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EVALUATION OF THE ROTR 1: AN INNOVATIVE DEVICE TO REACTIVELY STRENGTHEN THE SHOULDER

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by

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DEDICATION

To my friends: Thank you for providing me endless smiles, memories, and fun. I would not have been able to get through the past six years without you all.

To my mentors: Your endless support and positive attitude has driven me to be the best that I can be. Thank you for putting up with my stressed-out days and crazy ideas.

To my family: This is for you. Through thick and thin, good and bad, you've supported me in everything that I've ever done. Thank you for allowing me to find my why and pursue my passion.

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EVALUATION OF THE ROTR 1: AN INNOVATIVE DEVICE TO REACTIVELY STRENGTHEN THE SHOULDER

Abstract

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This study assesses the effectiveness of an innovative shoulder training and rehabilitation device, the Rotr 1. The device uses mechanically created motion to disturb the balance of muscular forces around the shoulder, thereby facilitating dynamic training of the muscles. The hypothesis is that random disturbances provided by the device would potentially increase shoulder muscle activation as users try to resist the device's motion. To test the efficacy of the device, shoulder muscle activation from two groups (ten non-athletes and seven athletes), was assessed in three different shoulder positions and four different exercise conditions (aka configurations). Muscle activation of seven different shoulder muscles was recorded using electromyography (EMG). 3D motion capture was used to ensure repeatability of the positions during testing. ANOVA was done to assess the differences in muscle activation across groups, positions and exercise conditions. This device has the potential to improve performance and rehabilitation of overhead athletes, by increasing the body's ability to effectively react and protect the shoulder.

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LIST OF ABBREVIATIONS

EMG	Electromyography
BB	Bodyblade
MVIC	Maximum voluntary isometric contraction
ESC	Electronic speed control
R	The R project for statistical computation
lbf	Pounds-force

Chapter 1: Introduction

According to the 2016 United States Bureau of Labor report, approximately 32 shoulder injury cases were reported per 10,000 full time employees, equating to a median of 26 days away from work – more than double any other body part [1]. A 2006 national comparative study of US high school athletic trainers revealed that the shoulder joint was the most prevalent injury for both males and females across 9 different sports resulting in approximately 44% of the injured players missing multiple weeks of playing time [2]. Additionally, the CDC reported in 2015 that shoulder issues (pain, rotator cuff, etc.) equated to approximately twelve million orthopedic visits [3]. Clearly, the shoulder has been and remains a part of the body that is prone to injury and causes numerous lost days of work and school within the United States. Yet shoulder strengthening and rehabilitation innovations have been a stagnant area of clinical research yielding only a few known published articles within the past five years (our search in Scopus and PubMed resulted in less than five publications). These studies focused on post-surgery individuals' rehabilitation applications, quantifying muscle activities and best current rehabilitation/strengthening exercises [1] [2] [4] [5]. Additionally, current rehabilitation devices such as the Bodyblade [4] or resistance bands [5], do not allow injured or weaker athletes proper strengthening or rehabilitation. This is due to the patient's limited strength, which may lead to a longer or incomplete rehabilitation time. The focus of this thesis document is to 1) discuss biomechanics of shoulder injuries in overhead sports athletes, 2) introduce a strengthening and rehabilitation technology and 3) present a comprehensive study of one

innovation, ROTR 1, that is designed to reactively strengthen [6] the muscles of the shoulder using a mechanized system.

Shoulder Injuries in Athletes of Overhead Sports

The shoulder joint sacrifices stability for extreme rotational and multi-directional translational degrees of freedom [7] [1]. The shoulder muscle complex - a set of muscles in and around the shoulder -interacts in a synchronized fashion to support, stabilize, and coordinate strong and precise actions as shown in Figure 1 [8]. In overhead throwing activities, co-contraction of the shoulder muscle complex provides power for the action and also decreases the likelihood of injury [9]. Improper co-contraction of the muscles during activity can cause variation in motor control, flexibility, and endurance, among others, and is the most probable cause of injury to the shoulder complex [10] [11]. The overhead throw, which is the most invasive overhead activity, places angular velocities reaching 7250°/s and shear forces equating to about 50% of body weight, which can result in severe and lasting injuries [11]. Common shoulder injuries in overhead throwing athletes include chronic anterior subluxation, rotator cuff tears, and labrum tears (or SLAP tears) [12]. Common to each of these injuries are anterior and posterior glenohumeral instability, which leads to excessive translational motion of the joint [12]. Due to the severity of these injuries, most athletes require surgery then rehabilitation or consistent rehabilitation exercises to prevent further damage. Wilk et al. identifies four distinct phases of the rehabilitation process that are necessary for proper and effective strengthening. The four phases include, normalizing shoulder mobility, creating a functional scapular base, dy-

namic stability, and attaining proper function [11]. Any alteration in shoulder biomechanics or shoulder complex dysfunction requires rehabilitation and strengthening to return to proper range of motion, stability, and fully functional movements.

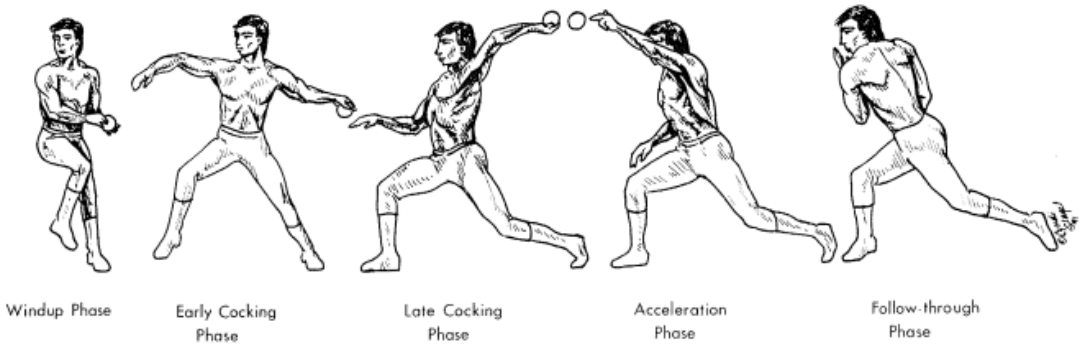

Figure 1. The phases of the baseball pitch. Adapted from Bradley and Tibone to illustrate the co-contraction of the musculature needed in this movement.

Biomechanics of The Overhead Throwing Activity

Classification of the stages of the overhead throw is usually modeled after a baseball pitcher's motion due to the extreme angles and stresses that is placed on the shoulder and arm (figure 1). Studies on shoulder kinetics and kinematics during a pitch have concluded that the phases of the pitch always follow the same progression: wind-up, stride, arm clocking, arm acceleration, arm deceleration, follow through [13] [14] [15]. Fleisig et al. then quantified the angles and angular velocities for each phase of the pitch. It was found that the kinetics and kinematics of the arm are relatively similar when compared across subjects; thus, allowing for constant generalized angles and forces for each phase of the pitching motion. The deltoid muscles are co-contracted most during the wind-up and deceleration motions of the arm [15]. The middle range of the progression incorporates extensive work from the dynamic stabilizers of the shoulder. The main components of this is the rotator cuff (supraspinatus, infraspinatus, teres minor, and subscapularis), bicep, triceps,

pectoralis major, latissimus dorsi, and the trapezius muscles [15]. The pitching motion is a robust movement that incorporates the entire body to be properly executed. These eight muscles, which experience the most force during the pitching motion, were studied for this thesis project based on the findings of Fleisig et al. and Escamilla et al.

Strengthening and Rehabilitation Technology

The Bodyblade (BB) is a commonly used device that utilizes oscillatory motion, provided by the user, for strengthening and rehabilitation applications [4]. Physical therapists have used this device for enhanced functional stability, improved endurance, increased strength, amongst other things [16]. The theory behind BB and similar oscillating devices' theory has not been studied in any known publications. Escamilla et al. describes the use of the BB as an oscillating pattern that can be used in various positions [4]. The oscillation and movement patterns of the BB is used to activate the muscles of the shoulder complex. The movers (pectoralis major, latissimus dorsi, and deltoid) and stabilizers (rotator cuff, bicep and triceps) are worked when the BB is used for prolonged periods of time [4]. The oscillating patterns of the BB is controlled by the user creating the oscillation then keeping it in a static equilibrium position for prolonged periods of time [16]. Even though the BB has been in use for more than two decades, scientific support for the efficacy of the device isn't present [4]. There is some scientific evidence that BB increases muscular activity in the shoulder complex [2] [17], but it is unknown if the BB affects the co-contraction patterns in the shoulder complex (our searches in Scopus and PubMed only resulted in two publications).

Similarly, shoulder stabilization, strengthening, and rehabilitation techniques using elastic resistance bands or weighted resistance balls have very little scientific backing from electromyographically (EMG) data, with only one publication specifically quantifying EMG data for resistance band exercises [5]. Often, resistance exercises using elastic bands are performed as isometric exercises to isolate muscles and provide a safe, controlled exercise routine. To optimize elastic therapy bands, proper knowledge of the physiological and material characteristics is necessary [18]. Meyers et al found that none of the 12 resistance band exercises tested resulted in moderate (>20% MVIC) activation for all 9 muscles tested [5]. Instead a regimen of seven different exercises must be performed to moderately activate all the muscles important for the throwing motion [5]. Optimally performing these exercises requires supervision from an athletic trainer or physical therapists, making these exercises time and resource consuming. Both the BB and elastic resistance devices target a very specific niche and require space and expertise to optimize the use. Additionally, overhead throwing athletes require improved *dynamic* (i.e. during activity) stabilization.

Static rehabilitation systems, like BB and elastic resistance bands, are being replaced by dynamic resistance exercises forcing the user to react during action, increasing their performance and decreasing the likelihood of injury. Reactive strengthening, the ability for the body to change quickly from an eccentric to a concentric contraction, is shown to effectively increase performance in activities such as basketball and sprinting [6]. This strengthening technique focuses on proper muscular contraction during action (i.e. dynamic control) to produce the maximum force and protection for the joints. There is a need to develop strengthening and rehabilitation devices that focuses on *reactive*

strengthening and proper muscle recruitment to maximize performance and joint protection, which is required for overhead throwing athletes.

Though some devices are being created for dynamic resistance exercises, none have been marketed for the shoulder. The concept of resisting an induced perturbation of the shoulder complex is used in few current strengthening/rehabilitation devices [2] [4]. These devices utilize static conditions to activate the shoulder muscles – the user must drive the device back and forth to be effective. They may not be effective in meeting the dynamic shoulder stabilization needs for these athletes.

In this study, an innovative device, Rotr 1 (provisional patent number 62662862), was created to use dynamic, mechanically created oscillations to disturb the balance of muscular forces around the shoulder. Devices like the BB also require users to provide mechanical oscillations, then react to the error in the system (the created oscillations). However the error in the system created by the BB is user-induced, making it not as effective because the user must act then react to the stimuli. Also, user-induced method of 'act then react' has an in-built predictability of the incoming error signal. The neuro-muscular system responds best to learning from unpredictable errors brought upon it that disturbs its equilibrium. The body's ability to react to an incoming unfavorable, unpredictable situation will ultimately determine its protection from injury.

The innovative device, Rotr 1 creates a random (*thus unpredictable)* force *(thus unfavorable),* via motor driven oscillations that the user must keep in an equilibrium state. The main goal of the Rotr 1 is to use a reactive style of strengthening of the shoulder complex that increases the body's ability to adapt and protect the shoulder in various situations.

The proposed dynamic shoulder strengthening device, the Rotr 1, uses the same principles as the current devices on the market, but eliminates the need for user input to produce a quasi-static position. The main goal of this rehabilitation device is to elevate performance of shoulder complex muscles during any overhead activities, by increasing the body's ability to effectively react and protect the shoulder during action by proper muscle recruitment.

Uniqueness of the Rotr 1

The Rotr 1 uses a spinning center disk, whose angle of rotation is changed causing a 'jerk' that induces the perturbation. The uniqueness of this device is that it eliminates the need for the user to drive the device. By eliminating the user-induced method of 'act then react', the device will allow for concentrated muscular activation to unpredictable forces, without the conscious effort drive the device.

I tested this device through complex research design that investigates the effects of mechanically induced perturbation by the Rotr 1, in various shoulder positions, in both athletes and non-athletes. This study will benefit athletes and trade workers improve their shoulder strength in an easy to use, compact, and portable device (Rotr 1).

This project contained two sub-studies: mechanical testing of the Rotr 1 and the physiological (EMG) testing of shoulder muscles while using the Rotr 1. The specific aims of the mechanical testing of the Rotr 1 were:

1. To capture the accelerations created by the jerk of the Rotr 1 in the x, y, and z directions.
2. To calculate the force produced by the Rotr 1 based on the captured accelerations.

3. To establish repeatability and reproducibility of the Rotr 1's generated jerk.

Three questions were then posed to test the physiological implications of the Rotr 1:

1) Does training (athletes) affect the change in muscular drive when using the device?
2) Does the jerk of the device change the drive of the muscles of the shoulder complex?
3) Does the position of the arm affect the change in drive of the muscles, brought by the jerk of the device?

It is hypothesized that:

1) Athletes will have lower muscular activity overall compared to non-athletes due to their increased motor control from sports training.
2) The device will increase shoulder muscle activity when subjects resist the device's produced jerk.
3) The shoulder muscle activation (as measured by EMG) will change according to the position of the arm.

Answering the proposed mechanical and physiological aims will assess the body's ability to reactively support the shoulder and the Rotr 1's ability to actively contribute to this type of dynamic, reactive training.

All the following chapters are arranged in the same order, first information about Rotr 1 mechanical testing then physiological testing of shoulder muscles while using the Rotr 1 will be presented. So, in chapter 2, the Rotr 1 will be first introduced and detailed, then the physiological testing including the subjects, testing methodology, and data analysis will

be detailed. In chapter 3, the results of the mechanical testing will be first detailed, then the motion capture data and EMG testing will be detailed. Finally, in chapter 4 the results of mechanical testing and basic theory of the device will be first discussed, followed by discussion of physiological testing. Then, results, conclusions made, and future considerations will be discussed.

Chapter 2: Methodology

The Device, Rotr 1

A mechanically controlled, dynamic shoulder strengthening and rehabilitation device, The Rotr 1 (seen in figure 2) was designed and manufactured to cause mechanically derived random motion that the user must react to and resist. Since the motion is random, the user is training the reactive capabilities of their shoulder muscles, increasing their body's ability to efficiently protect the shoulder joint. Reactive training is a term usually associated with plyometric and lower body training in sports such as soccer [6]. It is a subset of normal training regimens that require the body to generate stabilizing forces instantaneously to respond to a demand placed on the body. Lower body reactive programs are well supported and backed with various machines; whereas, upper body reactive training routines are scarce and hardly used. The study of reactive shoulder strengthening and rehabilitation devices are a new and under research area.

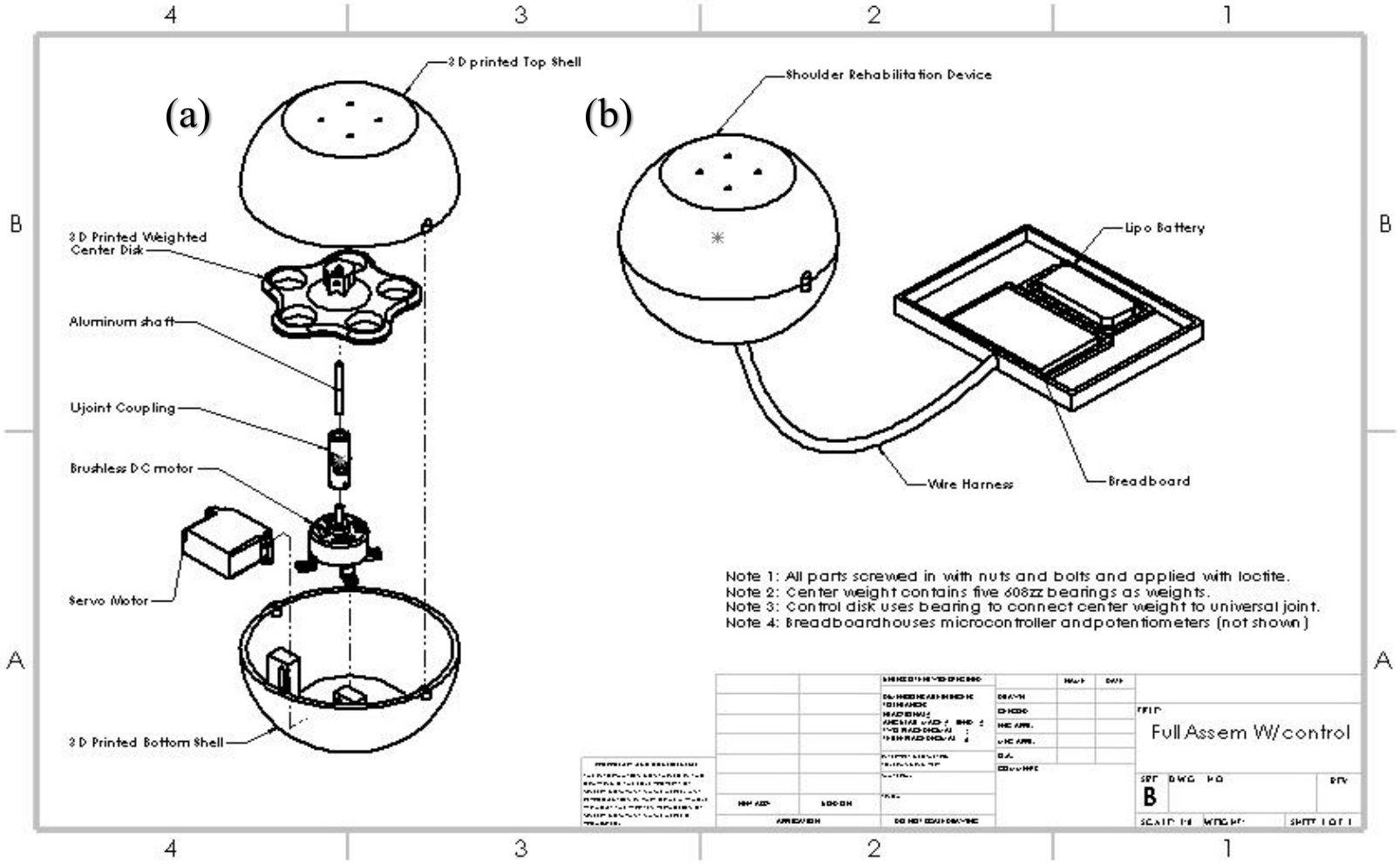

Figure 2. (a) Device xplod view with important components labeled. The shell and weighted disk is 3D printed. Everything is screwed in using bolts and Loctite. (b) Full device configuration including breadboard and battery housing. The device is hardwired in and everything is controlled through a microcontroller on the breadboard.

The outer shell of the Rotr 1 was designed in a ball-like shape for better grip. The overall diameter of the shell is about 6 inches and is held together with screws. The central disk was designed to have varying and interchangeable weights. The interchangeable weight was added to the disk using bearings (4, 5, and 6 bearings were considered). The disk with 5 bearings was empirically chosen to give the best combination of spin speed and weight. A metal shaft was fitted into the center of the disk. Using a universal coupling, the disk was connected to the brushless motor. A smaller 'control disk' connected the servo motors to the weighted disk through custom control arms. A brushless motor controlled the spin of the disk via an ESC programmed to a microcontroller. The servo motors controlled the change in pitch of the disk with a maximum angle change of 30 degrees. The system was hardwired to a breadboard and controlled by a microcontroller. The system was powered through the ESC's battery connection. The speed of the brushless motor and pitch of the servo motors were controlled using two potentiometers.

Mechanical Testing

To test the force produced by the device, an accelerometer was affixed to the device and suspended from a rope to dampen the vibration produced. A pilot test of fifteen trials was collected. Each trial collected data for three seconds (200 samples per second) and one 'jerk' was performed at the two second mark. In R (R Core Team 2013), the data was full wave rectified and the RMS is taken using a moving window to smooth out the signal and remove noise. The peak acceleration was extracted from the data and imported to Excel. In Excel, the force was calculated in newtons using the device's weight (0.5 kg) and the peak accelerations extracted from the data. Then, using the conversion factor of 0.225 lbf/1N, the pounds-force was found for each trial's x, y, z direction. A

Gage R&R was used as a preliminary study to assess the inherent variation within the system. A Gage R&R was performed to validate preliminary data sets, check for calibration requirements, and assess the capability of the measurement system. The results of this Gage R&R will validate our testing apparatus and procedure, as well as, suggest improvements for further testing. The Gage R&R was performed on the calculated pound-force values to assess the significance between each trial and direction, then find the reproducibility, and reliability percentages of the values.

Physiological Testing

This study involved repeated electromyographical (EMG) measurements of eight muscles around the shoulder in random arm positions with various configurations. Innovative technology involving external mechanically produced perturbation and isometric contraction of the shoulder complex was used.

Participants

A total of seventeen healthy volunteers, 10 non-athletes and 7 athletes, without any current or previous shoulder injuries, past surgeries, or any possible ailments that may change the biomechanics of the shoulder participated in the study. All participants were recruited from the general student body at The University of the Pacific. This study was approved by the University's institutional review board (IRB) and each participant gave written informed consent prior to participation.

Materials

Subjects were asked to wear comfortable shorts, no shoes, and no shirt (sports bra for females). The electrode placement areas were prepped by shaving and abrading prior to

placement of the electrodes. Eight wireless Delsys electrodes were placed parallel to the fibers of each muscles studied on the subject's dominant side adapted from Criswell et al [19].

Prior to each subject's arrival, calibration of the motion capture system was performed to block visible markers and set a new z-axis. Once all electrodes were placed on the body, each subject was dressed in the motion capture suit, head cap, and booties. 37 baseline markers were placed on the suit as detailed in the OptiTrack manual. A 3D skeleton was created using Motive motion capture software before the study was started. The "T position" was used for calibration of the 3D system throughout the study.

Procedure

The device was tested in three different positions (figure 2). The positions were chosen to represent the progression of the throwing motion. In each position, four configurations were tested to determine the efficacy of the device (table 1). The subject had no prior knowledge or use of the device prior to starting the study. All exercises were performed seated with their feet firmly planted on the floor. The test administrator instructed the subjects of the proper use of the device – relaxing the hand and forearm allowing the device to move the entire arm – and supervised proper use during the study. All trials were performed in a single hour session.

Once the MVIC was completed, the subject was instructed on the use of the device and the system was recalibrated if needed. The device was demonstrated to each subject by the test administrator; however, subjects were not allowed to handle the device in any way prior to the start of testing. The subject was then shown the three positions used in the trial

(figure 3) and instructed to practice each position before beginning the test. Each subject was instructed to do their best to return to the same positions each time during the study, using visual and memory cues. Subjects were then instructed to assume a random position/configuration (table 1) by the test administrator. The test administrator provided a

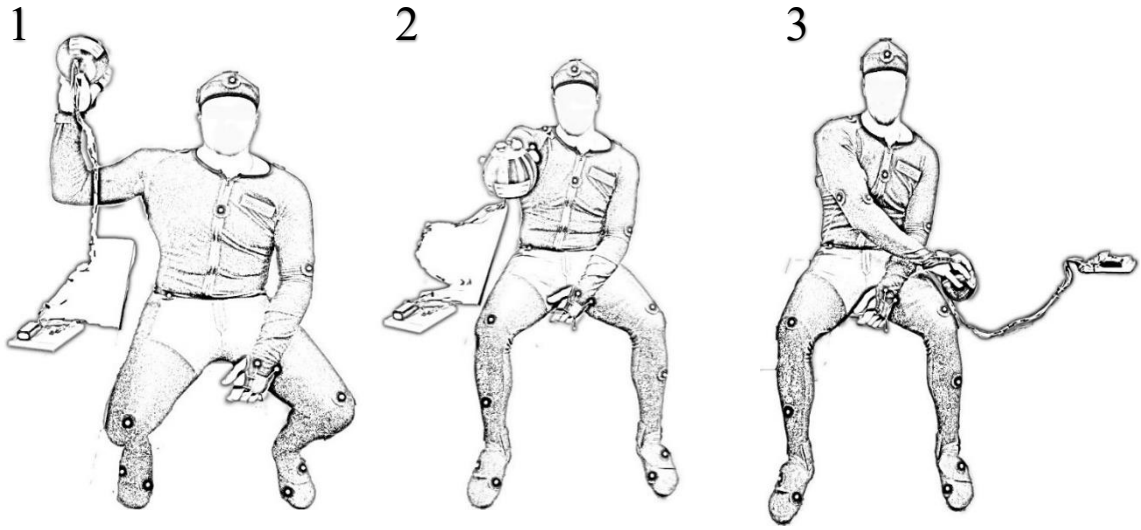

Figure 3. Arm positions labeled next to each figure. In each position, four configurations were used to test the effectiveness and input strength necessary to use the device. The data collected from each configuration are then compared between each over using ANOVA analysis.

random 'jerk' intensity for each trial to avoid learning or any bias from the subject or administrator. A total of 12 position/configuration set ups were used and a total of 3 trials were performed for each set up. Each trial lasted 10 seconds with a 30 second rest in-between trials.

Table 1. Position and Configuration set up. This matrix was used to randomize trials during data collection.

	Position 1	**Position 2**	**Position 3**
Configuration 1	Without Ball	Without Ball	Without Ball
Configuration 2	With Ball	With Ball	With Ball
Configuration 3	With Ball On	With Ball On	With Ball On
Configuration 4	With Ball On + Active Resist	With Ball On + Active Resist	With Ball On + Active Resist

Maximum Voluntary Isometric Contraction (MVIC)

Once the electrodes were placed on the subject and the motion capture system was calibrated, the subject was instructed to sit on a low, no-back stool. Maximum voluntary isometric contraction (MVIC) data was collected for each muscle as described by the Center for Disease Control (CDC) [20]. Subject was instructed to give their maximum muscular contraction for 10 seconds, then 30 seconds of rest was given to minimize the effect of fatigue. The MVIC for each subject was performed in the same order: anterior deltoid, middle deltoid, posterior deltoid, bicep brachii, triceps brachii, pectoralis major, latissimus dorsi, and middle trapezius.

Data analysis

Motion Capture Processing

Motion capture data was exported as x, y, z positional data points for all 37 markers used in each trial. The markers' positional data of the proximal and posterior shoulder, proximal arm, elbow, wrist and hand of the dominant arm for each subject was extracted using R. The data from each subject's individual markers was full wave rectified (absolute value of

all data points taken). The rectified data was then organized by positional grouping/marker/orientation (e.g. all subjects positional data for position 1/top shoulder/x orientation, position 1/top shoulder/y orientation, etc.). The standard deviation for the positional data points of the organized data sets was calculated and the percentage of points within one standard deviation of the mean was used to indicate the positional accuracy between athletes and non-athletes.

EMG Processing

The raw EMG signal was full-wave rectified and smoothed with a 10 ms moving window over the duration of the 10 second trial. The maximum value of the rectified signal was extracted and normalized as percent max of MVIC. Configuration 1, from the table above, was used as my 'baseline' muscle activity and my starting point for comparison. A sample progression of EMG processing can be found in appendix A Figure 10.

EMG Statistical Analysis

A two-way nested ANVOA was employed ($p < 0.05$) to assess if the interaction was between or within position and configuration. A one-way Kruskal-Wallis analysis of variance (ANOVA) was employed ($p < 0.05$) to assess the difference amongst the four configurations for each subject. A two way (2 x 2) fixed measures ANOVA was employed ($p < 0.05$) to assess the difference amongst the three positions. Tukey HSD post-hoc analysis was employed to assess the pairwise comparisons and identify the differences.

Chapter 3: Results

Mechanical Testing

It was found that there was no significant difference between trials, but significance between directions. This indicates that the device was creating a significant but constant acceleration in the x, y, and z direction for all the 15 pilot trials. The repeatability of the device was found to be 63.7% and the reproducibility was found to be 77.1%, shown in table 2. These values suggest that the Rotr 1's force output is random yet consistant – a favorable result. The repeatability was low because the 'jerk' is provided by the test administrator and could be made more consistent if it was automated. The device outputted approximately 1.6 lbf without the 'jerk' caused by the precession of the center disk. The 'jerk' produced between 4.97 lbf and 11.4 lbf.

Table 2. ANOVA and Gage R&R results. There was no significance between trials, but significance between the directions suggesting the randomness, yet consistency of the force output of the Rotr 1.

	SS	df	MS	F	p-value	sig
Trial	19.24408	14	1.374577	0.911604	0.557487	no
Direction	69.20669	2	34.60334	22.94854	1.26E-06	yes
Repeatability	63.70%					
Reproducibility	77.10%					

Physiological Testing

The mean (±STD) height, weight, and age for the entire group was 66.8±4.3 in, 148.6±35.6 lb, and 21.2±1.7 years. Athletes were found to have higher positional accuracy (~87%

position markers within one standard deviation of mean) than non-athletes (~82% position makers within one standard deviation of mean), see figure 4.

The interaction between the fixed variable, position, and the random variable, configuration, was assessed before the interaction within each variable (shown in table 3). The anterior deltoid (P=.922), middle deltoid (P=.886), posterior deltoid (P=.999), biceps brachii (P=.999), triceps brachii (P=999), and latissimus dorsi (P=.988) show no significance between position and configuration; however, the pectoralis major (P=.0006) showed significance between the variables.

The non-athletes showed a greater percent activation than the athletes in six of the seven muscle groups tested and their corresponding positions/configurations (Figure 5). Similar trends were found for other muscle groups tested; except pectoralis major for which non-athletes showed less percent activation (see appendix A figure 11 and 12). Further investigation of the male and female data showed that the average percent activation was similar for both genders in the two groups athletes and non-athletes (e.g. all male non-athletes had similar percent activation).

Samples of male (figure 6) and female (figure 6) data are presented with progressing configurations on three different muscles and all three positions. A trend of increasing percent activation is seen between configurations. The magnitude of percent activation between configuration 1 (control) and configuration 4 (working against device) are similar for all trials (~0.1% increase). This increase in percent activation, however, was not statistically significant (alpha=0.05) using Kruskal-Wallis and two-way ANOVA analysis. A similar trend was found in all other muscles except for the pectoralis major and posterior deltoid (see appendix A figure 13 and 14).

Positional accuracy was found to be extremely important due to the difference in percent activation in muscular activation between positions (figure 7). Two samples (middle and posterior deltoid) are used to show an approximate 20% difference in activation of the muscles between positions one and three. A similar trend was found for other muscle groups and positions, except male and female athlete's latissimus dorsi and triceps (see appendix A figure 15 and 16).

Table 3. Nested ANOVA results showing the pectoralis major as the only muscle group that was significant between position and configuration. The other muscle groups showed no significance.

				Alpha	0.05	
Muscle	SS	df	MS	F	p-value	sig
Pectoralis Major	1.91632	44	0.043553	2.088143	0.000607	yes
Anterior Deltoid	4.787561	44	0.108808	0.691394	0.92168	no
Middle Deltoid	1.183345	44	0.026894	0.730846	0.88561	no
Posterior Deltoid	3.22856	44	0.073376	0.196924	1	no
Bicep	0.364021	44	0.008273	0.379592	0.999821	no
Triceps	1.119834	44	0.025451	0.424787	0.999278	no
Latissimus Dorsi	2.158361	44	0.049054	0.547083	0.988963	no

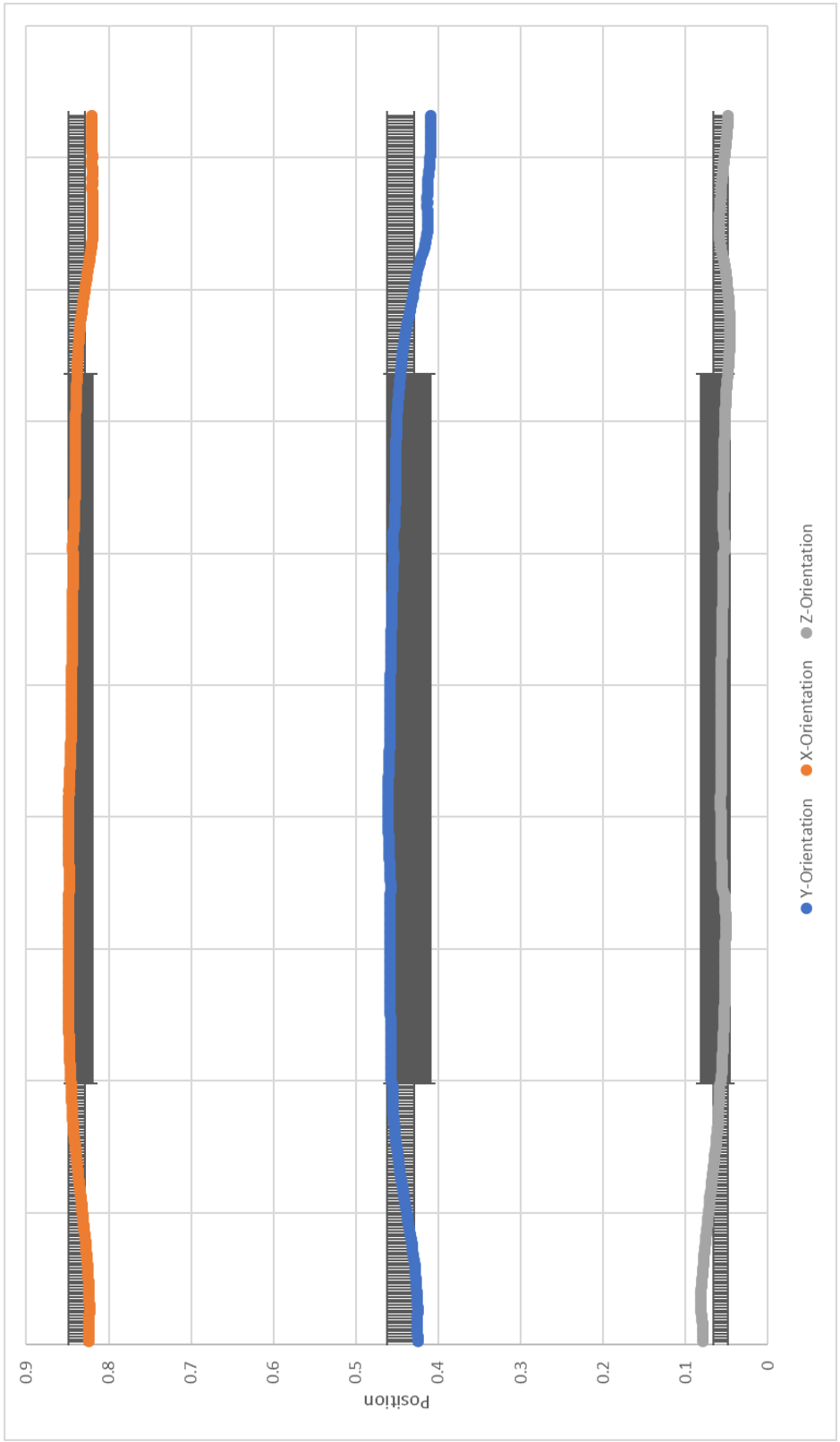

Figure 4. Graphic representation of organized positional data for the posterior shoulder marker. Standard deviation bar present to illustrate the percent of data within one standard deviation of the mean, represented by the dark grey region on each orientation cluster

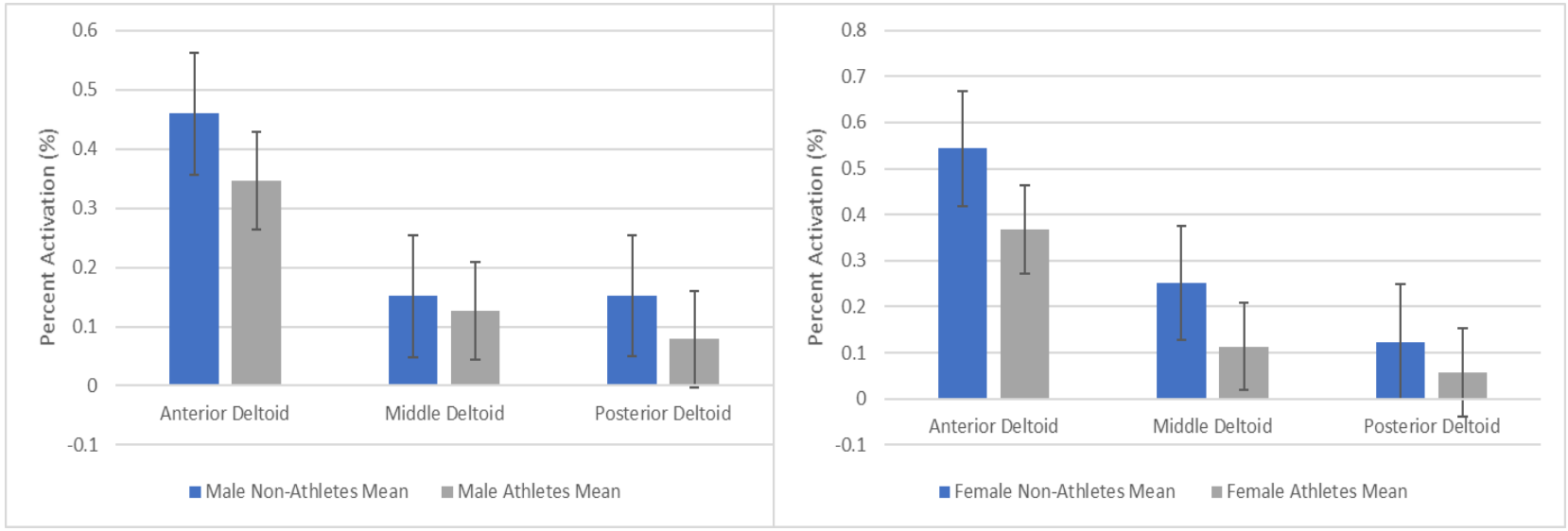

Figure 5. Graphic representation of normalized electromyographical (EMG) activity (% activation) between athletes and non-athletes for three muscles. Athletes had overall lower percent activation versus non-athletes, believed to be due to their increased motor control.

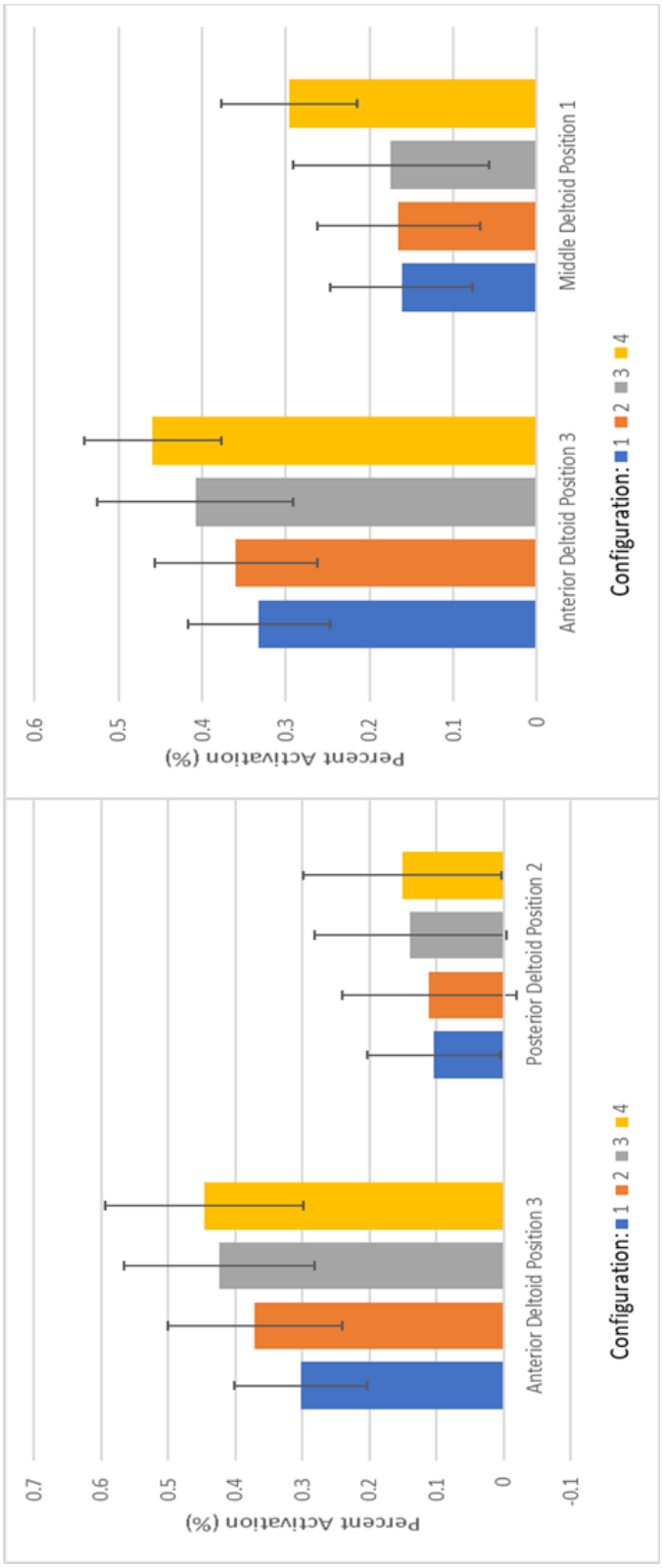

Figure 6. Graphic representation of normalized electromyographical (EMG) activity (% activation) for four sample muscles/positions. These graphs illustrate the trend in increasing percent activation found in all muscles/positions. The increasing trend of activation, through not statistically significant, verifies the effectiveness of the Rotr 1's ability to increase muscular activity.

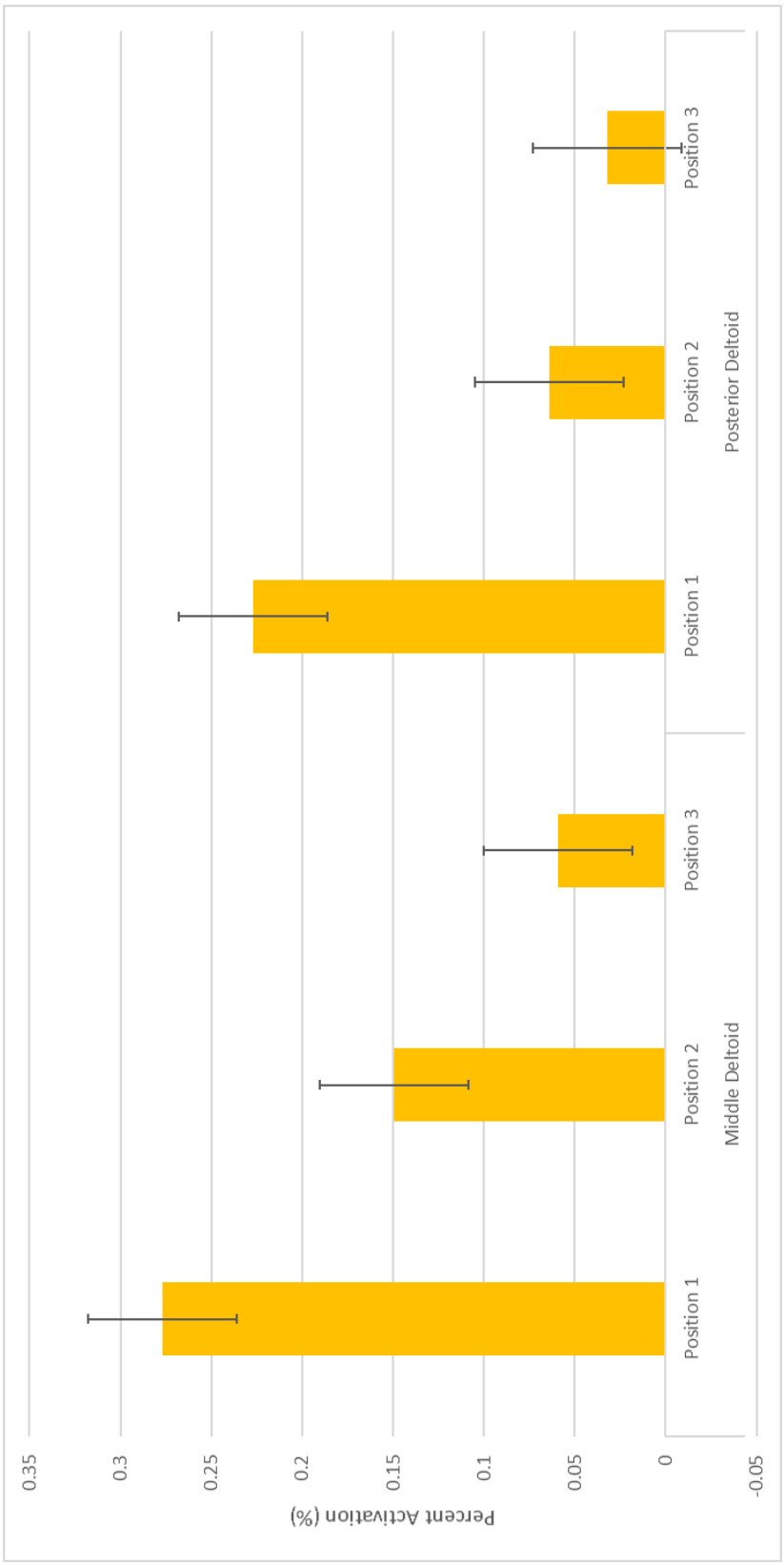

Figure 7. Graphic representation of normalized electromyographical (EMG) activity (% activation) between the positions for two sample muscles. These graphs show the difference that position makes for the percent activation of the muscles tested

Chapter 4: Discussion

The Rotr 1

Reactive strengthening, the ability for the body to change quickly from an eccentric to a concentric contraction, is a technique used to effectively increase performance in activities such as basketball and sprinting [6]. This strengthening technique focuses on proper muscular contraction during action to produce the maximum force and protection for the joints. Current shoulder strengthening and rehabilitation devices, however, aren't focused on proper muscle recruitment to maximize performance and protection. I have designed and manufactured a mechanically controlled, dynamic shoulder strengthening and rehabilitation device, The Rotr 1 (seen in figure 8). This device causes a mechanically derived random motion that the user must resist. Since the motion is random, the user is training the reactive capabilities of their shoulder muscles, increasing their body's ability to efficiently protect the shoulder joint.

Figure 8. Final assembly of the device used for testing. The wired connection is soldered directly to the motors and leads to the breadboard.

The outer shell was designed in a ball-like shape to make it easy to hold. The first 3D printed prototype was a perfect sphere, which was hard to grip. Instead, the finalized design had a flat top and bottom portion, while maintaining the ball-like shape. This made it possible to mount the motors easily to the base and provides the user ample grip while using the device. The overall diameter of the shell is about 6 inches and is held together with screws.

The central disk was designed to have varying and interchangeable weights. The interchangeable weight was added to the disk using bearings (4, 5, and 6 bearings were tested). The disk with 5 bearings was chosen empirically to give the best combination of spin speed and weight. A metal shaft was fitted into the center of the disk. Using a universal coupling, the disk was connected to the brushless motor. A smaller 'control disk' connected the servo motors to the weighted disk through custom control arms. A brushless motor controlled the spin of the disk via an ESC programmed to a microcontroller. The servo motors controlled the change in pitch of the disk with a maximum angle change of 30 degrees.

The system was hardwired to a breadboard and controlled by a microcontroller. The system was powered through the ESC's battery connection. The speed of the brushless motor and pitch of the servo motors were controlled using two potentiometers. The potentiometers send a value (0 to 1068) to the microcontroller, which corresponded to the speed or pitch of the motors respectively. Currently, the device is controlled manually, but future iterations of the device will have preset 'levels' that will control the speed and pitch automatically, so the user only needs to react to the device to use it.

The Rotr 1 works by providing a force for the user to resist against. The center disk spinning around a fixed axis creates an angular acceleration which causes the device to precess around the fixed axis. The precession causes a force to be created in the x/y planes that is felt by the user as vibration (see figure 9). The change in pitch of the axis causes the force to be applied in the direction of the axis change. The disk takes approximately one quarter of a second to change its pitch a return to the neutral axis point. This creates a 'jerk' like motion that produces force in the direction of the pitch change. Since the change in pitch is random, the direction of the force changes randomly and is felt in all three dimensions by the user.

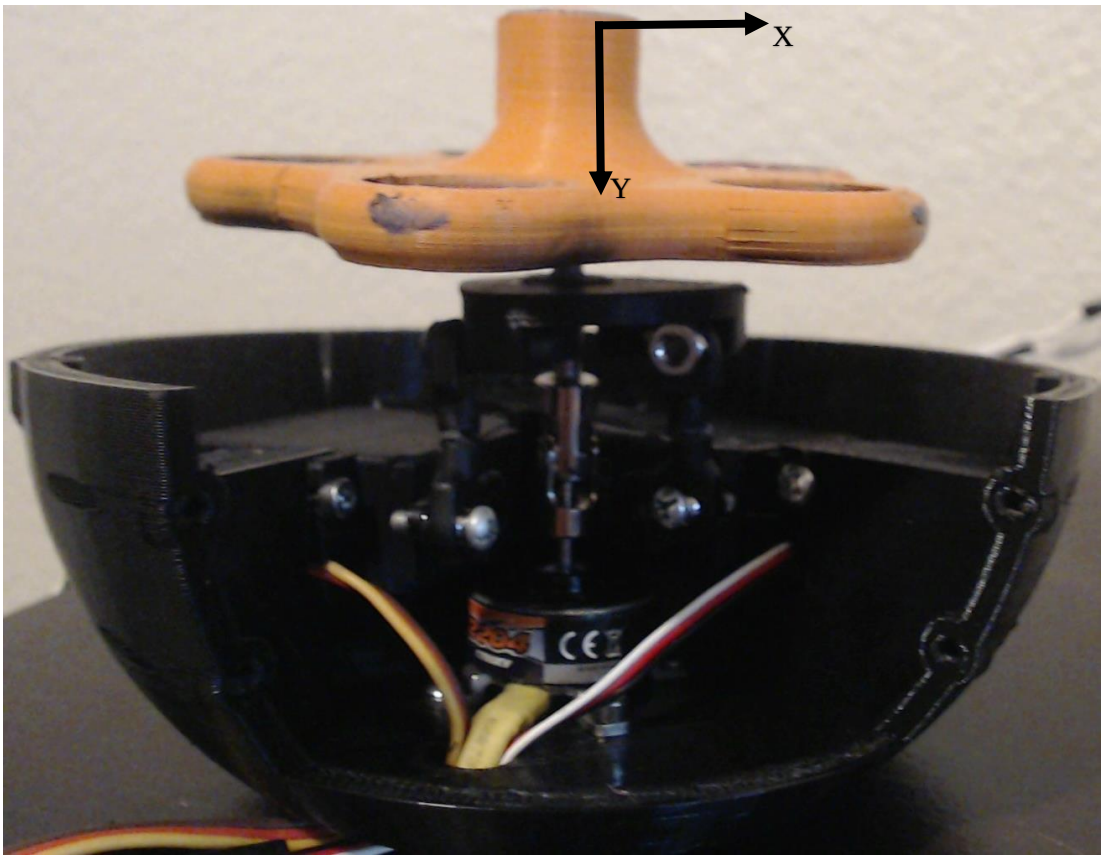

Figure 9. The center disk (orange piece) rotates around the metal center shaft which causes a precessing force. The change in pitch of the disk causes a force to be produced that the user must react against in the x/y planes.

Physiological Testing

Data collected from two subjects, one female non-athlete and one male non-athlete, was not used for data analysis because the subject's demographic did not match the average of the control and experimental groups. The muscle activation and MVIC values for these subjects appeared to be outliers from the group. This could be due to muscle cross-talk (given the subject's lean body mass) or unfamiliarity with muscular control during exercise. Likewise, I excluded analysis of the middle trapezius muscle due to inconsistency in the MVIC data amongst the subjects. The data showed that many of the subjects (both athletes and non-athletes) exhibited limited voluntary contraction of the middle trapezius muscle so MVIC data was inconsistent. The inconsistent MVIC data negatively impacted the EMG results as they indicated over one hundred percent activation for the two outlier subjects across most trials.

Athletes vs. Non-athletes

Athletes exhibited lower percent activation of the shoulder muscles tested as compared to non-athletes for all test configurations. This can be explained by their increased motor control and muscle activation brought about by athletic training. Thus, it is likely that the athletes required lower activation of the muscles to generate the same amount of force as non-athletes. Athletes, through cyclic training, increase their body's ability to respond and learn to adapt to errors brought upon the body. This practice increases the body's motor learning for task-specific movements and allows the body to react better to incoming stimulus [21]. In studies that compare elite athletes to novices, it was found that motor-evoked potential (MEP) increased with cyclic stimulation [22]. Dai et al. found that

the MEP curve produced by athletes was steeper than non-athletes. Thus, it was concluded that athletes were able to increase excitation due to their long-term training. Athletes were able to generate more muscle force for lower muscle activation [23]. Athletes, through cyclic training, increase their body's ability to respond and learn to adapt to errors brought upon the body. This practice increases the body's motor learning for task-specific movements and allows the body to react better to incoming stimulus [21]. Proprioception is the body's sense of position and motion through signals responding to mechanical deformation within the body [24]. Athletes have a better sense of joint position, kinesthesia, and sensation of resistance, allowing the body to create precise, controlled movements. Preparatory activation and reactive contraction of muscles also provides a more functionally stable joint by increasing muscle stiffness [25]. In our study, athletes exhibited lower percent activation throughout the study which, was caused by their body's ability to react to the stimulus better than non-athletes.

Muscle Activation

Data showed a trend of increasing percent activation of the shoulder muscles with use of the Rotr 1 in different exercise conditions (i.e. test configuration). Even though the results did not reach statistical significance, the percent activation for all the tested muscles, except the pectoralis major and posterior deltoid, was lowest in configuration 1 (no ball) and greatest in configuration 4 (with ball + active resist) for all shoulder positions and in all subjects. Escamilla et al. performed a similar study, but instead of using the Rotr 1 used the BB to quantify percent activation of muscles around the shoulder. Comparable percent activation values were found for the anterior/posterior deltoid, latissimus dorsi, and pectoralis major

in the study [4]. This implies that muscle activation by the Rotr 1 is comparable to the BB, a well established rehabilitation and strengthening technique for the shoulder.

Arm Position

Arm position is very important in the activation of muscles, given the force generated by the muscle is influenced by the length-tension relationship and angle of muscle pull. In my study, the percent activation of the anterior deltoid muscle changed between the three positions (greatest in position 1 and least in position 3). However, the posterior deltoid showed greatest percent activation in position 3 and least in position 2. A similar trend was found for other muscle groups and positions, except the latissimus dorsi and triceps of athletes (see appendix A table 6). The results of my study validate and support the importance of proper joint alignment (i.e. position for proper muscle activation). Therefore, athletic trainers (AT), sport scientists (SS), and any users of the Rotr 1, must be mindful of their arm position when operating this rehabilitation device. AT and SS utilize sport specific exercises to train athletes based on their sport [4] [16]. Since the Rotr 1 is comparable to BB in its ability to activate the muscles of the shoulder, sport specific exercises and training protocols can be developed to optimize the Rotr 1's use.

Limitations

After testing was completed a few elements were identified that could have potentially influenced results of the study. To record a better signal and avoid noise in the physiological recordings, the EMG and motion capture systems were not integrated for this study. Integrating the two systems could have provided improved analysis of the EMG results with joint angles. However, that was not the purpose of this study and could be a potential consideration for future studies.

Secondly, not providing training (or practice time) with the Rotr 1 may have influenced the use of the device for few subjects. Familiarity with the device is important for proper and precise activation of muscles in rehabilitation applications. However, influence of familiarity and effects of training was not the purpose of this study and could be a potential consideration for future studies. A future study including training will have to account for learning effects and uniform degree of learning amongst the subjects. Our research questions were to address muscle activation with an unfamiliar device to avoid any biases and influences of training. A revised testing strategy could include a familiarization period with the device before the trial begins. This time would allow each subject to play around with, practice the use, and familiarize themselves with the device and the administration of the jerk provided in each trial. The subject would learn the proper muscular activation necessary to properly use the device and provide the most accurate results. However, providing a familiarization period with the device comes with its drawbacks and would need to be investigated in future studies.

Future Directions

The future direction of this study will explore the Rotr 1's ability as a rehabilitation tool, in dynamic situations, and for other sports/overhead activities. To assess the Rotr 1's ability as a rehabilitation tool, subjects with previous shoulder injuries or surgeries should be included in the study. Using the Rotr 1 as a rehabilitation tool was not the purpose of this study and it is important to assess the safety of the Rotr 1 while being used by a subject recovering from injury. Another possible future study could include dynamic EMG to assess the abilities of the device during shoulder movement such as a throwing motion. Dynamic EMG is an advanced technique that requires specialized equipment to study EMG

during motion and could allow for deeper muscles (e.g. rotator cuff muscles) to be studied. Studying the effectiveness of the device during dynamic motion, however, would assess the Rotr 1's capabilities during a sport specific movement (such as the pitching motion). Additionally, athletes from other overhead sports (e.g. waterpolo, volleyball, etc.), as well as, professionals that perform overhead activities (eg. painters, carpenters, etc.) could be studied to assess the device's effectiveness for all overhead applications.

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APPENDIX A: Supplemental Figures

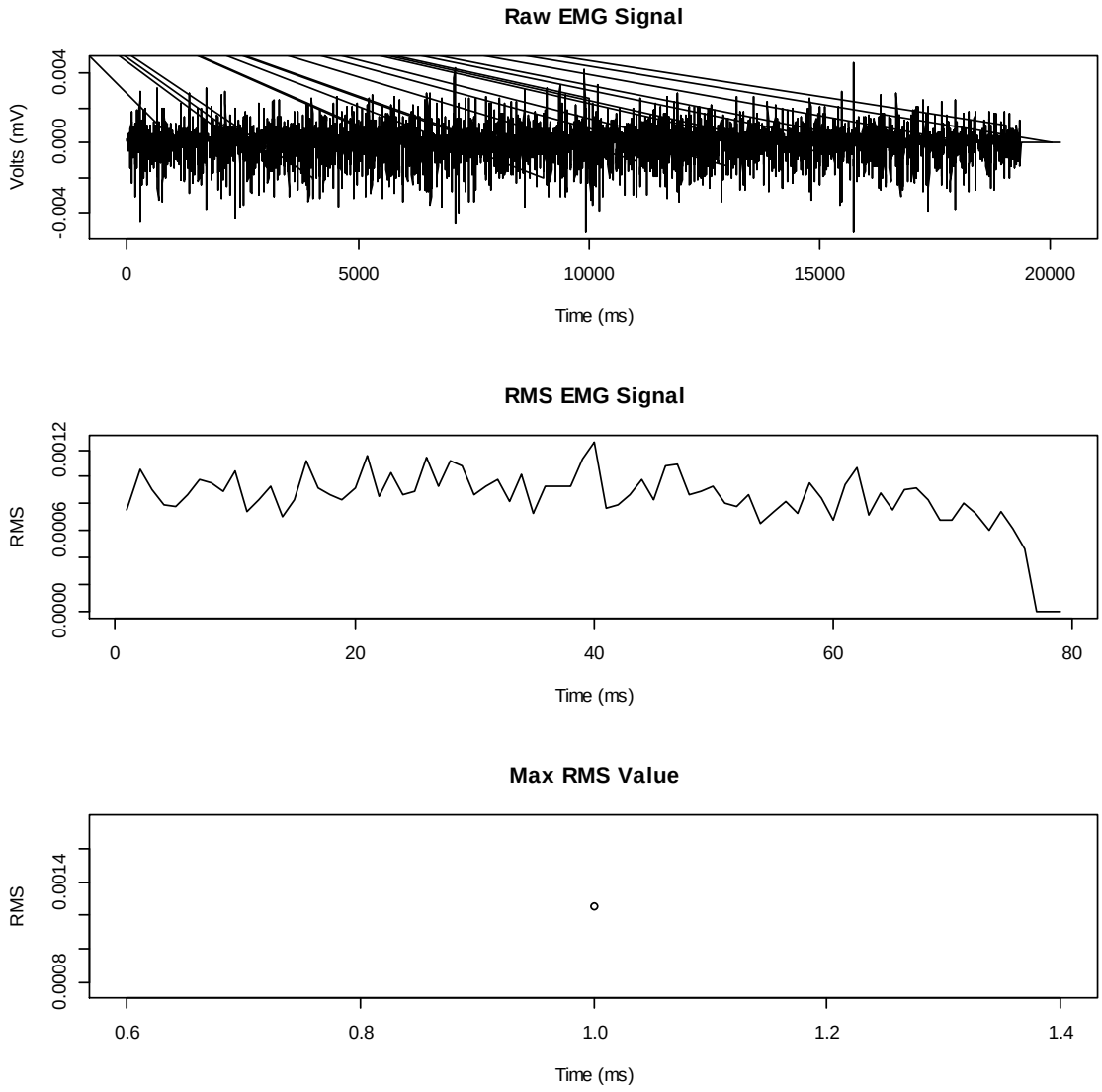
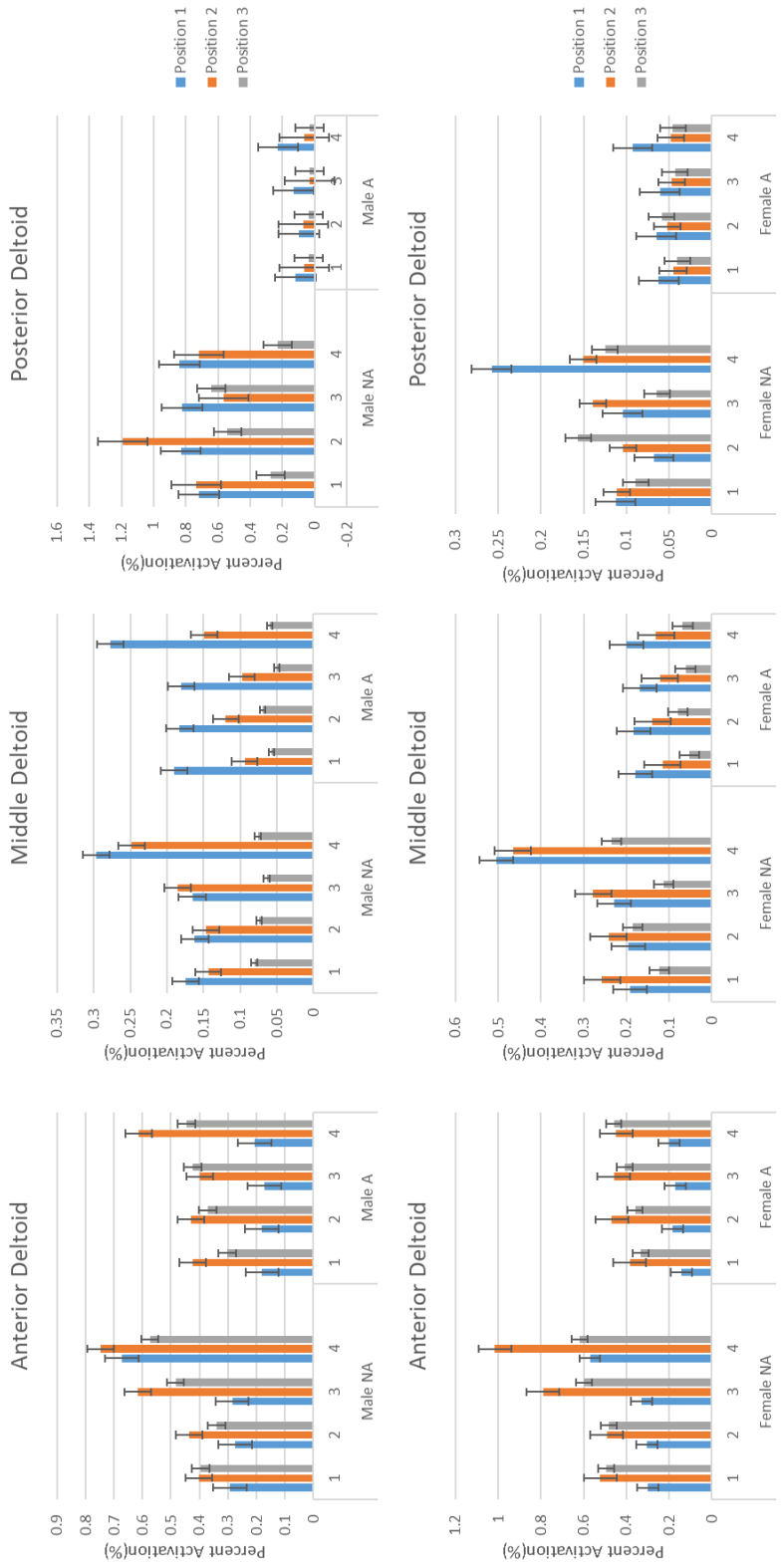


Figure 10. Sample of the raw processing progression. "Raw EMG Signal" graph shows a sample of the raw signal collected using the Delsys EMG system. This signal was full wave rectified (absolute value of all values taken) then the RMS values were calculated, shown in "RMS EMG Signal". Finally the max RMS value was extracted to be used for normalization and further calculations, shown as a single point "Max RMS Value".


Position 1
Position 2
Position 3
Posterior Deltoid
Middle Deltoid
Anterior Deltoid
Percent Activation(%)
Male NA
Male A
Female NA
Female A

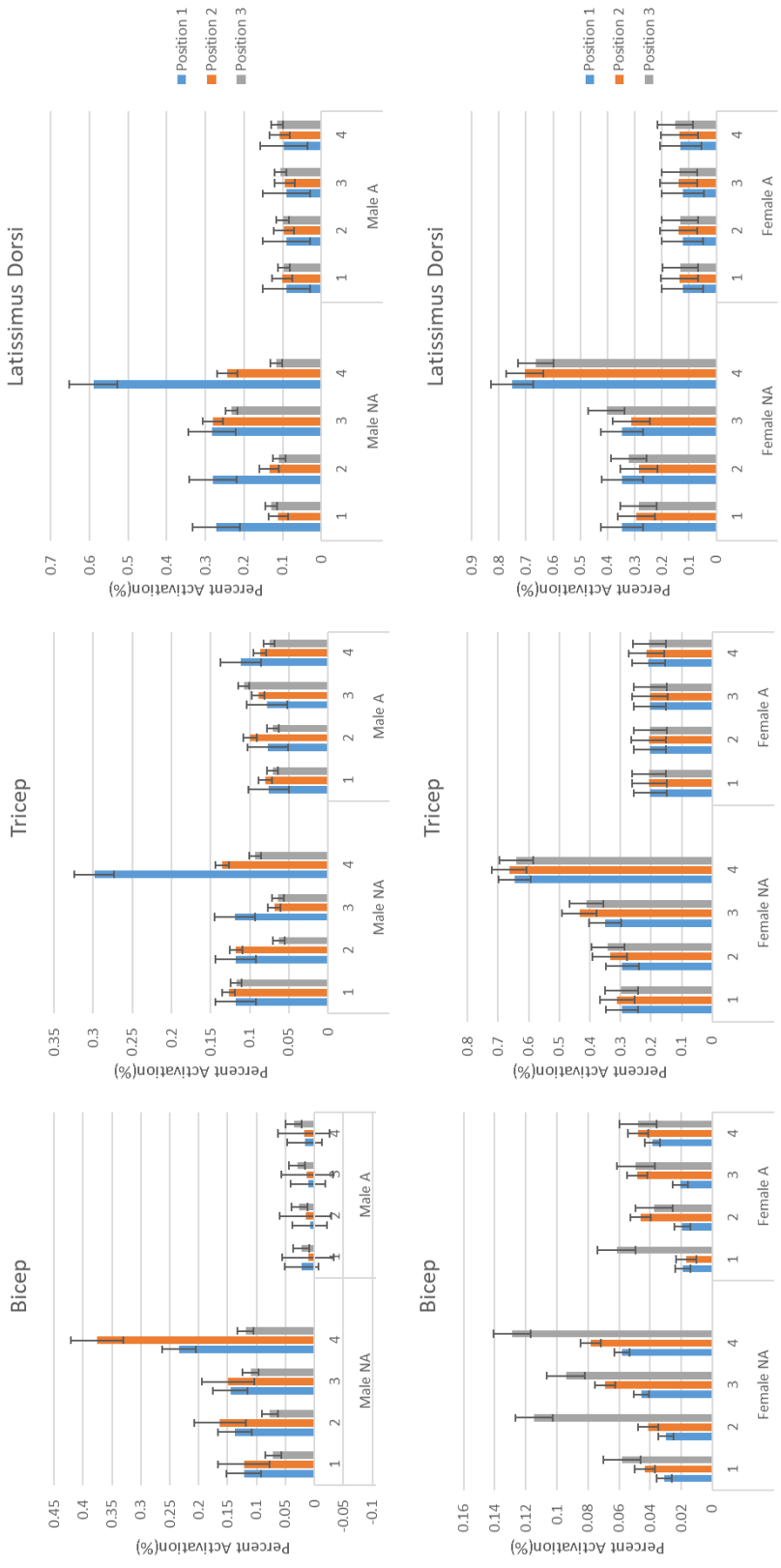


Figure 11. Comparison of male/female athletes/non-athletes for all muscles, positions, and configurations. Six of the seven muscles tested showed that athletes had overall lower percent activation than athletes.

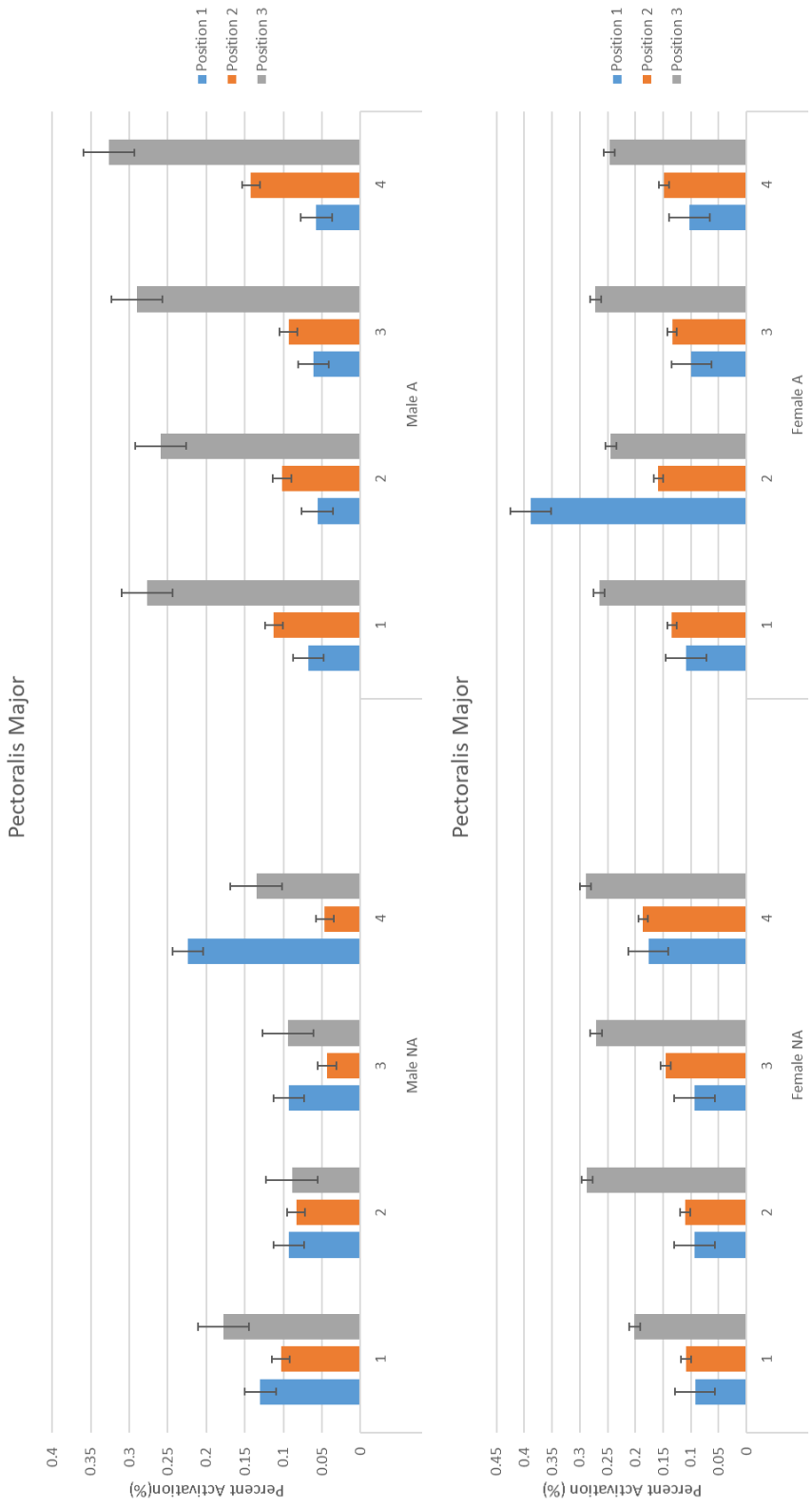


Figure 12. Comparison of male/female athletes/non-athletes for the pectoralis major only. The pectoralis major was the only muscle tested that showed athletes having a greater percent activation than non-athletes.

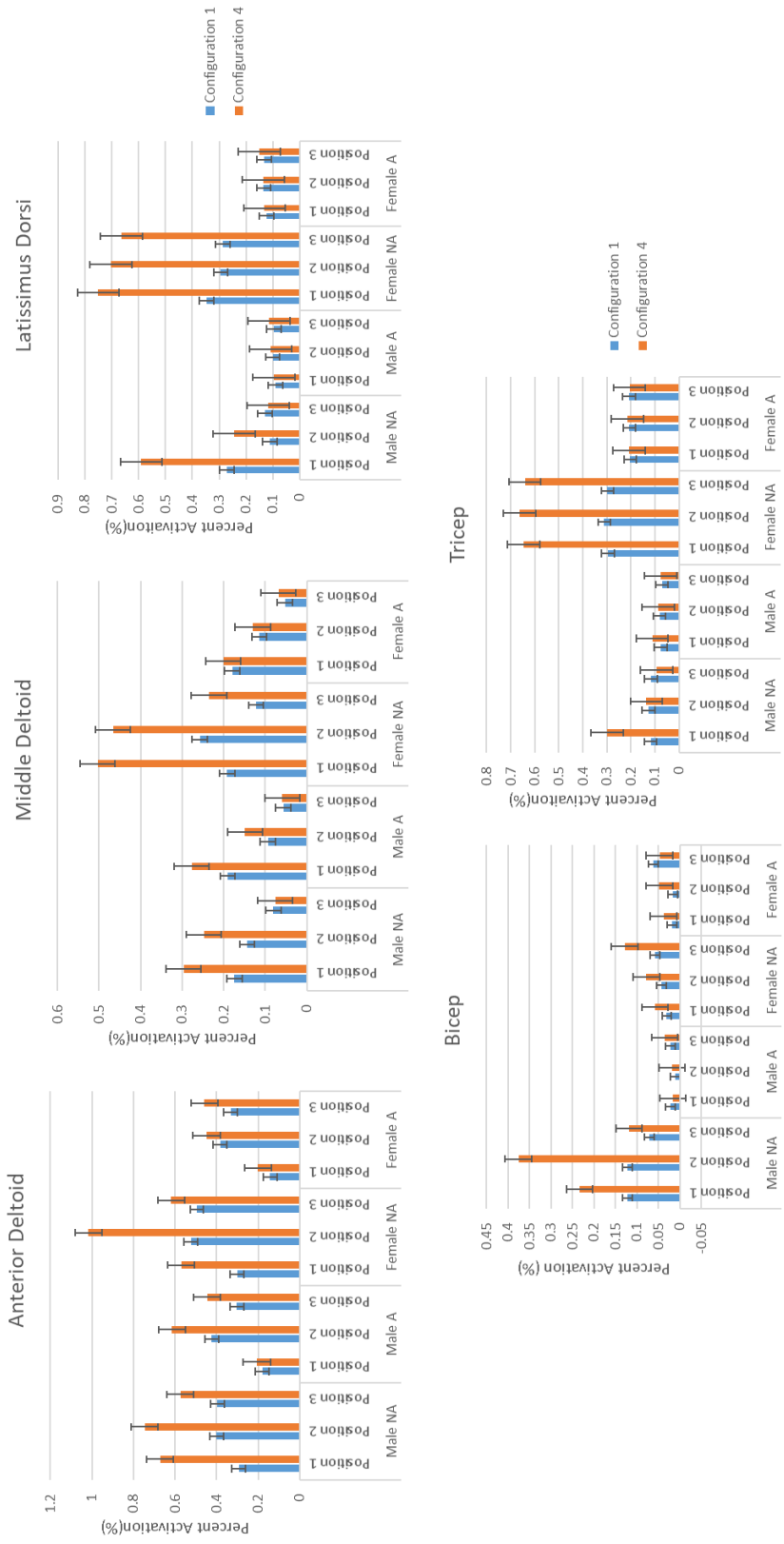


Figure 13. Comparison of configuration 1 and 4 for male/female athletes/non-athletes for all positions. A trend of increasing percent activation between configuration 1 (control) and configuration 4 (resisting against the device) is seen for all subjects.

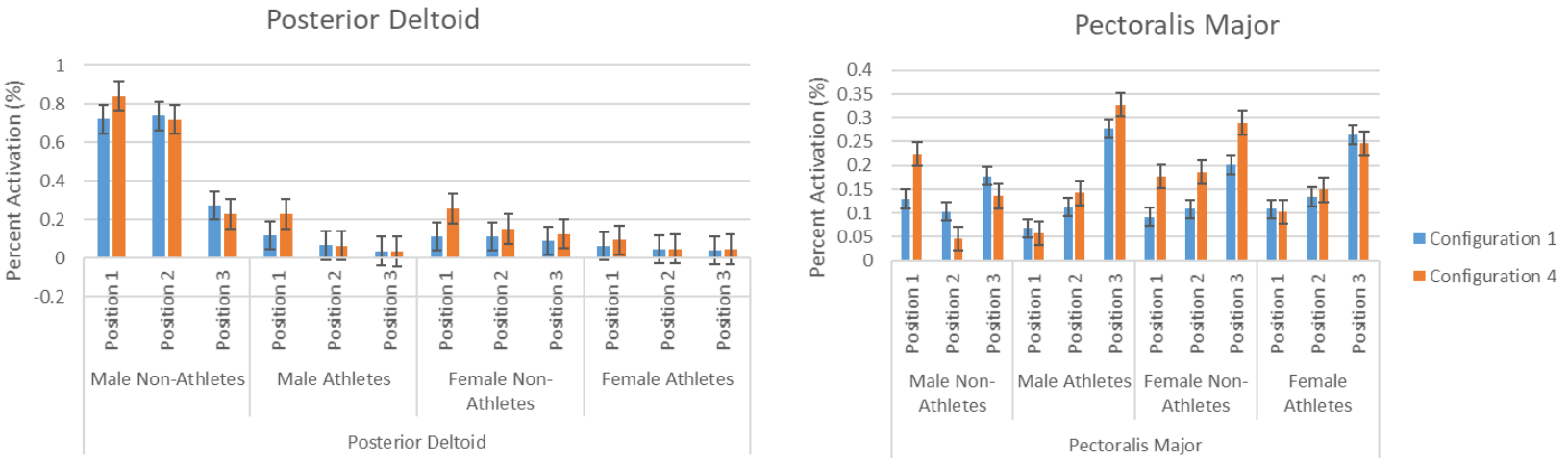


Figure 14. Comparison of the posterior deltoid and pectoralis major muscles between configuration 1 and 4. These two muscles showed an inconsistent trend in percent activation that doesn't follow the trend of increasing percent activation seen in the other five muscles.

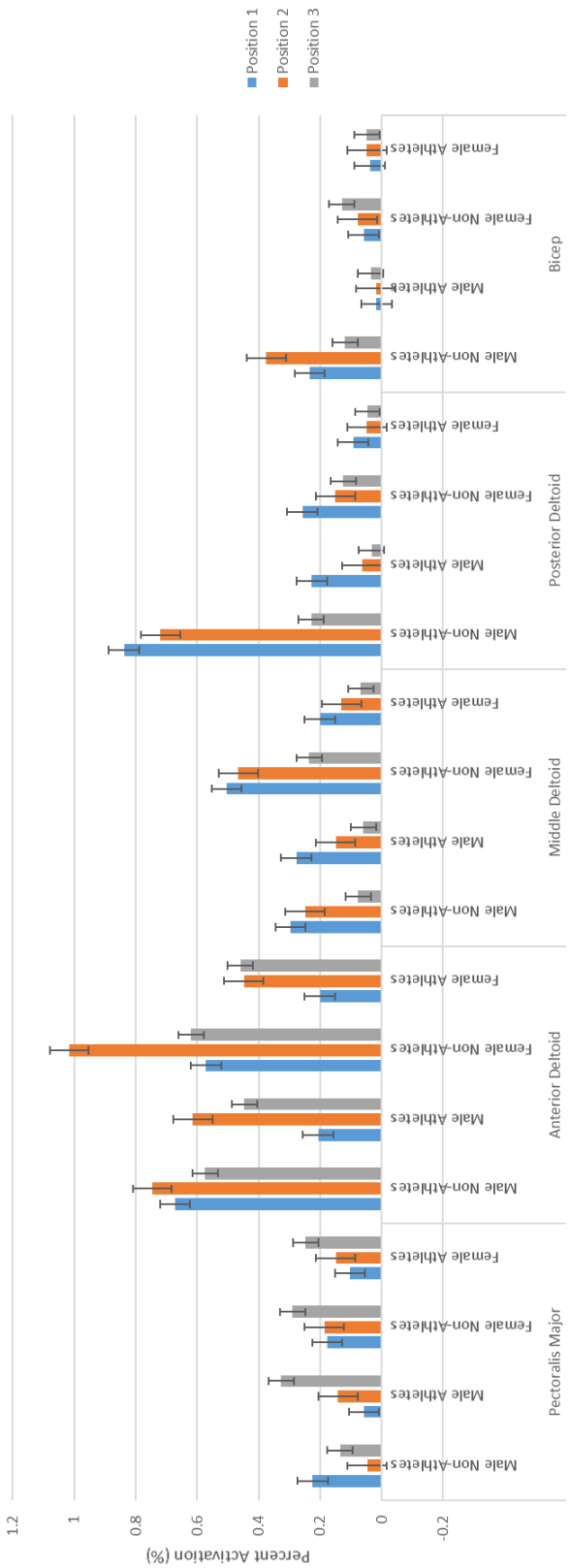


Figure 15. Comparison of configuration 4 for all positions, five muscles, and male/female athletes non-athletes. An approximate 20% difference in activation was present for these muscles between positions.

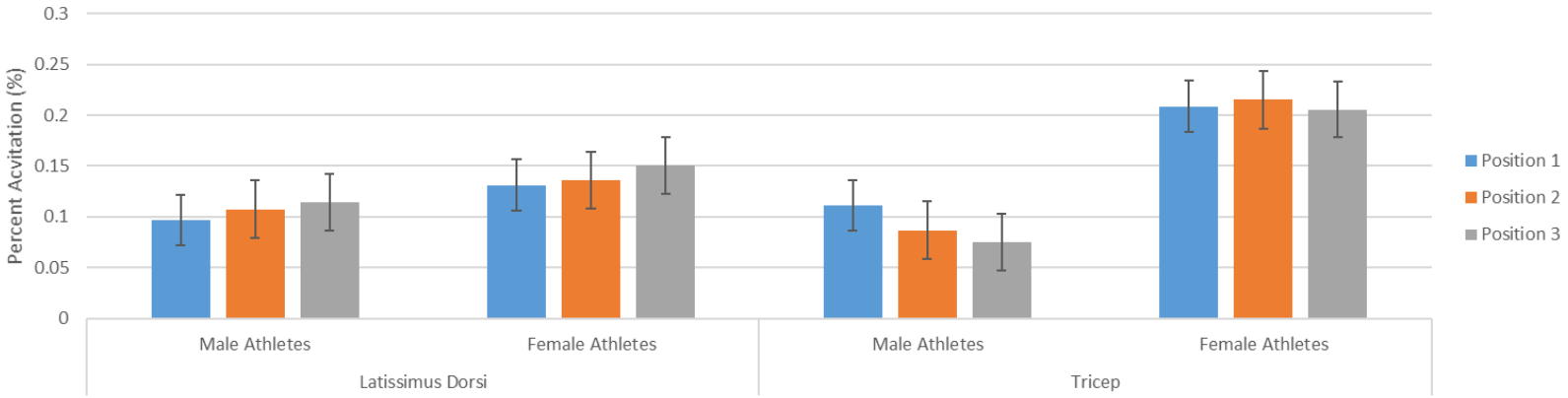


Figure 16. The male/female athletes' latissimus dorsi and tricep did not show the same trend of 20% difference between positions. Though a change in activation is present for these muscles, it isn't similar to the other muscles tested.

Appendix B: IRB Submission

IRB application checklist: For Investigators and Unit Reviewers

☒ Human subject research training is required for all personnel involved in data collection and analysis on this protocol. Training is also required for student advisors and unit reviewers. Training is required every three years. Go to CITI's online course to fulfill this requirement.

☒Complete the application thoroughly, all pages must be completed

- **Interviews conducted with audio recordings will be expedited #6 "Voice, video, digital or any imaging recordings made for research purposes…"**
- Explain your research as you would to a peer who is not an expert in your field, avoid jargon and acronyms.
- Information must be on the application itself and your research must be understood without the supplemental attachments, do **not** rely on a methodology section being attached

☒When assessing Benefits, risks, costs: *"Minimal" risk applies when "the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*

- All research will have at least "minimal" **loss of confidentiality** risks
  - "as in any type of research when recording data, loss of confidentiality is a minimal risk"
  - This risk is n/a ONLY if you are sending anonymous surveys in a non-public setting with non-sensitive questions that can not be identified with the subjects
  - Is confidentiality being maintained appropriately?
- **psychological** risk may have "minimal" risk during interviews/surveys due to anxiety of being interviewed/surveyed
  - Some surveys may be "minimal" due to the nature of the questions
- **Sociological** risks may be "minimal" if subjects names are used or if interview/survey involves questions related to their profession
- **Economic** risks may be at least "minimal" if travel is asked of subjects and other monetary costs

➢ **It is good practice to prepare for the worst when evaluating the risks in your research. This ensures you, the researcher, and Pacific have complied with federal regulations by disclosing all risks to your subjects.**

☒Obtain all signatures

- a Unit Reviewer is required. This must be a Chair, Dean or IRB member in your department.
- Advisors signature is required if the student is conducting research

☒ Informed Consent form is required (except Exempt #4)

- Use template attached *and fully discloses the same risks and descriptions listed in the application.*
- Use 6th grade language

Questions: email Office of Research and Sponsored Programs at osp@pacific.edu or call 209-946-7716

Protocol Review Number: _____
(Assigned by IRB)

University of the Pacific
Institutional Review Board
Human Subjects Activity Review Form

I. Project Information	
Investigator Name:	Bradley Hirayama
E-Mail Address:	b_hirayama@u.pacific.edu
College/School:	School of Engineering and Computer Science
Department:	Mechanical Engineering
If Student, Name of Advisor:	Dr. Preeti Oza
Advisor Dept:	Physical Therapy
Advisor email:	poza@pacific.edu
Other Thesis/Dissertation Committee Members:	Dr. Shadi Othman, Dr. Shelly Gulati
If Student, Expected Graduation Date:	May 2018
List all other personnel involved in the data collection/analysis:	Jamie Narciso
Project Title:	Utilizing Mechanically Induced Perturbation for the Study of the Shoulder Muscles with the Application to Overhead Throwing Sports.
Date CITI training completed (include certificate for all personnel involved in the data collection/analysis)	11/14/2016 – Brad 3/18/2017 - Jamie
Review category & number: See pg. 24 in the IRB Manual **(If exempt, attach required cover memo)** If your research involves pre-existing data, please complete the Existing Data Research Review Form only.	Expedited Review
When do you plan to begin this study* (date/year?) *This date should NOT be earlier than your submission date and should allow time for IRB review.	7/2017
What is the expected duration of the study?	One Year
Has this project been reviewed by any other IRB? If yes, stop completing this application and contact the IRB administrator to determine whether a Cooperative Agreement can be entered.	N/A

II. Project Support	
☐ Funded ☒ Unfunded	If funded, list source:
Does any conflict of interest exist between the funding source and the investigator? ☐ Yes ☒ No (refer to Conflict of Interest Policy)	If yes, describe:

Investigator Status (Check one)
☒ Student ☐ Faculty ☐ Administrator ☐ Other_____

Investigator Signature and Certification: In submitting this proposed project and signing below, I certify that:

1) I have read and understand the Investigator's Manual on Research with Human Subjects;
2) I will conduct the research involving human subjects as presented in the protocol and approved by the unit, faculty supervisor (if a student project), and IRB;
3) I will present any proposed modifications in the research to the IRB for review prior to implementation;
4) All conflicts of interest between myself and any funding agencies have been resolved to the satisfaction of the University of the Pacific Office of Sponsored Programs, and,
5) I will report to the IRB any problems or injuries to subjects.

Date: 4/20/17

Faculty Supervisor Review (if researcher is a student): My signature verifies that:

1) I will supervise this student's research project, and
2) The research complies with federal and University policies regarding protection of human subjects

Ap Date: 04/20/2017

Unit Review: The signature below verifies that the project:

1) Has been reviewed by the unit, and
2) Complies with federal and University regulations for research with human subjects.

Approval:_____ Date:_____

Name:_____

Unit reviewer may be: department chair, college dean, or a member of the Institution al Review Board within the researcher's department. Human Subject Research training is required for all unit reviewers.

Revised February 2016

INVESTIGATOR: Please provide answers to all of the following questions (attach additional pages as needed).

Applications must be signed, scanned as PDF documents, and submitted by e-mail to the IRB Administrator in Research and Sponsored Programs at osp@pacific.edu.

II. Purpose and Objectives of the Research

The purpose is to assess the effectiveness of a device, that provides mechanically induced perturbation, to activate shoulder muscles and increase co-contraction of shoulder muscles in athletes and non-athletes.

Specific aim 1: To assess the amplitude and frequency of Electromyography (EMG) signals of the shoulder muscles with and without the device in athletes and non-athletes.

Hypothesis 1: The amplitude and frequency of the EMG signals will increase with the device as compared to without the device, due to the increased muscle contraction of the shoulder muscles to hold the device; which is an increased weight in the hand.

Specific aim 2: To assess the amplitude and frequency of EMG signals of the shoulder muscles with and without mechanically induced perturbation provided by the device.

Hypothesis 2: The amplitude and frequency of the EMG signals will increase with mechanically induced perturbations as compared to without due to the increased muscle contraction induced by the movement of the device.

Specific aim 3: To assess the amplitude and frequency of EMG signals of the shoulder muscles with and without voluntary muscles contraction to control the shoulder movements, while mechanically induced perturbations are provided by the device.

Hypothesis 3: The amplitude and frequency of the EMG signals will increase with voluntary muscles contraction to control the shoulder movement as compared to without, due to the increased muscle contraction necessary to resist the perturbation provided by the device.

III. Contribution to, or development of, generalizable knowledge

The shoulder joint sacrifices stability for extreme rotational and multi-directional translation degrees of freedom (Baheti & Jamati, 2016). The extreme mobility of the shoulder is controlled by the muscular structure supporting, stabilizing, and coordinating the co-contractions to ensure a

strong and precise motion. Shoulder instability is a prevalent problem in overhead throwing sports such as baseball. The instability of the shoulder could be cause by the inability for the body to properly coordinate the co-contraction of the muscles required for the throwing motion. This study will explore the possibility of increasing the body's ability to co-contract the muscles of the shoulder to decrease the likelihood of injury. The effectiveness of the device, to increase the co-contraction of the shoulder muscles, will be assessed. Once established that the device can effectively increase shoulder muscle co-contractions, optimal exercise protocols could be created for athletes to use. The data collected in this study can also be applied to other populations with chronic shoulder injuries, such as workers with consistent overhead activates. According to OSHA, injuries to the shoulder (joint, rotator cuff, etc.) is in the top 5 of most reported occupational injuries. Workers that suffer these types of injuries undergo months of physical therapy, pain, and even lose their job due to inability to continue working (OSHA, 2013). Though the effectiveness of the device won't be studied specifically for this application, the knowledge obtained can be used for these applications as well.

IV. Description of Subject Population(s)

A.) Who are the subject groups and how are they being recruited?	The two groups studied will be athletes that engage in overhead throwing activities at least 4 days a week and non-athletes that haven't played overhead throwing sports in at least two years.
B.) What is the maximum # of subjects you will enroll?	20
C.) Are you advertising for subjects? ☐ Yes ☒ No If yes, include a copy of the proposed advertisement.	
D.) What are the criteria for selection and/or exclusion of subjects? (See page 21 in IRB Manual.)	Inclusion: Group 1 will consist of athletes participating in sports at least 4 days a week. Group 2 will consist of non-athletes that haven't played an overhead throwing sport in the last 2 years. Both groups will be within the ages 15-25. Individuals chosen for this study will need to be able to follow instructions of the protocol in their native language. Exclusion: Subjects must not have shoulder injuries, tears, surgeries, or anything that will change the internal biomechanics of the shoulder. Subjects must

	not have an active injury to the shoulder being assessed or any other musculoskeletal issues that could affect the biomechanics of the shouler.
E.) If special populations are being used, please justify. (See page 49 in IRB Manual.)	N/A

V. Activities Involving Human Subjects

A.) Describe the activities involving each subject group described in V.A.) Include the expected amount of time subjects will be involved in each activity, and where the activities will be conducted. ATTACH methodology section of your grant proposal, dissertation or thesis.

Both subject groups will undergo the same methodology. The entire study and analysis will take place in the south campus computer science lab. Each subject will be asked to participate for no more than 1.5 hours on one single day. See attached methodology section for detailed description of project data collection.

B.) How will the data be collected? Check all that apply:

- ☐ Questionnaires (**submit a copy**)
- ☐ Interviews (**submit list of questions**)
- ☐ Observances (briefly describe below)

- ☐ Standardized tests (list names of tests, AND attach copy of each test)

☒ Other (describe)

EMG data will be collected by Delsys Trigno wireless EMG system. The EMG signals collected will be processed and the amplitude and frequency will be calculated.

VI. Data

A.) How will the data be recorded (notes, tapes, computer files, completed questionnaires or tests, etc.)?

Data will be recorded via a laptop computer that is password protected. No medical information will be collected for this study. Data will be saved on two computers- one is owned by the physical therapy department and the other by the computer science department.

B.) Will medical records or other patient data be accessed? Refer to the IRB Investigators Manual for the 18 identifiers listed in HIPAA regulations and a sample HIPAA Authorization

☐ Yes ☒ No

If yes, complete the HIPAA Privacy Rule Questionnaire and provide a copy of the HIPAA Authorization Form that will be used.

C.) Who will have access to the gathered data, and how will confidentiality be maintained *during* the study, *after* the study, and *in reporting* of results?

Primary investigator (myself), supervising advisor (Dr. Oza), research assistant (Jamie Narciso), and my thesis committee members will be the only individuals who will have access to the gathered data. Data and files will be stored in a password protected computer and all subject information will be stored in a separate file. Data will be saved on two password-protected computers- one is owned by the physical therapy department and the other by the computer science department. All data will be de-identified during and after the study. Only summary results will be reported such that no data/results can be linked to an individual.

D.) What are the plans for the data after completion of this study (publication/presentation), and *how* and *when* will the data be maintained or destroyed? Describe method(s) of destroying the data, including any audio or visual recordings.

Data will be compiled, analyzed and presented as part of my thesis. I will use this data to present the summarized results orally and through poster sessions at conferences. I plan to use this data to publish an article of the results of this project in the *Journal of Biomechanics*. All data will be kept in a password protected computer and all identifiers will be coded and only distinguishable to the primary investigator (myself).

VII. Benefits, Risks, Costs

A.) What are the potential benefits to humanity?

This study will increase the knowledge of co-contraction of the shoulder for overhead throwing athletes vs. non-athletes, which will enable establishment of training and rehabilitation protocols. The study will also contribute to the general knowledge base of biomechanics of the shoulder.

B.) What are the potential benefits to the subjects?

There are no immediate benefits and no loss to the subjects.

C.) What compensation, if any, will be offered to the subjects and how will payment be scheduled throughout the study?

None. Participation in the study is voluntary for every subject.

D.) Assessment and Description of Risks. See section VIII, in the IRB Manual for descriptions of risks.

1.) What risks to the subject are most likely to be encountered, and at what level?

Type of Risk	Not applicable to this study	Minimal	More than Minimal	Not Sure
Physical	☐	☒	☐	☐

Psychological (emotional, behavioral, etc. – including anxiety)	☒	☐	☐	☐
Sociological (embarrassment, loss of respect of others, labeling a subject in a way that will have negative consequences.)	☒	☐	☐	☐
Loss of confidentiality	☐	☒	☐	☐
Criminal or civil liability	☒	☐	☐	☐
Deception	☒	☐	☐	☐
Economic	☒	☐	☐	☐
Other (explain)		☐	☐	☐

2.) Describe all risks identified in D1. **Include this information in Informed Consent form also.**

Physical- Minimal physical risk is involved because the subject will be asked to hold a weighted device and perform some physical activation of the shoulder muscles, while holding the device. However, no muscle injury or physical exertion is expected while holding the device or during activation of the shoulder muscles. The device weighs only about 2 lbs, which is lighter and more durable than most exercise equipment. Additionally, rest will be provided to the subjects in between the different experimental protocols, so as to ensure less fatigue and fatigue-induced discomfort. No long-term effects/injuries are anticipated. The device, which will apply perturbations, will be checked for safety prior to use by every subject. Additionally, pilot assessments will be done before the start of this study to ensure safety and the experimental protocol.

Loss of confidentiality- Minimal risk for loss of confidentiality is possible, but I will only record deidentified data, save all data in a password protected computer and only allow approved people to view the data.

E.) What safeguards will you use to eliminate or minimize each of these risks? If subjects experience adverse reactions, how will they be managed?

There is minimal risk involved because subjects are asked to physically activate muscles. This study includes risk in the methodology (see attached methodology section) so no long-term risks are anticipated. The device, which will provide perturbation, will be checked thoroughly and used in pilot assessment to established safe use and handling. Subjects will have the option to stop the study at any time if they choose.

There is a minimal loss of confidentiality risk that will be mitigated by only recording deidentified data, which will be saved on two password protected computer and only approved personal will be allowed to view the data.

F.) What are the costs, if any, to the subjects (monetary, time, etc.)?

Time costs- Each subject will spend about one and a half hours to complete this study. However, this anticipated cost will be only for one day. All care will be taken to avoid unnecessary time cost for the subjects.

VIII. Other Compliance Issues

A.) If this project may be subject to other regulations, such as state or local laws protecting special populations, or the use of a new drug or device, please identify and discuss.

The new device, shown in appendix figure 5, was pilot tested to ensure safety. The device is designed to be non-invasive and the subject has the option to drop the device at any time during the study, if the subject desires to discontinue or in case of any discomfort. However, no discomfort is anticipated.

B.) If this project involves any of the following activities, requiring consideration by another committee, please check:

- ☐ Animal Use and Care
- ☐ Radiation Safety (including use of x-rays, microwaves)
- ☐ Biological Safety (including recombinant DNA, biohazards)
- ☐ Chemical Safety (including hazardous waste materials, chemical carcinogens, flammable, lab safety)

IX. Informed Consent

A.) How will the study be explained to the subjects, and by whom?

The study will be explained thoroughly to the subject prior to start by the primary investigator (myself) with the help the informed consent form and additional informational material like diagrams (if required). Informed consent forms will be signed in the presence of a witness. The subjects will have the option to discontinue the study at any time, if they so desire.

B.) Attach informed consent form(s) you will use in the study (refer to Section IX in the Manual).

C.) Indicate rationale for any special conditions relating to informed consent (e.g., request for approval to obtain oral consent or waiver of documentation).

N/A

INFORMED CONSENT

Utilizing Mechanically Induced Perturbation for the Study of the Shoulder Muscles with the Application to Overhead Throwing Sports.

My name is Brad Hirayama, and I am a masters student at the University of the Pacific, School of Engineering and Computer Science. You were selected as a possible participant in this study because of your participation/non-participation in an overhead throwing sport.

The purpose of this research is to assess the effectiveness of a ball- like device, which will periodically cause your hand to move. The resistance against this movement will cause the muscles of and around your shoulder to contract simultaneously. If you decide to participate, you will be asked to come to the south campus computer science lab and your height, weight, and age demographics will be verbally taken. Then, EMG electrodes (surface electrodes) will be placed around your shoulder joint on 8 different muscle locations (figure 1 in appendix). You will then be dressed in the proper motion capture suit and the markers will be placed on the suit (figure 2 in appendix). You will be positioned for data collection (seated, supine, or prone position) in the motion analysis lab. EMG signal during maximal muscle contraction of muscles of interest (trapezius, bicep, tricep, middle/anterior/posterior deltoid, pectoralis major, and latissimus dorsi) will be recorded during clinical manual muscle testing of the individual muscles. This testing method is routinely done by clinicians (therapists, doctors, athletic trainers, etc.) and is a non-invasive method, during which the subject holds a position for 10 seconds. The administrator will ask you to hold maximum muscle contraction for 10 seconds by applying appropriate force on the arm (explained further in the appendix). You will then be given 30 seconds to relax. You will then have your arm positioned in the full external position and data will be collected under 4 conditions (figure 4 in appendix). Each condition will have 3 trials, lasting 10 seconds each, and 30 seconds of rest given in-between trials. This process will be repeated with three different positions – full external rotation, middle range rotation, full internal rotation. Your participation in this study will last about one and a half hours on one single day.

There is minimal physical and loss of confidentiality risks involved for participation with this study. There is minimal risk involved because you are asked to physically activate muscles, which may cause some short duration muscle fatigue and fatigue induced discomfort. However, you will be holding the muscle contractions only for 10 seconds, so the chances for significant muscle fatigue or discomfort is less. **This study includes risk management in the methodology (see attached methodology section) so no long-term risks are anticipated.** The device, which will cause your arm to move, has been checked thoroughly and used in pilot assessment to establish its safe use and handling. You will

have the option to stop the study at any time if you choose. There is a minimal loss of confidentiality risk that will be lessened by only recording coded patient information and de-identified data during and after the study, which will be saved on two password protected computers and only approved personal will be allowed to view the data. Additionally, only summarized results of our study will be published/presented, so the results cannot be traced back to you or your participation in the study. There are some benefits to this research, particularly that this study will increase the knowledge of simultaneous contraction of the shoulder muscles for overhead throwing tasks in athletes vs. non-athletes. The study will also contribute to improved understanding of the biomechanics of the shoulder as applied to overhead activities in all populations.

If you have any questions about the research at any time, please call myself (Brad Hirayama) @ 808.342.0347 or email at bradhirayama@gmail.com or Dr. Oza, my faculty advisor @ 209.946.3903. If you have any questions about your rights as a participant in a research project please call the Research & Graduate Studies Office, University of the Pacific (209) 946-7716. In the event of a research-related injury, please contact your regular medical provider and bill through your normal insurance carrier, then contact the Office of Research & Graduate Studies.

Any information that is obtained in connection with this study and that is identifiable with you will remain confidential and will be disclosed only with your permission. Only de-identified data, which will be saved on two password protected computers, will be recorded to ensure your confidentiality. The data obtained will be maintained in a safe, locked location and will be destroyed after a period of three years after the study is completed. Only the primary investigator (myself), supervising advisor (Dr. Oza), research assisstant (Jamie Narciso), and my thesis committee members will have access to the gathered data.

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you are free to discontinue participation at any time with out penalty or loss of benefits to which you are otherwise entitled.

Your signature below indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled, that you will receive a copy of this form, and that you are not waiving any legal claims, rights or remedies. Jamie, my research assisstant, or Dr. Oza, my research advisor, will be applicable witness signatures for this form.

You will be offered a copy of this signed form to keep.

Signature Date

_____ _____

Witness Date

_____ _____

Appendix C: Plans for Publication of this Thesis Project

The physiological testing study of my thesis is being written for publication in the Journal of Biomechanics or a related journal. Work is ongoing (as of 4/25/18). I am currently revisiting the draft for publication in consultation with my thesis committee member Dr. Preeti Oza, PT, PhD.

Appendix D: Patent Information

Provisional patent number 62662862. Active October 2017 – October 2018.