SPECIFIC AIMS

Appropriate workplace design for occupational tasks is critical to maximizing productivity and minimizing work-related musculoskeletal disorders. Push-pull tasks, in particular, are significantly related to shoulder complaints [1]. In order to effectively design workplaces for these tasks, knowledge of the demands placed on muscles and joints is needed. While much is known on mechanical loading of the low back during push-pull tasks, less is known regarding shoulder loading [2]. Recent studies have attempted to fill these gaps [3,4]; however, these studies focused on full-body cart pushing and isometric tasks. Loading under these conditions cannot be applied directly to dynamic tasks such as opening and closing hatches since electromyogram (EMG) and force exertion under dynamic conditions can be much different from those recorded isometrically [5,6], and foot placement influences pushing force [7]. Therefore, the objectives of this research are 1) to quantify mechanical loading of muscle and joints during dynamic push-pull tasks, and 2) to evaluate how a previous rotator cuff tear alters muscle loading during these tasks. These objectives will be accomplished through the following specific aims:

Specific Aim 1: Determine the effect of task direction and task target on muscle demand during dynamic unimanual and bimanual push-pull tasks.

Rationale: Task target has been shown to influence muscle demand during lifting [8] and isometric push-pull tasks [3]. Knowledge of muscle loading under dynamic push-pull tasks is needed to enable appropriate workstation design for these tasks. Methods: We will collect EMG data of healthy young subjects performing unimanual and bimanual dynamic push-pull tasks in the sagittal and horizontal plane. Hypothesis 1: (i) Superior and lateral task locations will increase muscle demand. (ii) Task type will influence muscle demand.

Specific Aim 2: Evaluate how task direction and task target during dynamic unimanual and bimanual push-pull tasks influences joint reaction loads.

Rationale: Dynamic cart pushing results in larger translational forces than compressive forces at the glenohumeral joint [4]. Dynamic isolated upper extremity push-pull tasks may also destabilize the glenohumeral joint and thereby increase the risk of shoulder musculoskeletal disorder with cumulative exposure. Methods: Subject specific models will be developed by scaling a previously developed and validated upper extremity model [9] to the anthropometry and strength of participants. We will extend the computed muscle control (CMC) algorithm [41] to incorporate EMG data and better account for joint reaction forces [12,53]. Resulting output from these EMG-driven CMC simulations will be used to calculate joint reaction forces acting at the glenohumeral joint for each scaled model. Hypothesis 2: (i) Task target will influence the ratio of translational to compressive forces acting at the shoulder. (ii) Pushing will result in larger ratios of translational to compressive forces than pulling.

Specific Aim 3: Investigate whether a single rotator cuff tear results in increased rotator cuff tendon forces on the unimpaired limb during bimanual push-pull tasks.

Rationale: Asymptomatic rotator cuff tears are twice as common as symptomatic tears in the general population [10], and a single rotator cuff tear is linked with increased risk for a contralateral tear [11]. Working with an asymptomatic rotator cuff tear may result in increased rotator cuff tendon force in the unimpaired limb during bimanual tasks and contribute to this increased risk. Methods: Bimanual healthy models will be created by mirroring the unilateral models and scaling to the strength and anthropometry of participants. From the healthy models, a rotator cuff patient model set will be created by removing the supraspinatus to simulate the tear. Computed muscle control simulations will be performed with both model sets for all the bimanual tasks, and resulting rotator cuff tendon forces in the unimpaired limb will be compared with the matched limb of the healthy control. Hypothesis 3: (i) A tear will result in increased rotator cuff tendon forces in the unimpaired limb to complete the task. (ii) More demanding tasks will result in increased compensation in the unimpaired limb.
RESEARCH STRATEGY

Significance:

Work-related musculoskeletal disorders place a large burden on the economy and workers’ health with musculoskeletal disorders being the leading cause of work disability and lost productivity [13]. Physically demanding occupations such as military service members have a high occurrence of musculoskeletal disorders, with active duty non-deployed service members having an injury rate of 62.8% [55]. Annual direct costs of musculoskeletal disorders in the private sector have been estimated at $215 billion [13], and even conservative estimates of this cost range between $45 and $54 billion [14]. Shoulder injuries, in particular, are taxing on worker health and the economy. A study of worker compensation claims found that 30.6% of claims involving the shoulder resulted in over seven days of lost work and that shoulder claims resulted in the second highest total cost behind lumbar spine claims [15].

While ergonomics research has identified push-pull tasks to be significantly related to shoulder complaints [1], little is known regarding biomechanical demands placed on shoulder muscles and joints as a result of these exertions [2]. The existing literature typically focuses on loading during full-body cart pushing [4,16,17] or strength capacity [18,19]. Since most modern industrial workspaces are typically characterized by predominantly light repetitive work [21], there is a need to quantify biomechanical demands during submaximal exertions as well. In an effort to characterize such tasks, McDonald et al. [3] evaluated EMG signals from submaximal isometric push-pull tasks within the reachable workspace. Isometric tasks, however, only represent a subset of push-pull exertions, and this work may not be directly applicable to dynamic tasks such as the opening or closing of hatches since EMG and force exertion under dynamic conditions frequently differ [5,6]. The proposed research will fill this gap and enable appropriate workspace design for such tasks by quantifying muscle demand and joint loading during dynamic submaximal push-pull exertions.

Workspace design for push-pull tasks must consider both muscle demand and joint loading, to ensure worker safety and increase productivity. The proposed work will quantify how muscle demand, a measure of the overall load placed on the muscular system, varies with both task direction and task target. Muscle demand is influenced by task target during lifting [8] and isometric push-pull tasks [3], and by task direction during isometric tasks [3,32,50]. By quantifying how muscle demand varies with task direction and target location, workspaces can be design to reduce fatigue and associated risk of overuse [51]. The proposed research will also expand knowledge of joint loading to prevent workspace designs that require motions resulting in joint instability. Previous research has shown that glenohumeral instability is a concern when pushing during postural stability [24] and cart pushing [4] tasks. Preventive measures developed as a result of this research will reduce the risk of shoulder musculoskeletal injuries and lower the associated economic burden.

To further understand risk factors of shoulder musculoskeletal disorders, the proposed work will examine conditions associated with bilateral rotator cuff tears by considering how a single rotator cuff injury affects contralateral tendon loading. A single rotator cuff tear is linked with increased risk for a contralateral tear [11] and asymptomatic rotator cuff tears are twice as common as symptomatic tears in the general population [10]. Working with an asymptomatic rotator cuff tear may result in increased rotator cuff tendon force in the unimpaired limb during bimanual tasks and contribute to this increased risk.

Innovation:

This proposed work incorporates both methodological and scientific innovations:

1) **Development of a testing protocol to analyze dynamic push-pull tasks across the reachable workspace in a consistent manner.** Dynamics tasks are typically unconstrained, resulting in variable kinematics [33,44,48]. This variability introduces potential confounding factors into analysis of task and task target. This work proposes constraining the direction of exertion during pushing and pulling via a custom linear track attachment for a pulley resistance system to reduce variability between participants and trials. The custom device will allow analysis of dynamic push-pull exertions throughout the reachable workspace with minimal variability in the direction of the exertion. This reduction in variability will improve analysis of how muscle demand and joint loading are altered as a function of task target and exertion direction.

2) **Development of a strength scaling OpenSim plugin that uses experimental strength and EMG data.** Strength scaling by adjusting a muscle’s maximum isometric force is a common procedure in musculoskeletal modeling. Estimates of maximal isometric muscle force are typically derived from experimental measures of muscle volume and specific tension [37,44]. The high cost and processing
time associated with experimental measures of muscle volume from MRI data make this procedure
infeasible for most simulation studies. Thus, strength scaling of all or at least some of the muscles in a
model is often performed to match population means reported in the literature [37,44,52].

Previous work has shown that strength scaling can be performed successfully through
optimization techniques [8]. In this proposed work, we plan on expanding upon this previously developed
technique, developing a standard protocol for collecting strength scaling data, and creating a strength
scaling plugin for OpenSim [34], an open source musculoskeletal modeling program. By disseminating
this protocol and strength scaling plugin, future studies will be able to easily scale their musculoskeletal
models resulting in more realistic calculations of muscle forces.

3) **Develop an EMG-driven computed muscle control plugin for OpenSim.** The human body is a highly
redundant system with both postural and actuator redundancy. Due to actuator redundancy, muscle
activations for a motion are often calculated through an optimization. One common optimization method
is computed muscle control [41] which uses static optimization and forward integration to calculate
muscle activations that allow the model to optimally track the measured joint postures. In this proposed
work, we will expand upon the CMC method to enable incorporation of experimental EMG data. By adding
a penalty function to the static optimization of CMC, simulation outputs will be forced to track experimental
excitation data, resulting in more realistic simulation outputs. We will develop a plugin for this expansion
of the CMC algorithm and disseminate it to the open source community.

4) **Analyze how compensation for a unilateral injury affects tendon forces in the unimpaired limb.** A
single rotator cuff injury increases the risk of having a contralateral tear [11]; however, no study has
analyzed how compensation for a unilateral injury affects loading on the unimpaired limb. Unilateral injury
compensation during bimanual task likely alters the distribution of loading and thereby increases the risk
of injury for the unimpaired limb. This proposed work includes novel simulations to investigate whether
this reasoning is true. The simulations will include simulating a rotator cuff tear and analyzing the effects
of the injury on the tendon forces in the unimpaired limb during bimanual tasks. This work can provide a
basis for future studies evaluating how unilateral injury affects loading on the contralateral limb.

**Approach**

**Specific Aim 1:** Determine the effect of task direction and task target on muscle demand during dynamic
unimanual and bimanual push-pull tasks.

**Rationale:** Task target has been shown to influence muscle demand during lifting [8] and isometric push-pull
tasks [3]. Knowledge of muscle loading under dynamic push-pull tasks is needed to enable appropriate
workstation design for these tasks.

**Subject population**
A series of one- and two-handed push-pull tasks across the reachable workspace will be performed by 20
healthy young adults between the ages of 19 to 40 years (10M/10F). The participants will be recruited from the
local community using the following inclusion criteria: 1) no history of injury or pathology of the upper limb, 2) no
neuromuscular impairments, and 3) have no physical impediments to performing the required physical exertions.
Participants will be screened for shoulder pain and weakness by administering a modified Jobe’s test, a manual
clinical test for assessing the presence of a rotator cuff tear with 81% sensitivity and 89% specificity [46]. The
participant’s dominant hand will be used for unimanual tasks, and hand dominance will be determined by the
Edinburgh questionnaire [47]. Prior to testing, anthropometric measurements will be taken for each participant
for model scaling purposes.

**Instrumentation**
Bilateral electromyographic recordings of the anterior, middle, and posterior deltoid, biceps brachii, lateral head
of triceps brachii, latissimus dorsi, pectoralis major, and serratus anterior will be collected during maximum
voluntary contractions (MVC) and the testing protocol. Recording will be made at 1000Hz using 1-cm surface
electrodes with 16-channel capacity (Noraxon MyoMuscle, Noraxon, Scottsdale, AZ). The skin overlying the
location of markers will be shaved and cleaned with alcohol prior to electrode placement. Prior to testing,
participants will perform three sets of MVC for each muscle recorded to be used in the subsequent normalization
process. Raw EMG data will be filtered with a 39th order Hamming-window linear high-pass filter (0.2Hz cutoff
frequency) to remove any offset, rectified, and normalized to the recorded MVC for each muscle [9].
Kinematic data will be collected during the testing protocol, but will be used exclusively in aims 2 and 3. Kinematics will be recorded at 200 Hz using 11 Hawk and Kestrel cameras (Motion Analysis Corporation, Santa Rosa, CA) tracking 1 cm retroreflective markers placed on anatomical landmarks. Marker locations will be extended from a unilateral protocol (Figure 1) [33] to a 22-marker bilateral set. Prior to the testing protocol, a static trial in which all markers are visible to the cameras will be performed for scaling purposes. Data will be post-processed and smoothed with a 6 Hz Butterworth filter (Cortex, Motion Analysis Corporation, Santa Rosa, CA).

Figure 1. Marker locations in the standard unilateral protocol [33] will be extended to a bilateral set by mirroring all markers.

**Maximum voluntary contractions (MVC)**

In order to appropriately scale musculoskeletal models for aims 2 and 3, maximum isometric joint moments for both limbs will be evaluated at the shoulder and elbow using a dynamometer (Biodex System4 QuickSet, Biodex, Shirley, NY), following a previously described standard protocol [25,26,27]. Participants will be seated with their torso in a vertical posture and the hips flexed to 90°. The torso will be restrained using straps to prevent changes in posture during the trials. At the shoulder, maximum isometric abduction moment will be assessed with the shoulder abducted to 60° and the elbow braced in full extension. At the elbow, maximum isometric flexion moment will be assessed with the shoulder in neutral abduction and the elbow flexed to 90°. Three trials of each moment will be obtained, and participants will be provided with standardized verbal and visual feedback to encourage maximal voluntary contraction (MVC). To minimize the effects of fatigue, 60 seconds of rest will be provided in between trials. Data will be sampled at 100Hz, and a custom software program (Matlab, The Mathworks Inc., Natick, MA) will be used to determine the peak exertion sustained for at least 0.5 s.

Additionally, maximal isometric push-pull capacity with the arm in 90° forward flexion will be determined for each participant using a closed-chain attachment for the dynamometer, and these trials will be analyzed in a similar manner. Six trials using the dominant hand will be collected (three push/three pull). The maximal peak exertion achieved over these six trials will be used to determine loading for pushing and pulling tasks.

Studies of sustained isometric, continuous dynamic, and intermittent isometric contractions have reported fatigue thresholds ranging from 7-25% MVC [28,29,30], with intermittent contractions associated with higher thresholds. The testing protocol will allow for 30 seconds of rest between trials and 3 minutes of rest between tasks and, as a result, will be most similar to the intermittent contractions evaluated in the literature. Therefore, loading will be set at 15% MVC to avoid participants from fatiguing.

**Testing protocol**

Participant will perform tasks in a seated position (chair height: 0.53m) with their torso restrained by straps. Tasks will be performed on a custom pulley resistance system to reduce variability in the direction of applied force between participants and trials. The custom device (Figure 2) will include a linear track with variable height/angle attached to a resistance pulley system (Powertec Strength, Powertec Fitness, Long Beach, CA). For pulling, participants will hold the fixed-length handle in the dominant hand (unilateral tasks) or both hands (bilateral tasks) and pull towards the torso. They will begin with the hand away from the body along the desired trajectory at a distance of 80% of full limb length, and will pull until the humerus is in a neutral posture (Figure 3). Pushing tasks will be accomplished in a similar manner. Task speed will be standardized by means of a metronome.

Figure 2. Custom resistance system designed to control hand movement direction during trials.
To evaluate the effects of superior-inferior target position, tasks will be performed in the sagittal plane with forward flexion limb angles of 20°, 90°, 130°, and 170°. To evaluate the effects of medial-lateral target position, a second set of tasks will be performed in the horizontal plane with the shoulder elevated to 90°, with targets at 0° (abduction plane), 45°, 90° (sagittal plane), and 135° elevation plane as defined by the International Society of Biomechanics [31]. Limb angles will be confirmed with a hand-held goniometer. Participants will perform three repetitions of each task for a total of 84 exertions per participant. To prevent fatigue, participants will be provided with 30 seconds and 3 minutes of rest between each repetition and task respectively. The order of tasks will be randomized to avoid any ordering effects.

Data Analysis

**Muscle demand** for each task will be calculated as an average of each participant’s weighted total of EMG output normalized to peak EMG signal from the MVC trial for that muscle [32]. Physiological cross-sectional areas (PCSA) from the literature [12, 40, 49] will be used to determine weights for each muscle.

\[
\text{Muscle demand} = \frac{\sum_{i=1}^{8} \text{Norm}_{-}\text{EMG}_i \times \text{PCSA}_i}{\sum_{i=1}^{8} \text{PCSA}_i}
\]

Differences in muscle demand will be analyzed across two independent variables, task target and task type (unimanual push, unimanual pull, bimanual push, and bimanual pull) using a two-way repeated measure ANOVA and Tukey’s honest significant difference post-hoc test. Significance will be set at a p value of <0.05 and adjusted for multiple comparisons using a Holm sequential Bonferroni correction.

**Specific Aim 2:** Evaluate how task direction and task target during dynamic unimanual and bimanual push-pull tasks influence joint reaction loads.

**Rationale:** Dynamic cart pushing results in larger translational forces than compressive forces at the glenohumeral joint [4]. Dynamic isolated upper extremity push-pull tasks may also destabilize the glenohumeral joint and thereby increase the risk of shoulder musculoskeletal disorder with cumulative exposure.

**Modeling**

A previously developed and validated unilateral upper extremity musculoskeletal model [9] will be used for one-handed tasks; for two-handed tasks this model will be extended to a bimanual model by mirroring joint definitions, muscle paths, and muscle properties to the contralateral side. Both unimanual and bimanual models will be scaled to participants’ anthropometry using the static motion capture trials. The scaling algorithm will adjust the model’s anthropometry to match kinematic data of physical retroreflective markers to corresponding virtual markers on the model. The results of this scaling procedure will be validated against anthropometric measurements of participants’ limb length.

The standard OpenSim model represents the strength of a 50th percentile young male, and this base model will be scaled to participants’ strength using a genetic algorithm [36] with optimization parameters based reported in prior work [8]. This optimization will adjust the model’s maximum isometric force for each of the 50 muscles [8] by minimizing the difference between the recorded MVC moments and the model’s maximum isometric moments. The model’s muscles will be grouped by the joint of primary action, and the muscle groups rather than individual muscles will be scaled to preserve muscle volume distribution. To further preserve muscle volume...
distribution across joints, wrist muscles will be scaled using an average of the determined elbow and shoulder scale factors, since wrist strength will not be measured in this study.

$$\min \sum_{i=1}^{2} (\text{Model peak moment} - \text{MVC moment})^2$$

The strength scaling optimization will be performed individually on each arm of the bimanual model using isometric moments from the MVC trials. Scaled maximum isometric forces for the dominant hand of the bimanual model will be transferred to the unimanual model. Other muscle parameters including optimal fiber length will remain unchanged [37], and are based on previously measured values from anatomical and functional studies of the upper limb [9].

Strength-optimized models will be validated by performing a static optimization of the push-pull MVC trial using the optimized models and comparing calculated muscle activations with normalized EMG data. During the push-pull trial, the push-pull force will be applied as an external resistance to the hand. The static algorithm attempts to minimize metabolic cost, modeled as activation squared, such that the moments about a joint produced by muscles matches the joint moment determined through inverse dynamics.

$$\min \sum_{k=1}^{50} (a(t)_k)^2 \text{ subject to } \sum_{k=1}^{50} a(t)_k * f_{m_k} * r_{kj} = \tau(t)_j$$

where $$a(t)_k$$ is muscle activation for kth muscle, $$f_{m_k}$$ represents the activation scalable muscle force dependent on force-length-velocity surface for the kth muscle, $$r_{kj}$$ is the moment arm for the kth muscle about the jth joint, and $$\tau(t)_j$$ is the net-torque about the jth joint.

Simulations

Joint postures for the unimanual push-pull tasks will be extracted from marker locations using the anthropometrically scaled musculoskeletal model implemented in OpenSim (v3.2) [34]. The model contains three degrees of freedom (DOF) for the shoulder (elevation plane, shoulder elevation, axial rotation), one DOF for the elbow (flexion), one DOF for the forearm (pronation/supination), and 2 DOF for the wrist (flexion and deviation) as defined by the International Society of Biomechanics [31]. Scapular and clavicular orientations are specified by a regression equation that was simplified to depend solely on thoracohumeral angle [35]. Inverse kinematics will be performed on the kinematic marker data to match physical markers data with virtual markers on the model, using a least squares regression. Resulting joint kinematics will be filtered with a zero-phase filter in MATLAB (The Mathworks Inc., Natick, MA).

Net joint moments required to perform the specific joint kinematics will be determined using inverse dynamics for each unimanual push-pull task. The inverse dynamics algorithm uses model anthropometry, kinematics, and external forces to calculate the net joint torques. The push-pull load will be modeled as an external force on the model in the direction of the applied exertion.

Computed muscle control algorithm (CMC) [41] will be used to determine muscle activations for muscle actuators for which EMG was not recorded. CMC uses static optimization and forward integration to calculate muscle activations that allow the model to optimally track the measured joint postures. For these simulations, an external force in the direction of the task target will be added to the model to correspond with the resistance of the loads in the experimental tasks. For the bimanual tasks, this load will be modeled assuming symmetry and an equal external force that sums to the total resistance will be applied to each hand. The static optimization will be altered to incorporate recorded EMG signals and to meet a glenohumeral joint stability requirement [12,53]. To resolve muscle redundancy, CMC minimizes a cost function that is proportional to metabolic cost of the system [42,43]. A penalty function will be incorporated into the static optimization such that a penalty proportional to the difference between calculated muscle activations and EMG data is applied; thereby, forcing the simulation to track experimental data. A 5% tolerance will be placed on the EMG data to account for possible errors in calculating the normalized EMG.

$$C \sum_{i=1}^{7} (\text{Norm}_\text{EMG}_i - a(t)_i)^2$$

To prevent theoretical subluxation in the model, three additional constraints will be placed on the glenohumeral contact force [53]. These constraints are derived from empirical cadaver data describing directional glenohumeral joint dislocation force ratios along eight equally spaced compass directions [55]. During the optimization, the glenohumeral contact force will be calculated as a linear non-negative combination of values.
in each direction that do not exceed any directional dislocation ratio threshold, thereby, theoretically maintaining a non-dislocating joint. By preventing dislocation, more realistic muscle activations can be computed [12,53]. The constraint is repeated for each global direction and is of the form:

\[ J_{CF} = \sum_{i=1}^{8} c_i S_i \]

\( J_{CF} \) is joint contact force, \( c_i \) is the ratio coefficient in the \( i \)th glenoid orientation and \( S_i \) is the dislocation force ratio in the \( i \)th glenoid orientation.

**Data Analysis**

Joint reaction forces at the glenohumeral joint resulting from the calculated muscle activations will be calculated in the superior/inferior, anterior/posterior, and medial/lateral directions using the joint analysis tool in OpenSim. For each task, peak joint reaction force will be calculated and the ratio of translational to compressive forces will be calculated. The ratio of translation to compressive force will be analyzed across two independent variables, task target and task type (unimanual push, unimanual pull, bimanual push, and bimanual pull) using a two-way ANOVA and Tukey’s honest significant difference post-hoc test.

**Specific Aim 3:** Investigate whether a single rotator cuff tear results in increased rotator cuff tendon forces on the unimpaired limb during bimanual push-pull tasks.

**Rationale:** Asymptomatic rotator cuff tears are twice as common as symptomatic tears in the general population [10], and a single rotator cuff tear is linked with increased risk for a contralateral tear [11]. Working with an asymptomatic rotator cuff tear may result in increased rotator cuff tendon force in the unimpaired limb during bimanual tasks and contribute to this increased risk.

**Modeling**

The strength- and anthropometry-scaled bimanual models from aim 2 will be used as a set of healthy control models. The supraspinatus is the most commonly torn portion of the rotator cuff [54]; therefore, from these healthy models, a population of rotator cuff tear models will be created by removing the supraspinatus from the dominant arm [44,45].

**Simulations**

CMC simulations will be performed with the rotator cuff tear models to track the kinematics and joint moments from the healthy participants of aim 1. Constraining tear compensation to match the EMG from a healthy population would not be realistic; therefore, these simulations will not be EMG-driven. The CMC optimization, however, will include constraints on the glenohumeral joint contact force since preventing subluxation is still realistic. The muscle forces calculated in aim 2 for the bimanual models will be used for the control population.

**Data Analysis**

Tendon forces for the supraspinatus, infraspinatus, subscapularis, and teres minor in the non-dominant/uninjured arm will be calculated using the muscle analysis tool in OpenSim. Average tendon force for each population will be computed, and differences in tendon forces will be analyzed across the two subject groups using a one-way ANOVA and Tukey’s honest significant difference post-hoc test.

Task demand for each task will be determined from the weighted muscle demand for the bimanual tasks of aim 1. The effect of muscle demand on the ratio of tendon forces between rotator cuff models and controls will be analyzed using a one-way ANOVA.
Summary
This proposed work will 1) quantify mechanical loading of muscle and joints during dynamic push-pull tasks, and 2) evaluate how a previous rotator cuff tear alters muscle loading during these tasks. Push-pull tasks are significantly related to shoulder musculoskeletal complaints [1]; however, muscle and joint loading during dynamic submaximal tasks exertions such as opening and closing hatches are underrepresented in the literature. This work will fill these gaps and thereby enable the design of workspaces that minimize the risk of musculoskeletal disorder. This work forms a foundation for development of preventive measures, which can in turn help reduce the large economic burden caused by work-related musculoskeletal disorders.

Management and Timeline:
It is anticipated that this work will be accomplished in two and a half years, with the following proposed schedule

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<td>Subject recruitment</td>
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