporting, etc.).
2. Obtain any required ancillary approvals from ISU. For example, financial conflicts of interest related to the research must be reviewed by ISU's Office for Research Integrity. Studies using x-rays or DXA scans require approval from ISU's Radiation Safety Committee.
3. Ensure that research activities are not initiated until approval from the Reviewing IRB is finalized.
4. Strictly adhere to the protocol approved by the Reviewing IRB. Ensure the ISU research team understands the approved protocol and uses only approved materials. Provide proper oversight of the project and project staff to ensure protection of human subjects and compliance with the approved protocol.
5. Coordinate with the Reviewing-Site PI to seek prior approval for any changes to the research, including changes in procedures, materials, study personnel, funding, etc.
6. Provide the Reviewing-Site PI with information necessary for continuing review (e.g., study progress, enrollment, new information, etc.

7. If IRB approval from the Reviewing IRB lapses, stop all human subjects research activities (unless continuation is necessary to prevent harm to subjects).

8. Report to the Reviewing-Site PI or Reviewing IRB, in accordance with its policies/procedures, any:

    - unanticipated problems involving risks to subjects or others,
    - serious adverse events,
    - complaints about the research, or
    - protocol deviations/noncompliance.

9. Cooperate with any post-approval monitoring of the research conducted by the reviewing site or by ISU.

10. Cooperate with any federal or institutional audits, or with any investigations conducted by the reviewing site or by ISU (e.g., investigations regarding noncompliance, an unanticipated problem, etc.).

11. Maintain all research records as required by federal regulations and institutional policies. ISU requires that IRB-related research records (e.g., signed informed consent documents, etc.) be retained for three years after the study is complete. The Reviewing IRB may require a longer retention period.

12. Promptly inform the ISU IRB, the Reviewing IRB, and the Reviewing-Site PI of any of the following:

    - Your role as Principal Investigator on the research is ending. For example:
        - Your formal affiliation with ISU is ending (e.g., you are leaving ISU). A change in institutional affiliation of the ISU PI requires changes to the reliance agreement.
        - Your position changes such that you are no longer eligible to independently serve as Principal Investigator in accordance with the PI Eligibility Guidelines specified by the Office of the Vice President for Research.
        - You are unable to serve as PI due to other commitments (e.g., a new position, a long-term sabbatical, etc.).
    - Any addition of or change to federal funding for this research. The reliance agreement established for the project covers only the funding sources specifically referenced in the IRB application; it should not be used as documentation of IRB approval for any other funding sources. You should submit an Amendment for Modification in IRBManager to notify the ISU IRB.

13. When the research is complete, submit an Amendment for Closure in IRBManager at ISU.