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TITLE: Arthroscopic Versus Open Stabilization of Shoulder Instability with Subcortical Bone Loss

PRINCIPAL INVESTIGATOR: Adam J. Popchak

CONTRACTING ORGANIZATION: University of Pittsburgh

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14. ABSTRACT The objective of this project is to determine the optimal surgical procedure (arthroscopic Bankart with remplissage of Hills-Sachs lesion, open Bankart, Latarjet) and post-operative rehabilitation strategy, with identification of risk-factors for treatment of 400 military personnel and civilians between the ages of 17-50 with acute or recurrent anterior shoulder instability with subcritical bone loss. To date, we have received IRB and HRPO approval for 5 sites. There are 6 military and 4 civilian sites working through local IRB approval. Once they have IRB approval, they will be submitted to Pitt IRB Reliance for onboarding. One civilian site is onboarded to the University of Pittsburgh sIRB and is collecting documents to submit to the HRPO for approval. Research activities over the past year have included initiating recruitment at participating sites that are open to recruitment, randomizing participants, beginning follow up procedures, and monitoring. Significant attention has been placed on obtaining all regulatory approvals to activate participating sites for all military sites and recently added civilian locations. Creating and launching a central study website, continued performance of quarterly investigator meetings, monthly steering committee meetings, and monthly coordinator meetings. At this time, we are open for recruitment at 4 sites, with 1 pending within 3-4 weeks. Focus will continue to be on getting sites open to enrollment to achieve our recruitment goals.		

15. SUBJECT TERMS					
Acute, recurrent anterior shoulder instability, subcritical bone loss; optimal surgical procedure; post-operative rehabilitation; return to pre-injury activity level; military duty, work, and sports.					
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1. INTRODUCTION:

Military personnel are the most at-risk populations for shoulder instability and more than 80% of these individuals have recurrent instability with non-operative treatment. Traumatic and recurrent shoulder instability produces progressive bone loss to the osseous stabilizing structures of the glenoid and humerus. Loss of articular support predisposes the shoulder to recurrent instability, contributes to failure following surgical management, impairs physical performance, and prolongs limited duty/disability.

Glenoid bone loss in the subcritical range, defined as loss of the glenoid between 10% - 20% has been accepted as a contributing factor for failure of isolated arthroscopic Bankart repair and is an accepted primary indication to perform an augmented stabilization procedure. To date, there are no prospective comparative Level 1 studies to determine optimal surgical treatment for shoulder instability with subcritical glenoid bone loss, but commonly includes three procedures:

Arthroscopic Bankart with remplissage, open Bankart repair, and open Latarjet. Furthermore, there are no studies that assess functional recovery and return to military duty, work and sports after these stabilization procedures. Optimizing the management of shoulder instability by identifying the optimal treatment and rehabilitation strategy, will mitigate the risk to Service Members for re-injury, optimize military medical readiness, and maximize the lethality of our fighting force.

The overall objective of this project is to determine the optimal surgical procedure (arthroscopic Bankart with remplissage of Hill-Sachs lesion, open Bankart, Latarjet) and post-operative rehabilitation strategy, with identification of risk factors, for treatment of military personnel and civilians with acute or recurrent anterior shoulder instability with subcritical bone loss, defined as 10% - 20% of the glenoid. Aim 1: we will recruit and randomize 400 individuals with anterior shoulder instability and sub-critical bone loss to one of three surgical stabilization procedures. We hypothesize that the open Bankart and Latarjet will lead to improved patient-reported outcomes at 6 months and 1-year, faster and more complete return to duty or activity, and a reduced rate of recurrent instability at 2-years compared to arthroscopic Bankart repair with remplissage. Aim 2: We will determine if rehabilitation that optimizes range of motion, strength, and functional performance produces clinical data that predicts successful patient-reported outcomes, return to duty and activity, and recurrent instability. We hypothesize that interim testing of range of motion, strength, and functional testing, as part of clinical rehabilitation guidelines, will enhance return to duty and activity and will predict successful or unsuccessful return to duty or activity and patient-reported outcomes at 6-months and 1-year, and recurrent instability at 2-years. Primary outcomes include patient-reported physical function (Western Ontario Shoulder Instability Index), time to return to duty or activity and recurrent instability. Secondary outcomes will include additional shoulder-specific and generic patient-reported outcomes, recovery of range of motion, complications/adverse events, re-injury and additional surgical procedures, which will be determined through usual-care clinical follow-up. Given the activity demands of military personnel, anterior shoulder instability with subcritical bone loss, represents a substantial cost and burden to the military health system. This project provides a unique opportunity to optimize the surgical treatment and rehabilitation for individuals with anterior shoulder instability and subcritical bone loss.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Anterior shoulder instability; subcritical bone loss; surgical stabilization; optimal surgery, post-operative rehabilitation; return to pre-injury activity; military duty, work, sports; functional testing

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The overall objectives for this project are to investigate the effects of surgical stabilization (arthroscopic Bankart repair with remplissage of Hill-Sachs lesion, open Bankart, Latarjet) for the treatment of military personnel and civilians that have anterior shoulder instability with subcritical bone loss, and to identify predictors related to post-operative rehabilitation of patient-reported outcome, return to military duty, work, and sports, and recurrent instability. To achieve these objectives, we will conduct a randomized clinical trial. The aims for this trial are:

Aim 1: To determine the effects of arthroscopic Bankart repair with remplissage of a Hill-Sachs lesion versus open Bankart versus Latarjet on patient reported outcomes (Western Ontario Shoulder Instability score [WOSI], time to RTD/A at pre-injury levels, and recurrent instability/re-injury at 6-months, 1- and 2-years.

Aim 2: To determine if participation in rehabilitation that optimizes range of motion, strength, and functional performance predicts WOSI score, successful RTD/A, and recurrent instability.

The major task to complete these trials are:

Major Tasks	Start Date	End Date	Completion Status
Major Task 1: Study Start-up	09/30/2020	Ongoing	90%
Major Task 2: Subject Recruitment	01/20/2022	Ongoing	4%
Major Task 3: Clinical Monitoring & Quality Control Procedures	01/20/2022	Ongoing	4%
Major Task 4: Subject Follow-up	01/28/2022	Ongoing	3%
Major Task 5: Study Governance	05/19/2020	Ongoing	80%
Major Task 6: Analyze and Disseminate Results	Pending	-	0%

What was accomplished under these goals?

The description and status of each subtask are listed in the table below.

Major Task 1 – Study Start-up				
Major Task 1 – Study Start-Up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 1: Clinical Coordinating Center Regulatory Documents				
Coordinating Center IRB protocol review & approval (Pitt)	Months 1-6	10.09.2020	12.12.2020	100%
1. To date, modifications to the existing single IRB has been submitted to add 6 external sites (Duke University Health System, Naval Medical Center San Diego, Rhode Island Hospital/Lifespan, The Steadman Philippon Research Institute, University of Connecticut Health Center, and Wake Forest University Health Sciences) all receiving approval. Four (4) out of the 6 external sites (Rhode Island Hospital/Lifespan, Duke University Health System, Wake Forest University Health Sciences, University of Connecticut Health Center) have received HRPO approval. The Steadman Philippon Research Institute (Steadman Clinic) are currently under HRPO review for approval (as of 10.12.2022).				
Coordinating Center HRPO Review & Approval	Months 1-6	01.10.2021	04.02.2021	100%
1. No updates for this reporting period.				
Finalize Manual of Operations	Months 1-6	03.01.2020	12.08.2021	100%
1. A finalized Manual of Operations was completed in December of 2021 2. The MOP is updated regularly when required. (Current version is number 6)				

Major Task 1 – Study Start-Up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 2: Prepare Local Site Regulatory Documents				
Local site IRB Protocol Review & Approval	Months 1-9	01.20.2021	Ongoing	75%
<ol style="list-style-type: none"> 1. Representatives from the University of Pittsburgh sIRB have reached out to new additional sites to establish reliance (Ohio State University Medical Center, University of North Carolina) and planned are Vanderbilt University Medical Center and The Mayo Clinic, Scottsdale. 2. Sites officially completed and achieved local site IRB protocol review and approval include: <ol style="list-style-type: none"> a. University of Pittsburgh Medical Center b. Rhode Island Hospital/Lifespan c. Wake Forest University Health System d. Duke University Health System e. University of Connecticut Health System f. The Steadman Philippon Research Institute / Vail Health g. Naval Medical Center San Diego (in local review, pending approval) 3. All other, currently onboarded sites, are working on establishing the local context form and informed consent forms to achieve local IRB approval. Two sites are still working on establishing the reliance agreement (IAIR). This step has been particularly difficult to complete for many sites, in particular all military sites (please see detailed updates below): <ol style="list-style-type: none"> a. UPMC/Pitt – Achieved; open to recruitment and enrollment b. Rhode Island Hospital/Lifespan – Achieved; open to recruitment and enrollment c. Wake Forest University Health System – Achieved; open to recruitment and enrollment d. Duke University Health System – Achieved; open to recruitment and enrollment. e. University of Connecticut Health Center – Achieved, opening of enrollment pending full execution of the subaward and completion of site initiation visits f. The Steadman Philippon Research Institute / Vail Health – Achieved, opening of enrollment pending completion of site visits g. Ohio State University Medical Center – Reliance agreement in place. Working on getting Informed Consents and Local Context Forms since June 2022. h. University of North Carolina Health System – Reliance agreement in place. Working on getting Informed Consents and Local Context Forms since August 2022. i. University of Virginia – site has been placed in a holding status as we work on on-boarding other sites as well as adding other sites. j. Vanderbilt University – beginning discussions to determine ability to add site to the study team. k. The Mayo Clinic – Scottsdale – beginning discussions to determine ability to add site to the study team. l. Walter Reed Military Medical Center – IAIR completed in March/April of 2022. Have been working on getting the Informed Consents and Local Context Form since April 2022. m. SAMMC/Brooke Army – IAIR completed in March/April 2022. Have been working on getting Informed Consents and Local Context Form since June 2022. n. Keller Army Community Hospital – After initiating IAIR process in March 2022, DHA determined they would not be able to establish a reliance agreement with the University of Pittsburgh over differences related to the indemnification process. o. Evans Army Community Hospital – Site-specific document drafts are finalized and local submission is prepped within eIRB. Once outstanding items are obtained, local administrative review can commence. Outstanding items include: 1) IAIR, 2) personnel documents, 3) identification of research monitor. p. Naval Medicine Readiness and Training Command, Annapolis – Site-specific document drafts are finalized and local submission is prepped within eIRB. Once outstanding items below are obtained, local administrative review (likely by WRNMMC) can commence. Outstanding items include: 1) IAIR, Local context form, identification of a local research monitor. Site-specific documents and IAIR draft were sent to Commanding Officer on 9.27.2022. Currently awaiting letter of approval. q. Naval Medical Center San Diego – Reliance Agreement established in April 2022. CRADA in negotiation since May 2022. Local site-specific submission was reviewed by NMCSO CID full committee on 9.21.2022. On 10.6.2022, the CID IRB/IACUC Administrator stated all 9.21.2022 agenda items should be concurred by leadership within 60 days and correspondence will follow. Correspondence has yet to be received. 				

<p>r. Naval Medical Center Camp Lejeune – Reliance agreement established in May 2022. Site-specific document drafts are finalized, and local submission is prepped within eIRB. Once Outstanding items are obtained, local administrative review can commence. Outstanding items include: 1) identification of a local research monitor. On 10.4.2022, HPA stated that an individual was identified to serve as RM and the responsibilities were provided by the Geneva Foundation. Currently awaiting further response/commitment.</p> <p>4. Completed reliance agreements remain for: 1) Evans Army Community Hospital, 2) Naval Medicine Readiness and Training Command, Annapolis, 3) Keller Army Community Hospital [will only re-engage once DHA reliance issues have been resolved]. Will need to establish reliance agreements for 1) Vanderbilt University and 2) Mayo Clinic Scottsdale, as they pursue participation.</p> <p>5. Meetings have been held with or progress has been discussed with additional sites regarding progress of local IRB review and approval. Regular monitoring of progress is taking place with local coordinators and with representatives from the Geneva Foundation</p>				
Local site HRPO Review & Approval	Months 1-9	04.09.2021	-	40%
<p>1. HRPO approved sites include: 1) Pitt/UPMC, 2) RIH, 3) Wake Forest University, 4) Duke Health System, 5) University of Connecticut Health Center, and 6) The Steadman Clinic.</p> <p>2. As approvals for local IRB and ceding of IRB to Pitt occur, HRPO submissions will immediately occur.</p>				

Major Task 1 – Study Start-Up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 3: Execute Subcontract Agreements				
Execute subcontract & Data Use Agreements Between Coordinating Center and Sites	Months 1-6	01.15.2020	Ongoing	75%
<p>1. Subcontracts established for:</p> <ol style="list-style-type: none"> Rhode Island Hospital (RIH) Wake Forest University The Steadman Clinic – Vail The Geneva Foundation (EACH, NMRTC-A, NMCSO, NMCCL, KACH) The Henry-Jackson Foundation (WRNMMC, SAMMC/BAMC) Duke University <p>2. Subcontracts in review or awaiting signatures:</p> <ol style="list-style-type: none"> University of Connecticut (in-review) <p>3. Subcontracts in development:</p> <ol style="list-style-type: none"> University of North Carolina Ohio State University Vanderbilt University Mayo Clinic Scottsdale <p>4. Subcontract on Hold:</p> <ol style="list-style-type: none"> University of Virginia <p>5. Data Use Agreement:</p> <ol style="list-style-type: none"> Fully Executed DHA DSA #22-2828 with incorporated DHA DSAA and approved DRT 9.29.2022 Will remain active until 9.29.2023. Will need to be renewed after. 				

Major Task 1 – Study Start-Up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 4: Finalize Data Capture System				
Finalize all Case Report Forms in electronic data capture system	Months 1-6	06.23.2020	10.10.2021	100%
1. No updates or changes since last quarterly report				
Test Data Capture System	Months 1-6	Nov. 2021	Dec. 2021	100%
1. Completed. No updates or changes since last quarterly report.				

Major Task 1 – Study Start-Up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 5: Final Randomization Schema				
Finalize randomization schema	Months 1-6	02.10.2021	06.23.2021	100%
<ol style="list-style-type: none"> Completed in quarter 3 of year 1. No new items to report 				

Major Task 1 – Study Start-Up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 6: Finalize Post-operative Rehabilitation Guidelines				
Finalize post-operative rehabilitation guidelines for patients and physical therapists	Months 1-6	10.21.2020	10.1.2021	100%
<ol style="list-style-type: none"> No updates or changes since last quarterly report. 				

Major Task 1 – Study Start-Up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 7: Investigator Training				
Investigator Meeting & Protocol Training	Months 1-6	10.29.2020	Ongoing	88%
<ol style="list-style-type: none"> Quarterly Investigator meetings held regularly. Last held on 9.9.2022 Discuss site status updates, screening and recruitment data, additional sites to approach for participation in the trial, subcommittee updates, expected frequencies of adverse events, recruitment materials. 				
Site initiation visit	Months 1-6	Expected 2 nd quarter of year 2	pending	40%
<ol style="list-style-type: none"> Site initiation visits held until IRB and HRPO approvals are in place and site is ready to begin recruitment (after review of recruitment and enrollment procedures with coordinating center). SIV 1 set for Thursday 10.13.2022 for University of Connecticut. Anticipate next site will be the Steadman Clinic – Vail. 				

Major Task 2 – Subject Recruitment

Major Task 2 – Subject Recruitment	SOW Timeline	Start Date	End Date	Completion Status
Subtask 7: Distribution of Recruitment Materials				
Distribution of Recruitment Materials	Months 6	September 2021	Ongoing	75%
<ol style="list-style-type: none"> 1. Recruitment video is still in progress (obtaining recordings) 2. Study website is set to launch in October 2022. Created by the University of Pittsburgh Communications and Marketing. Approved by University of Pittsburgh IRB October 2022. 3. Recruitment Flyer, FAQ, and Investigator Pocket Card available. 				

Major Task 2 – Subject Recruitment	SOW Timeline	Start Date	End Date	Completion Status
Subtask 8: Subject Recruitment & Enrollment				
Subject Recruitment & Enrollment	Months 6-24	1.21.2022	Ongoing	2%
<ol style="list-style-type: none"> 1. Subject recruitment and enrollment is open at 4 clinical sites (Pitt/UPMC, RIH, Wake Forest University, Duke University Health System) 2. University of Connecticut expected to be open to recruitment in November 2022. 3. The Steadman Clinic expected to be open to recruitment in December 2022. 				

Major Task 2 – Subject Recruitment	SOW Timeline	Start Date	End Date	Completion Status	
Subtask 9: Monthly Monitoring of Recruitment					
Monthly Monitoring of Recruitment	Months 6-30	1.21.2022	Ongoing	2%	
1. Prescreening by site:					
Site	Activation Date	Total Pre-Screenings	Prescreened Ineligible	Eligible & Not Willing	Eligible & Willing
Total		69	47	12	10
RIH/Univ Ortho.	3.7.22	17	8	8	1
Pitt/UPMC	1.24.22	51	39	4	8
Wake Forest	7.21.22	0	0	0	0
Duke Health	10.12.22	2	0	0	2
2. Randomized by site:					
Site	Eligible & Willing	Consented	Randomized		
Total	10	4	2		
Pitt/UPMC	8	2	2		
RIH	1	0	0		
Wake Forest University	0	0	0		
Duke	2	2	0		

Major Task 3 – Clinical Monitoring & Quality Control Procedures

Major Task 3 – Clinical Monitoring & Quality Control Procedures	SOW Timeline	Start Date	End Date	Completion Status
Subtask 10: Conduct Remote Interim Visit				
Conduct Remote Interim Visit	Months 6-24	To start January 2023	-	5%
<ol style="list-style-type: none"> Structure of interim visit established To date, not required Will be examined and planned after all site initiation visits occur and/or screening & recruitment is open at anticipated capacity. Can start at open / activated sites 1 year after opening to recruitment. 				

Major Task 3 – Clinical Monitoring & Quality Control Procedures	SOW Timeline	Start Date	End Date	Completion Status
Subtask 11: Conduct Interim Site Visit				
Conduct Interim Site Visit	Months 13-48	Pending	-	0%
<ol style="list-style-type: none"> Structure of interim visit established To date, not required Will be examined and planned after all site initiation visits occur 				

Major Task 3 – Clinical Monitoring & Quality Control Procedures	SOW Timeline	Start Date	End Date	Completion Status
Subtask 12: Conduct Review of Monthly Quality Report				
Conduct Review of Monthly Quality Report	Months 6-48	June 2022	Ongoing	2%
<ol style="list-style-type: none"> Quality Report format and data to be pulled and reviewed established Initial reported completed for Year 1, Quarter 3 for participant data 				

Major Task 3 – Clinical Monitoring & Quality Control Procedures	SOW Timeline	Start Date	End Date	Completion Status
Subtask 13: Prepare Materials for DSMB				
Prepare Materials for DSMB	Months 6-48	11.18.2021	In progress	50%
<ol style="list-style-type: none"> 1st DSMB meeting occurred on 11.81.2021 DSMB approval to start trial received 1.13.2022 Next DSMB meeting set for 11.16.2022 				

Major Task 3 – Clinical Monitoring & Quality Control Procedures	SOW Timeline	Start Date	End Date	Completion Status
Subtask 14: Monitor Data for AEs & SAEs				
Monitor Data for AEs & SAEs	Months 6-48	Pending	-	18%
<ol style="list-style-type: none"> Monitoring has commenced with the start of recruitment and enrollment 1.24.2022 To date, no AEs or SAEs have been reported in the EDC 				

Major Task 3 – Clinical Monitoring & Quality Control Procedures	SOW Timeline	Start Date	End Date	Completion Status
Subtask 15: Monitor & Address Protocol Deviations				

Monitor & Address Protocol Deviations	Months 6-48	1.24.2022	Ongoing	10%
1. No Protocol deviations to date				

Major Task 3 – Clinical Monitoring & Quality Control Procedures	SOW Timeline	Start Date	End Date	Completion Status
Subtask 16: Monitor & Address Adherence & Fidelity to Randomization Assignment				
Monitor & Address Adherence & Fidelity to Randomization Assignment	Months 6-48	1.24.2022	Ongoing	8%
1. No departures from adherence to fidelity to randomized assignment to date 2. Continued monitoring required and discussed at weekly meetings at Coordinating Center				

Major Task 4 – Subject Follow-up

Major Task 4 – Subject Follow-up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 17: Collect Clinical Follow-up Data				
Collect clinical follow-up data	Months 6-48	2.5.2022	Ongoing	4%
<ol style="list-style-type: none"> 1. Collected follow-up data on currently enrolled subjects 2. No follow-up data has been missed through this reporting cycle. 				

Major Task 4 – Subject Follow-up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 18: Collect Physical Therapy Self-Report Form				
Collect physical therapy self-report form	Months 6-48	2.12.2022	Ongoing	4%
<ol style="list-style-type: none"> 1. Collection initiated on currently enrolled subjects 2. No PT-Report (self-report) data has been missed through this reporting cycle. 				

Major Task 4 – Subject Follow-up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 19: Conduct Monthly Assessment of Return to Activity				
Conduct monthly assessment of return to activity	Months 10-48	April 2022	Ongoing	2%
<ol style="list-style-type: none"> 1. Collection of monthly assessment of return to activity began in April 2022 2. Through this reporting cycle, 80% completion of the monthly assessment of return to activity have been completed. 				

Major Task 4 – Subject Follow-up	SOW Timeline	Start Date	End Date	Completion Status
Subtask 20: Conduct subject Assessment of Patient-Reported Outcomes				
Conduct subject assessment of patient-reported outcomes	Months 6-48	April 2022	Ongoing	2%
<ol style="list-style-type: none"> 1. Collection of follow-up patient reported outcomes began in April 2022. 2. No patient-reported outcomes have been missed through this reporting cycle. 				

Major Task 5 – Study Governance

Major Task 5 – Study Governance	SOW Timeline	Start Date	End Date	Completion Status
Subtask 21: Monthly Conference Calls for ESC				
Monthly Conference Calls for ESC	Months 1-48	05.19.2020	Ongoing	75%
<ol style="list-style-type: none"> 1. The Executive Steering Committee has continued to meet monthly 2. Have discussed addition of specific sites, importance of getting sites onboarded, through regulatory hurdles, and activated, and recruitment plans/methods 3. Regular meetings are held on the 3rd (occasionally 4th) Thursday of each month. 4. Next ESC meeting will be October 20, 2022. 				

Major Task 5 – Study Governance	SOW Timeline	Start Date	End Date	Completion Status
Subtask 22: Quarterly Conference calls for all Investigators to discuss study progress				
Quarterly calls for Investigators to discuss study progress	Months 1-48	10.29.2020	Ongoing	38%
<ol style="list-style-type: none"> 1. Investigator Meeting for Year 2, Quarter 1 held on 12.9.2021 2. Investigator Meeting for Year 2, Quarter 2, held on 1.17.2022 3. Investigator Meeting for Year 2, Quarter 3, held on 5.26.2022 4. Investigator Meeting for Year 2, Quarter 4, held on 9.8.2022 				

Major Task 5 – Study Governance	SOW Timeline	Start Date	End Date	Completion Status
Subtask 23: Quarterly conference calls for study governance sub-committees				
Quarterly Conference calls for study governance sub-committees	Months 1-48	10.21.2020	Ongoing	55%
<ol style="list-style-type: none"> 1. Rehabilitation Committee – No changes. Currently no action required. 2. Forms Committee – No changes. Currently no action required. 3. Quality Control Committee – Will commence approximately 6 months after representative number of sites are open to enrollment and as monitoring data is obtained (expected January 2023). 4. Recruitment Committee – Quarterly Meeting dates include: 3.8.2022; 6.14.2022; and 9.13.2022. Next 12.13.2022. 5. Internal Adverse Events Committee – Currently no action required 6. Publications and Ancillary Studies – Currently, no action required. Will commence January 2023. 				

Major Task 5 – Study Governance	SOW Timeline	Start Date	End Date	Completion Status
Subtask 24: Conference Call for External Adverse events adjudication committee twice per year				
Conference call for external adverse events adjudication committee twice per year	Months 6-48	Pending	Ongoing	1%
<ol style="list-style-type: none"> 1. To start the twice per year frequency upon notification of the first adverse event occurrence. 				

Major Task 5 – Study Governance	SOW Timeline	Start Date	End Date	Completion Status
Subtask 25: Annual Investigator Meetings				
Annual Investigator meeting	Months 1-48	02.15.2021	Ongoing	100%
<ol style="list-style-type: none"> 1. Year 1 Annual Investigator Meeting finished 07.07.2021 2. Year 2 Annual Investigator Meeting was set to occur in-conjunction with Extremity War Injuries XVI, January 17, 2021 (Washington, DC). This was canceled due to Covid-19 cases and cancellation of the conference. 3. Year 2 Annual Investigator Meeting instead held virtually 1.17.2022. 4. Year 3 Annual Investigator Meeting planned to be held at Extremity War Injuries XVII. Date to be determined. 				

Notice of Award for Ancillary Study related to parent OASIS Trial.

Ancillary study of the parent OASIS trial, titled “The dynamic Glenoid Track: An Updated Model of Glenohumeral Cartilage Contact During In vivo Movement” began October 1, 2021. The length of the trial is 3 years. The purpose of the time-sensitive, mechanistic, ancillary study is to define the “dynamic glenoid track” and to develop and validate a patient-specific evaluation process, based upon the dynamic glenoid track, to predict shoulder function after three common surgeries to treat anterior shoulder instability. This study will employ in-vivo kinematics from biplane radiography and cartilage morphology from magnetic resonance imaging to measure glenohumeral contact regions during loaded and unloaded movement of the shoulder.

NIH/NIAMS; 1R01AR080425

10/01/2021 – 10/01/2024

What opportunities for training and professional development has the project provided?

Year 1 (2020 – 2021): Kelechi Adejumo, PT, ScD was a Postdoctoral Associate with the Institute of Clinical Research Education & Clinical and Translational Science Institute at the University of Pittsburgh and has accepted a role with the OASIS trial. She was responsible for overseeing and conducting quality control of the rehabilitation aspect of the trial and research follow-up visits.

End of Year 2 (September 2021) – Year 3 (September 2023): W. Alex Fails, PT, DPT is a Doctoral student within the Department of Physical Therapy at the University of Pittsburgh and will serve a role with the OASIS trial. Alex will be responsible for overseeing and conducting quality control of the rehabilitation aspects of the trial and research follow-up visits. Further, he is to be a primary point of contact to military sites falling under the Geneva Foundation. Alex will assist in getting the military sites through the regulatory milestones. Finally, it is expected that he will propose secondary and ancillary investigations related to or in conjunction with the OASIS trial. In particular, it is expected that Alex will impactfully contribute to the science and literature related to return to duty and activity assessment and achievement.

How were the results disseminated to communities of interest?

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

The plan for the next reporting period includes the following:

A. Complete Major Task 1: Study Start-Up

- 1.* Achieve local site IRB protocol review & approval at all remaining sites
 - a.* Naval Medical Center San Diego
 - b.* Walter Reed National Military Medical Center
 - c.* Brooke Army Medical Center / SAMMC
 - d.* Evans Army Community Hospital
 - e.* Naval Medical Readiness and Training Command, Annapolis
 - f.* Naval Medical Center Camp Lejeune
 - g.* Ohio State University Medical Center
 - h.* University of North Carolina at Chapel Hill
 - i.* Vanderbilt University

- j.* The Mayo Clinic, Scottsdale
2. Achieve Local Site HRPO Review & Approval
3. Initiate the execution of subaward and data use agreements with all participating sites
4. Continue with Investigator Meetings and Protocol trainings
5. Complete Site Initiation Visits at each performance site upon HRPO approval

B. Continue with Major Task 1: Study Start-Up

1. Collect additional sites' locally approved informed consent and local context form documents, submit modification(s) to include site(s) to sIRB until all sites have been completed.
2. Initiate and achieve approval for the HRPO review and approval process for all sites that have completed the reliance process and sIRB on-boarding with the University of Pittsburgh IRB
3. Finalized all subcontracts and Data Use Agreements at all collaborating clinical sites
4. Continue with quarterly Investigator Meetings

C. Complete Major Task 2: Distribution of Recruitment Materials

1. Launch study website for recruitment purposes
2. Distribute recruitment video after filming and processing, place on website after IRB approval.

D. Continue Major Task 2: Subject Recruitment & Enrollment

1. Complete site initiation visits and start recruitment at all approved sites
2. Complete site initiation visits and start recruitment at all approved sites
3. Continue with monthly monitoring of recruitment

E. Continue Major Task 3: Clinical Monitoring & Quality Control Procedures

1. Conduct interim remote visits as needed
2. Conduct interim site visits as needed
3. Continue with review of monthly quality reports
4. Meet with DSMB at recommended and approved intervals
5. Continue to monitor all data for AE and SAE occurrence
6. Continue to monitor for protocol deviations and fidelity to randomization

F. Continue Major Task 4: Subject Follow-up

1. Continue to collect clinical follow-up, physical therapy self-report forms, and PROs of any enrolled participants
2. Continue to conduct monthly assessments of return to activity

G. Continue Major Task 5: Study Governance

1. Continue with monthly Executive Steering Committee meetings
2. Continue to hold Investigators' call on quarterly basis
3. Conduct quarterly (or as-needed) subcommittee meetings.
4. Meet with External Adverse Events adjudication committee as needed and at expected frequency
5. Continue to hold annual investigator meeting

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

There have been no significant changes to the protocol over the past reporting year and therefore were not submitted to the Department of Defense for approval. The protocol was edited for clarity and to add specific details (version 3) that were not previously provided (10.29.2021). Since then, the protocol was updated to include information / approved scripts for prescreening, a recruitment flyer (version 4), and the long-term retention of data and stripping of identifiers (version 5).

Problems have primarily centered around the difficulty and time delay associated with achieving regulatory approvals for full on-boarding and opening of recruitment, especially at participating military treatment facilities. Obtaining reliance agreements, local IRB approvals, and local language for the informed consents and local context forms have been extremely difficulty and required much greater time that anticipated.

Changes in approach and reasons for change:

Changes in the protocol that have been made since the beginning of Year 2 of the project along with the rationale for the change are summarized in the table below. All changes have been submitted for review and achieved approval to the University of Pittsburgh IRB.

The change in approach to add additional participating sites, in particular civilian sites, was instituted to clear regulatory hurdles and get more sites open to recruitment in the shortest timeframe possible. With more sites open to recruitment, we can begin to achieve the objectives/aims of the project.

Protocol Changes and Modifications Table:

Section	Original Proposal	Proposed Modification	Rationale for Modification
All	Versions 1 & 2	Re-organization of protocol layout with increased details and specifics	To provide a more clear, easily readable version of the protocol. Further, the additional details provide increase information for all participating team members
8.10.2	None	Military “Defense Health Agency” (DHA) Systems that may be accessed to retrieve medical information related to standard of care procedures and visits	To achieve approval of the Data Sharing Agreement with the DHA, the systems that will be accessed were required to be listed in the application and the protocol.
5.3.2 & Appendix G	Efforts to Monitor and Maximize Subject Recruitment	Added IRB approved recruitment flyer	To maximize subject recruitment, a flyer can be placed in examination rooms with a link to an approved website with information regarding the trial.
16.7	No information	All research records will be maintained for at least 7 years following final reporting or publication of the project. After 7 years, identifiers will be destroyed, and de-	To provide clear and specific data retention practices should any local IRB require such an answer when performing their review.

		identified research records will be kept indefinitely. For minors, identifiable records will be maintained until child participants reach the age of 25 as required by University of Pittsburgh policy. After this time, identifiers will be destroyed, and de-identified records will be maintained indefinitely.	
Recruitment	Original civilian sites	<p>Have added: University of Connecticut Health Center</p> <p>In process of adding:</p> <ol style="list-style-type: none"> 1. Ohio State Medical Center 2. University of North Carolina at Chapel Hill 3. Vanderbilt University Medical Center 4. The Mayo Clinic - Scottsdale 	<p>Additional civilian sites have been added and will continue to be added to maximize all possible recruitment at several civilian centers. Specifically, we have targeted civilian centers, as we have had significant difficulty getting through the on-boarding process with military facilities.</p>

Actual or anticipated problems or delays and actions or plans to resolve them

We are behind our timeline for the commencement of recruitment and enrollment at 1 of the originally planned civilian sites and all military sites because we have experienced greater than anticipated delays in achieving all approvals when onboarding remote sites, including achieving IRB reliance, obtaining locally approved informed consent documents and local context forms, DoD HRPO approval, and meeting all regulatory requirements at all institutions.

Because of the delays in on-boarding and obtaining all approvals at all military sites and one of the originally planned civilian sites, this has led to a minimal number of sites being open to recruitment and enrollment. Thus, we have not met our Year 1(Quarter 3 & 4 projections) to recruit 132 participants and our Year 2 (Quarters 1 – 4) projections to recruit 268. Therefore, in our quad chart, we have updated the goals for CY 2022, 2023, and 2024 to reflect that we will recruit an additional 335 participants during CY 2022 through Quarter 2 of Year 4, 2024 and to finish recruitment in Q2 of CY2024. This will push final follow-up back to and into a no cost-extension period of 2025 - 2026.

To address the problem with delayed site activation and, therefore, limited enrollment, we are moving as quickly as possible to open additional civilian sites to assist with recruitment and enrollment. We believe the additional of high-volume civilian medical centers will assist in achieving the objective of expeditiously achieving site activation and therefore provide greater opportunities for participant recruitment.

Changes that had a significant impact on expenditures

Because of the delays in on-boarding sites, our actual expenditures have been less than projected, but we expect that these funds will be expanded as our enrollment and follow-up of subjects begins and increases, as well as on-boarding additional sites to assist with recruitment and target enrollment achievement. Further, the shifting to remote site visits for initiation as well as needing to hold the first 2 Annual Investigator Meetings virtually due to the pandemic has protected a sizeable amount of funds that can be utilized for the on-boarding of additional civilian participating sites.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

There have been no changes in the use or care of human subjects in this project. Initial IRB approval for the clinical coordinating center at the University of Pittsburgh was obtained on 12/12/2020 and the first continuing review of the project was submitted on 8/27/2021. Approval of the first continuing review was received on 10/12/2021. Second continuing review was submitted on 07/21/2022 and approval was received on 08/18/2022.

Date of Pitt IRB Approval	Modification / Renewal /Site Onboarded
12/12/2020	Initial Approval of Coordinating Center
03/04/2021	University of Pittsburgh Site onboarding
10/12/2021	Modifications listed in Annual Progress Report (Year 1) & first Continuing Review
11/30/2021	On-boarding Modification (Wake Forest University Health)
12/16/2021	On-boarding Modification (Rhode Island Hospital)
01/25/2022	Addition / change to study team members (non-investigator)
02/15/2022	Edit of U. Pittsburgh/UPMC informed consent (surgeon update)
04/12/2022	Wake Forest modification to consent forms
04/28/2022	On-boarding Modification of Duke University Health
07/6/2022	Change in non-investigator study team (Project Coordinator), add surgeon at U. Pittsburgh/UPMC, add surgeon at Duke University Health
07/12/2022	On-boarding of Naval Medical Center San Diego (still requires local approval by Navy)
08/18/2022	Continuing Review approval
08/26/2022	On-boarding Modification (University of Connecticut Health Center)
09/16/2022	On-boarding Modification (The Steadman Clinic – Vail)
10/05/2022	Updated language on data retention to Protocol (version 5), recruitment materials

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

5. PRODUCTS

- **Publications, conference papers, and presentations**

Nothing to report to date. As data begins to be collected, items will be processed.

Journal publications.

Nothing to report.

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report.

- **Website(s) or other Internet site(s)**

Have created a website to be used for recruitment purposes.

<https://www.oasistrialinfo.pitt.edu>

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

6. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Adam Popchak, PT PhD

Project Role: Principal Investigator

Researcher Identifier (e.g., ORCID ID): 0000-0002-4932-6541

Nearest person month worked: 4 calendar months

Contribution to Project: Dr. Popchak has been responsible for the overall design and conduct of the project and has served as the primary contact for all project-related correspondence. Dr. Popchak has led the efforts of the study team at the University of Pittsburgh during all aspects of the trial including the start-up phase of this multicenter clinical trial, including the efforts to obtain IRB and HRPO approval both at the University of Pittsburgh and at all participating sites, conducted the conference calls with the Executive Steering Committee, Investigators Meetings, Recruitment Committee, and Rehabilitation Committee. Completed all regulatory items, worked on development of training materials and protocols, and forms for entry into the electronic data capture system. Dr. Popchak created all materials for the Investigator meetings and presented the information along with Dr. Jonathan Dickens. Completion of all reporting documents to the DoD and to the coordinating center's IRB (U. Pittsburgh) has been the responsibility of Dr. Popchak. Dr. Popchak has been prominently involved in all site initiation visits and has led efforts to recruit and fast-track on-boarding of additional sites.

Name: Jonathan Dickens, MD

Project Role: Co-Principal Investigator / Qualified Surgical Investigator

Researcher Identifier

(e.g., ORCID ID):

Nearest person month worked: 2 calendar months

Contribution to Project: Dr. Dickens lead all discussions and obtained consensus related to the surgical aspects of the study. This has included helping to refine and finalize the eligibility criteria as well as the surgical findings and procedures. He has participated in the Executive Steering Committee, Investigator conference, and Rehabilitation Committee calls, led efforts to establish study branding, recruit members for the DSMB and additional participating sites, and created the surgical case report forms for entry into the EDC system. Dr. Dickens lead discussions regarding clinical and community equipoise of the study procedures. Dr. Dickens has also been prominently involved in all site initiation visits (1st of 2 SIVs) related to surgical aspects of the trial and overarching study design and methodology.

Name: James J. Irrgang PhD, PT, ATC

Project Role: Co-Investigator/Clinical Trials Design and Implementation Lead

Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 1 calendar months

Contribution to Project: In addition to the previous work Dr. Irrgang has provided for the trial, he has coordinated and lead the efforts to organize and address all required steps of the study start-up, monitoring, reporting, and coordination with the DSMB. Dr. Irrgang participates in weekly meetings the PI and Co-PIs of the University of Pittsburgh.

Name: Charity G. Patterson, PhD

Project Role: Biostatistician and Director of Data Coordinating Center

Researcher Identifier (e.g., ORCID ID): 0000-0002-0060-0124

Nearest person month worked: 1 calendar months

Contribution to Project: Dr. Patterson has coordinated and led efforts of the Data Center in the creation of study forms and the creation of the electronic data capture system housed at the University of Pittsburgh. Specifically, during Year 2, Dr. Patterson led efforts to submit the Data Security Agreement for DHA review and approval (achieved approval). Further Dr. Patterson has assisted with on-going monitoring and data queries for completeness.

Name: Alexandra Gil PhD

Project Role: Co-Investigator and Quality Control Coordinator

Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 1 calendar months

Contribution to Project: Dr. Gil presented and educated the Investigators on Adverse events and Serious Adverse events monitoring and reporting. She has been instrumental in development of quality control measures and processes. Dr. Gil is responsible for all education regarding AE, SAE, and UAP procedures and reporting. Dr. Gil has provided significant leadership on the training of new project coordinators.

Name: Alex Fails, PT, DPT

Project Role: Doctoral Student, Research Coordinator responsible for rehabilitation related items

Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 6 calendar months

Contribution to Project: Dr. Fails, who just came on-board in August 2022, has worked closely with Drs. Popchak and Irrgang during discussions and production of items related to the rehabilitation arm of the trial. He has assisted with the oversight of the rehabilitation protocol for distribution and use and the development of the training materials for the research testing procedures.. He will be responsible for the continued monitoring of data completeness / missingness and lead efforts to communicate with sites to obtain all missed data elements.

Name: Samia Aslam

Project Role: Project Coordinator **Researcher Identifier (e.g., ORCID ID):**

Nearest person month worked: 4.8 calendar months

Contribution to Project: Ms. Aslam has worked closely with Drs. Popchak, Dickens, Irrgang, Patterson, and Gil during all phases of the project to ensure the project is conducted in compliance with applicable research regulations. She has been responsible for planning the agenda, distributing meeting materials, and maintaining meeting minutes for the Executive Steering Committee meetings, Investigator meetings, monthly coordinator calls, and subcommittee meetings. Additionally, she took the lead role in coordinating all items related to the Site Initiation Visit process, action items for site activation, electronic data capture system training, and the development of the recruitment website. She has assisted with the development of the Clinical Monitoring, Adverse Events reporting, Data Safety and Monitoring, and set the DSMB meeting.

Name: Alec Howard, MPH

Project Role: Project Coordinator **Researcher Identifier (e.g., ORCID ID):**

Nearest person month worked: 4.8 calendar months

Contribution to Project: Mr. Howard has recently been brought on the OASIS team to provide further assistance with project coordination. He has worked closely with Drs. Popchak, Dickens, Irrgang, Patterson, and Gil during his recent time working on the project and ensures that the project is conducted in compliance with applicable research regulations. He has been responsible for IRB related items, assisted with development of materials for DoD submissions, assisted with the CR for the DoD and assisted in establishing clearly defined roles for all project and research coordinators associated with the OASIS trial. He will assist with the Clinical Monitoring, Adverse Events reporting, Data Safety and Monitoring, and create quarterly invoices for sites based on reported research activity in the data capture system.

Name: Robert Winners

Project Role: Systems Analyses (Electronic Data Capture Developer) **Researcher Identifier (e.g., ORCID ID):**

Nearest person month worked: 1 calendar months

Contribution to Project: Mr. Winners has built the electronic data collection system. In doing so, he has built and testing procedures for notifying teams of adverse events and problematic responses related to questions of emotional health of participants, procedures for administering patient-reported surveys,

and an application for adverse event adjudication. Further, Mr. Winners is responsible for modifying the EDC when new sites are brought on-board and are activated for recruitment.

Name: Benjamin Gibbons

Project Role: Systems Analyses (Electronic Data Capture Developer) *Researcher Identifier (e.g., ORCID ID):*

Nearest person month worked: 1 calendar months

Contribution to Project: Mr. Gibbons has built, formatted, tested, and revised the case report forms, patient reported outcomes, adverse events and change of status forms, and inclusion/exclusion forms so that they align with the study protocol. Mr. Gibbons left his position in the Data Center and thus the OASIS Trial in October/November of 2021 and is no longer actively involved with the OASIS trial.

Individuals from Collaborating Research Sites

Institution	Name	Project Role	Contribution to Project	Whole Person Month	Funding Support
Walter Reed National Military Medical Center	Jonathan Henry	RC	Preparation of local IRB submission; regulatory items	1 month	Grant (subcontract to Henry-Jackson Foundation)
	Kelly Kilcoyne	Site PI	Contributions to the Investigator Meetings; Forms Committee; Rehabilitation Committee	1 month	Institutional
University of Pittsburgh	Albert Lin	Site PI	Contributions to ESC and Investigator Meetings; Forms review	1 month	Institutional
	Bryson Lesniak	Site Co-I	Contributions to ESC and Investigator Meetings; Forms review	1 month	Institutional
	Jonathan Hughes	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Volker Musahl	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Stephen Rabuck	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
Rhode Island Hospital /	Brett Owens	Site PI	Contributions to ESC and Investigator	1 month	Institutional

University Orthopaedics			Meetings; Forms review		
	Michel Arcand	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Michael Hulstyn	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	E. Scott Paxton	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Cynthia Chrostek	RC	Preparation of local IRB submission; establishment of non-human subjects subcontract; Prescreening and regulatory compliance	1 month	Grant (subcontract to University Orthopaedics)
Steadman-Philippon Clinic (Vail)	Matt Provencher	Site PI	Contributions to the Investigator Meetings	1 month	Institutional
	Peter Millett	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Thomas Hackett	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Suzanne Page / Sara Robinson	RC	Preparation of local IRB submission; establishment of non-human	1 month	Grant (subcontract to Steadman-Philippon Clinic (Vail))

			subjects subcontract; setting SIVs		
Brooke Army Medical Center (San Antonio)	Andy Sheean	Site PI	Contributions to ESC and Investigator Meetings;	1 month	Institutional
	Eric Martinez	RC	Preparation of local IRB submission; Reliance agreement submission	1 month	Grant (subcontract to Henry-Jackson Foundation)
University of Virginia	None until subcontract established				
Evans Army Community Hospital	David Tennent	Site-PI	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Daniel Song	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Rosieann Cain	RC	Preparation of local IRB submission; Reliance agreement submission	1 month	Grant (subcontract to Geneva Foundation)
Naval Health Clinic Annapolis	Robert Waltz	Site-PI	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Jacob Dowe	RC	Preparation of local IRB submission; Reliance agreement submission	1 month	Grant (subcontract to Geneva Foundation)
Naval Medical	Lucas McDonald	Site PI	Contributions to ESC and	1 month	Institutional

Center San Diego			Investigator Meetings;		
	James Bailey	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Jennifer Smith	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Andrew Hurvitz	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Ashley Hughey	RC	Preparation of local IRB submission; reliance agreement, HRPO document collection	1 month	Grant (subcontract to Geneva Foundation)
Wake Forest University	Brian Waterman	Site PI	Contributions to ESC and Investigator Meetings; Forms review	1 month	Institutional
	Kevin Coates	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Benjamin Graves	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	John Hubbard	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional

	Nicholas Trasolini	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Megan Wolf	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Nina Cruz	RC	Preparation of local IRB submission; reliance and HRPO support, SIV completion, prescreening	1 month	Grant (subcontract to Wake Forest)
Duke University Health	Brian Lau	Site PI	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Jonathan Dickens	Study Co-PI Site Co-I	Study screening, recruitment, enrollment, surgery	2 months	Institutional
	Dean Taylor	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Scott Gibson	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Cassandra Rhodes	RC	Preparation of local IRB submission; Reliance, subcontract, and SIV support. Prescreening	1 month	Grant (subcontract to Duke University Health)

			and enrollment		
Naval Medical Center Camp Lejeune	Kyle Nappo	Site PI	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Toni Trujillo	RC	Preparation of local IRB submission, reliance agreement, local items	1 month	Grant (subcontract o Geneva Foundation)
University of Connecticut	Cory Edgar	Site PI	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Bob Arciero	Site Co-I	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Julie Burland	RC	Preparation of local IRB submission; reliance, SIVs, Prescreening, enrollment	1 month	Grant (subcontract to University of Connecticut Health Center)
Ohio State University Medical Center	Julie Bishop	Site PI	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Angela Pedroza	RC	Preparation of local IRB submission; collection of reliance agreement items, DoD items, subcontract	1 month	Grant (subcontract to Ohio State University Medical Center)
University of North	R. Alexander Creighton	Site PI	Study screening,	1 month	Institutional

Carolina at Chapel Hill			recruitment, enrollment, surgery		
	Bradley Lauck	RC	Preparation of local IRB submission; DoD requirements, Reliance items	1 month	Grant (subcontract to UNC at Chapel Hill)
Vanderbilt University Medical Center	Lance LeClere	Site PI	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	Laura Withrow	RC	Preparation of local IRB submission; subcontract work, reliance agreement, DoD requirement items.	1 month	Grant (subcontract to Vanderbilt University Medical Center)
The Mayo Clinic	John Tokish	Site PI	Study screening, recruitment, enrollment, surgery	1 month	Institutional
	TBD	RC	Preparation of local IRB submission; subcontract work, reliance agreement, DoD requirement items.	1 month	Grant (subcontract to The Mayo Clinic)

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Popchak, Adam

R01AR080425 (PI: Anderst)

10/01/2021 – 10/01/2024

1.2 calendar NIH

The Dynamic Glenoid Track: An Updated Model of Glenohumeral Cartilage Contact During In Vivo Movement

The optimal surgical treatment for patients with anterior shoulder instability and subcritical glenoid bone loss is unclear. This ancillary study will provide insight into the anatomic and kinematic mechanisms that lead to the loss and restoration of anterior shoulder stability. A patient-specific evaluation process will be developed and validated to help surgeons identify the optimal procedure for this challenging cohort.

Role: Co-I

GRANT13521790 (PI: Bell)

10/01/2022 – 10/01/2023

0.6 calendar NIH

CuffLink: Remotely Monitored Rotator Cuff Repair Rehabilitation at Home

The purpose of this study is to develop CuffLink Telehealth System for post-rotator cuff repair therapy by integrating the mechanical Strengthening & Stabilization System device with InterAction remote monitoring capabilities. The result of this project a product, designed for use with future direction of clinical applications with remote monitoring.

Role: Co-I

Dickens, J:

None started during this reporting period

Irrgang, JJ:

K23 AR080741-01 (PI: Sprague)

08/01/2022 – 07/31/2027

1.2 calendar NIH

Graft Harvest as a Model of Tendon Injury – Trajectory of Recovery and Clinical Outcomes

This K23 Career Development award will: 1) identify changes in graft site structure after graft harvest; 2) identify changes in graft site mechanical properties after graft harvest; and 3) Determine the association between change in graft site structural and mechanical properties with clinical outcomes after graft harvest.

Role: Co-I

RO1AR080310-01

09/01/2022 – 08/31/2027

0.36 calendar

NIH

Digital Biomarkers of Post-Traumatic Osteoarthritis: Toward Precision Rehabilitation

The objective of this study is to determine if characteristics of gait extracted from video and wearable sensors (digital biomarkers) can predict longitudinal changes in cartilage microstructure (early PTOA) extracted from quantitative Magnetic Resonance Imaging (qMRI). It is hypothesized that the future risk of PTOA can be predicted in the first few months after surgery using passively collected data from wearable sensors and video. To accomplish this objective, physical therapy, natural environment ambulation, and cartilage health will be monitored longitudinally. Exercise correctness

during pre- and post-operative physical therapy will be quantified using computer vision and machine

learning algorithms. Out-of-lab movement will be monitored at baseline (3 weeks), 3, and 9 months after surgery with epidermal sensors placed on the thighs and shanks. Quantitative MRI data will be collected at baseline (3 weeks), 3 and 18 months after the surgery. Aim 1 will determine if restoration of gait symmetry as measured by wearable sensors can predict quantitative MRI changes up to 18 months post-surgery. Aim 2 will determine if physical therapy quality, to the extent that is quantifiable with passive computer vision algorithms, can predict restoration of gait symmetry 9 months post-surgery.

Role: Site PI

Patterson, C:

None starting during this reporting period.

Gil, A:

None starting during this reporting period.

What other organizations were involved as partners?

The study collaborating institutions are listed in the table below. All of them have provided institutional support for planning and implementing the study at the site.

Site 1: Walter Reed National Military Medical Center 8901 Wisconsin Avenue Bethesda, MD 20889	Site 2: University of Pittsburgh / University of Pittsburgh Medical Center 3200 South Water Street Pittsburgh, PA 15203	Site 3: University Orthopaedics / Rhode Island Hospital 593 Eddy Street Providence, RI 02903
Site 4: Steadman-Philippon Research Institute (Vail Clinic) 181 West Meadow Drive Vail, Co 81657	Site 5: San Antonio Military Medical / Brooke Army 3551 Roger Brooke Drive Fort Sam Houston, TX 78234	Site 6: University of Virginia 136 Hospital Drive Charlottesville, VA 22904
Site 7: Evans Army Community Hospital 1650 Cochrane Circle Fort Carson, Co 80913	Site 8: Naval Medicine Readiness and Training Command – Annapolis (Formerly: U.S. Naval Health Clinic (Academy) Annapolis) 121 Blake Rd. Annapolis, MD 21402	Site 9: Naval Medical Center San Diego 34800 Bob Wilson Drive San Diego, CA 92134
Site 10: Wake Forest University Medical Center Boulevard Winston-Salem, NC 27157	Site 11: Naval Medical Center – Camp Lejeune 100 Brewster Blvd Camp Lejeune, NC 28547	*Site 12: Keller Community Army Hospital <i>(onboard pending/on hold due to IAIR)</i> 900 Washington Road West Point, NY 10996
Site 13: Duke University 2301 Erwin Rd Durham, NC 27710	Site 14: University of Connecticut 263 Farmington Avenue Farmington, CT 06030	*Site 15: Ohio State University Wexner Medical Center <i>(in progress)</i>

		2835 Fred Taylor Drive Columbus, OH 43202
*Site 16: University of North Carolina at Chapel Hill <i>(in progress)</i> 104 Airport Drive, Suite 2200 Campus Box 1350 Chapel Hill, NC 27599-1350	*Site 17: Vanderbilt University Medical Center <i>(in progress)</i> 1215 21 st Avenue South Nashville, TN 37232	*Site 18: The Mayo Clinic – Phoenix <i>(in progress)</i> 5777 E Mayo Blvd Phoenix, AZ 85054

*Sites to be added as documentation of the following are received: DoD Other Support; DoD Biosketch; Statement of Work; Budget; Budget Justification; RR Budget; Statement of Intent; Organizational Data; Representations; Indirect Cost Rate Agreement; Performance Site Information

7. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

Nothing to Report.

QUAD CHARTS:

Attached as Appendix A


8. APPENDICES:

- A. Quad Chart
- B. Study Status Update

Appendix A: Quad Chart (also included as attachment in eBRAP)

Arthroscopic versus Open Stabilization of Shoulder Instability with Subcritical Bone Loss

Log number – OR190059



PI's: Popchak & Dickens

Org: University of Pittsburgh

Award Amount: \$2,970,407


Study/Product Aim(s)

Aim 1: Determine the effect of arthroscopic Bankart repair with remplissage of a Hill-Sachs lesion versus open Bankart versus Latarjet on patient reported outcomes (Western Ontario Shoulder Instability score [WOSI]), recurrent/re-injury, and RTD/A at 6 months, 1 and 2 years.

Aim 2: Determine the effects of standardized rehabilitation based on surgical procedure and interim strength and functional assessments to predict RTD/A at 6 months and 1 year, and recurrent instability at 2 years.

Approach

A multicenter randomized clinical trial that will enroll military personnel and civilians, between the ages of 17 and 50, with glenoid bone loss between 10-20% after traumatic shoulder instability. Subjects will be randomized to receive either an arthroscopic Bankart with remplissage of a Hill-Sachs lesion, an open Bankart, or a Latarjet procedure. Subjects will then receive procedure-based rehabilitation for 0-12 weeks, followed by progressive rehabilitation. A battery of tests and measures will be conducted at 3, 4, and 6 months post-operatively to identify factors that relate to RTD/A and recurrent instability. Subjects will be followed for 24 months to determine time to return to duty, work, and sports, PROs, and for recurrent instability.



Study Flow Diagram: Individuals presenting with traumatic anterior shoulder dislocation will be screened for inclusion & exclusion criteria. Eligible individuals will be offered participation and will be randomized to 1 of 3 surgical procedures. Rehabilitation following surgery will be procedure specific for 12 weeks then standardized through the end of care. RTD/A testing will be conducted at 4 and 6 months post-operatively.

Accomplishments: Four sites open to enrollment (Pitt) (RIH) (Wake Forest) (Duke University). Recruitment has yielded 4 participants enrolled to date. Refining recruitment methods. Establishing required documents for military sites.

Timeline and Cost

Activities	CY	20	21	22	23	24
Obtain IRB & HRPO Approvals						
Recruitment for Aims 1 & 2						
Follow-up for Aims 1 & 2						
Analyze & Disseminate Results						
Estimated Budget (\$M)		\$0.01	\$0.10	\$0.10	\$1.9	\$0.86

Updated: 21 October 2022

Goals/Milestones:

CY20 Goals - Study start-up

- Obtain IRB approval for coordinating center
- Obtain IRB approval for local sites (6/18 achieved)
- Obtain HRPO approval for coordinating center
- Obtain HRPO approval for local sites (5/18 achieved; 1 in review)

CY21 Goals – Begin Recruitment & Follow-up

- Begin recruitment – target – 10% of total sample (Initiated Jan. 2022) (actual 1%)
- Begin interim follow-up

CY22 Goal – Continue with Recruitment and Follow-up

- Complete recruitment – target recruitment – 80% of total sample
- Continue interim follow-up

CY23 Goal – Complete recruitment and continue with Follow-up


- Complete recruitment – target recruitment – 100% of total sample
- Continue with interim follow-up & initiate 2-year follow-up

CY24 Goal – Complete Follow-up & Analyze & Disseminate Results


- Complete final follow-up
- Analyze data; write & submit abstracts & manuscripts

Budget Expenditure to Date (all values up to the end of September 2022)
 Actual Expenditure: \$456,613.18
 Percentage of Total Budget: 15.37% used as of September 2022.

Appendix B: Study Status update (Civilian Sites)

 Open Versus Arthroscopic Stabilization for Shoulder Instability <i>with</i> Subcritical Bone Loss			Documents					Regulatory Milestones							DATA Training		Research Testing Certifications			SIVs		
			CV	Human Subjects Training	Subcontract	Local Context Form	Consent Forms	Reliance Agreement	Pitt Reliance Submitted	Pitt IRB Reliance Approval	DoD HRPO Submission	HRPO Approval	Protocol Signature Page (PI)	Regulatory Binder Confirmed	Certification Started	Certification Complete	ROM	Strength	Functional Assessment	Site Initiation Visit #1	Site Initiation Visit #2	Action Items Completed
Civilian Site	Principal Investigator	Primary Coordinator																				
University of Pittsburgh	Adam Popchak, PhD	Samia Aslam/ Alec Howard	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
University Orthopaedics/ Lifespan	Brett Owens, MD	Cyndi Chrostek/ Ozair Meghani	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Wake Forest University	Brian Waterman, MD	Nina Cruz-Diaz/ Erica Lynn-Hartzell	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Duke University	Brian Lau, MD	Cassandra Rhodes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
University of Conn.	Corey Edgar, MD	Julie Burland, PhD	✓	✓	✓	✓	✓	✓	✓			✓		✓	✓	✓	✓	✓				
Steadman Philippon Research Institute (SPRI)	Matthew Provencher, MD	Sara Robinson	✓	✓	✓	✓	✓	✓	✓													
University of North Carolina	Alex Creighton, MD	Bradley Lauck	✓				✓	✓	✓													
Ohio State University	Julie Bishop, MD	Andrea Pedroza (current)	✓				✓	✓	✓													
Vanderbilt University	Lance LeClere, MD	Laura Withrow (current)																				
Mayo Clinic - Phoenix	John Tokish, MD	To be named																				
University of Virginia	Stephen Brockmeier, MD	Kaitlyn Shank/ Lizzie Leitch	✓																			

Appendix B (continued) Study Status Update (Military Sites)

 Open Versus Arthroscopic Stabilization for Shoulder Instability <i>with</i> Subcritical Bone Loss			Documents						Regulatory Milestones						DATA Training		Research Testing Certifications			SIVs		
			CV	Human Subjects Training	Subcontract	Local Context Form	Consent Forms	Reliance Agreement	Pitt Reliance Submitted	Pitt IRB Reliance Approval	DoD HRPO Submission	HRPO Approval	Protocol Signature Page (PI)	Regulatory Binder Confirmed	Certification Started	Certification Complete	ROM	Strength	Functional Assessment	Site Initiation Visit #1	Site Initiation Visit #2	Action Items Completed
Military Site	Principal Investigator	Primary Coordinator																				
Walter Reed National Military Medical Center	Kelly Kilcoyne, MD	Jonathan Henry	✓		✓			✓	✓	✓												
San Antonio Military Medical Center	Andrew Sheean, MD	Eric Martinez	✓		✓			✓	✓	✓												
Evans Army Community Hospital	David Tennent, MD	Roiseann Cain	✓		✓																	
Naval Medicine Readiness and Training Command – Annapolis	Robert Waltz, MD	Jacob Dowe	✓		✓																	
Naval Medical Center San Diego	Lucas McDonald, MD	Ashley Hughey	✓		✓	✓	✓	✓	✓	✓												
Naval Medical Center Camp Lejeune	Kyle Nappo, MD	Toni Trujillo	✓	✓	✓			✓	✓													
Keller Army Community Hospital	Michael Donohue, MD	TBD																				