

AWARD NUMBER: W81XWH-20-2-0055

TITLE: Open versus Arthroscopic Stabilization for Shoulder Instability with Subcritical Bone Loss (OASIS Trial)

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CONTRACTING ORGANIZATION: University of Pittsburgh, Pittsburgh, PA

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14. ABSTRACT <p>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 one site. There are 6 military and 5 civilian sites working through local IRB approval. Once they have IRB approval, they will be submitted to Pitt IRB Reliance for onboarding.</p> <p>Research activities over the past year have included finalizing the detailed study protocol, identifying the DSMB and setting the first DSMB meeting and preparing presentation of study for the DSMB. Creating and testing a central study database, a total of 5 investigator meetings; four remote and one in-person. To date, there has been a total of four rehabilitation committee meetings and monthly executive steering committee meetings.</p> <p>At this time, only the coordinating center at the University of Pittsburgh has been approved for recruitment. We anticipate recruitment will start at the University of Pittsburgh by the end of November 2021.</p>		

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:

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	80%
Major Task 2: Subject Recruitment	Pending (December 2021)	-	0%
Major Task 3: Clinical Monitoring & Quality Control Procedures	Pending	-	0%
Major Task 4: Subject Follow-up	Pending	-	0%
Major Task 5: Study Governance	05/19/2020	Ongoing	50%
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%
<ol style="list-style-type: none"> The process of establishing reliance agreements with the sites has begun after receiving DoD HRPO approval 04.02.2021 and the notification to the University of Pittsburgh IRB to initiate the process on 04.09.2021. During the final quarter of the first annual period, a modification to the existing single IRB has been submitted to add 1 external site (pending). Approval of the added site is pending directive comments made after initial review. We anticipate the re-submission to occur by the end of November 2021. This was delayed secondary to the need to process substantive modifications required for the initial DSMB meeting prior to the on-boarding of a site. 				
Coordinating Center HRPO Review & Approval	Months 1-6	01.10.2021	04.02.2021	100%
<ol style="list-style-type: none"> No updates for this reporting period. 				
Finalize Manual of Operations	Months 1-6	03.01.2020	Expected 10.30.2021	95% (version 1)
<ol style="list-style-type: none"> A detailed manual of operations will be completed in October 2021. The manual and its associated protocol are formatted using the guidelines established by the National Institute for Dental and Craniofacial Research. Further updates will be added as sub-committees complete tasks, suggest edits or modifications, and after items discussed at future Investigator's Meetings occur. The manual of operations will be complete, with current version labeled, before recruitment and enrollment begins at the University of Pittsburgh/UPMC. 				
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	70%
<ol style="list-style-type: none"> Representatives from the University of Pittsburgh sIRB have reached out to each site (with the exception of 1 who has yet to identify local IRB representatives) and provided them with the templates of the approved documents. Start-up, non-human subjects subcontract funds have been established to provide sites with startup funds for those that have requested financial support for startup procedures (3 completed: Geneva Foundation, Steadman Philippon-Vail, Wake Forest University) Completed reliance agreements are in place for 1) Wake Forest University and 2) Naval Medical Center San Diego. Pitt IRB Reliance has sent a partially executed reliance agreement to Brooke Army Medical Center, San Antonio on 9.22.2021 Modification to University of Pittsburgh sIRB to add Wake Forest and Naval Medical Center San Diego submitted 10.13.2021 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. 				
Local site HRPO Review & Approval	Months 1-9	04.09.2021	-	10%
<ol style="list-style-type: none"> No change during the final quarter. As approvals for local IRB and ceding of IRB to Pitt occur, HRPO submissions will occur. Important first steps of obtaining local IRB approval and starting the modification process at Pitt has begun and provides some progress in obtaining this ultimate approval. Local modification to add 1) Wake Forest University and 2) Naval Medical Center San Diego to the University of Pittsburgh IRB submitted October 13, 2021. After approval, the HRPO process for those sites will commence. 				

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	25%
<ol style="list-style-type: none"> Have executed 3 “non-human subjects” contracts to cover time and expenses related to study startup and coordinator support. (Geneva Foundation fully executed) (Steadman-Philippon Clinic Vail) (Wake Forest) Full subcontract and data use agreements will be executed after reliance is established and sites are approved to the University of Pittsburgh IRB. 				

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%
<ol style="list-style-type: none"> 100% of forms are finalized for EDC Forms fully built in Electronic Data Capture (EDC) system, expected completion November 2021) 				
Test Data Capture System	Months 1-6	Expected Nov. 2021	Ongoing	0%
<ol style="list-style-type: none"> The development of the Data Capture System is currently in progress. Testing of the data capture system is expected to occur in November 2021. Logic testing of the Data Capture System will occur in early November 2021. Validation and testing of individual forms and the branching logic in the EDC is expected to take place in late November 2021 in preparation for recruitment in quarter 1 of year 2 (December 2021). 				

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"> Rehabilitation guidelines are prepared for distribution to sites that include the rehabilitation guidelines, quick reference tables, and testing procedures with directions. Final approval of the guidelines obtained at the ESC meeting in September 2021 Training videos and supplements for testing procedures prepared and catalogued for reference (Oct. 2021) 				

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	85%
<ol style="list-style-type: none"> Kickoff Investigator Meeting 10.29.2020 Series of 3 Remote Investigator Meeting [1) 05.27.2021; 2) 06.10.2021; 3) 06.24.2021] as lead up to in-person investigator meeting In-Person Investigator meeting Year 1 (07.07.2021) Remote Investigator meeting 4 (09.09.2021) Investigator meetings occurring on quarterly schedule after 4th remote meeting. Materials of past meetings archived and accessible in shared folder for all investigators and support staff. 				

Site initiation visit	Months 1-6	Expected 2 nd quarter of year 2	pending	15%
<ol style="list-style-type: none"> 1. 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). 2. It is expected the site visits will begin the 1st quarter of year 2 (at the University of Pittsburgh). 3. Training webinars set to begin for support staff at each site in November 2021 (11.03.2021; 11.17.2021) 4. Training webinars will set the stage for Site Initiation Visits as recruitment approaches. 				

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	10%
<ol style="list-style-type: none"> 1. A script for a recruitment video that can/will be played for potential participants has been created. 2. The script has been sent to select study investigators to review and edit 3. Once final version is agreed upon, all investigators will record a video of them reading the script. 4. Once all videos are received, we will have a production team piece together a recruitment video. 5. This will be the primary material that will be distributed for recruitment purposes. 6. Small study cards / reminders will be provided for clinical staff (non-patient facing). 				

Major Task 2 – Subject Recruitment	SOW Timeline	Start Date	End Date	Completion Status
Subtask 8: Subject Recruitment & Enrollment				
Subject Recruitment & Enrollment	Months 6-24	Expected Dec. 2021	-	0%
<ol style="list-style-type: none"> 1. Expected that recruitment begins at the University of Pittsburgh site in December 2021. 				

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	Pending	-	0%
<ol style="list-style-type: none"> 1. Will begin in conjunction with the beginning of recruitment and enrollment. 				

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	Pending	-	2%
1. Structure of interim visit established				

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	Pending	-	0%
1. Structure of review for monthly quality control reports established				

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	October 2021	In progress	50%
<ol style="list-style-type: none"> Scheduling of the initial DSMB meeting for study protocol approval is in progress. Initial DSMB meeting to occur November 18th 7-8pm EST. Final edits to the clinical protocol presentation for the DSMB currently in progress. 				

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	-	5%
<ol style="list-style-type: none"> Will use Internal and External Adverse Events Adjudication process Internal and External members to serve on the Adverse Events Adjudication Committee are currently being sought. Procedures for AEs & SAE monitoring and reporting are in place. 				

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	Pending	-	5%
1. Structure and methods of monitoring established.				

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	Pending	-	5%
1. Structure and methods for monitoring established.				

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	Pending	-	0%

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	Pending	-	0%

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	Pending	-	0%

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	70%
<ol style="list-style-type: none"> 1. The Executive Steering Committee has met monthly since May 2020 to discuss and refine study procedures. 2. Regular meetings are held on the 3rd Thursday of each month. 				

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	35%
<ol style="list-style-type: none"> 1. After the initial series of “Kick-Off” Investigator meetings, quarterly meetings are set to take place. 2. During the 4th quarter of year 1, quarterly conference calls for Investigators will be initiated to update on study status. 				

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	10.29.2020	Ongoing	35%
<ol style="list-style-type: none"> 1. Rehabilitation Committee has met on 4 occasions and has established rehabilitation guidelines 2. Forms committee met in-person at Investigator Meeting 3. Other committees (Publications & Ancillary Studies, Quality Control, and Recruitment) will meet as sites start to receive local site and HRPO approval. 				

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	0%

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	07.07.2021 (year 1)	100%
<ol style="list-style-type: none"> 1. Year 1 Annual Investigator Meeting finished 07.07.2021 2. Year 2 Annual Investigator Meeting set to occur in-conjunction with Extremity War Injuries XVI, January 17, 2021 (Washington, DC). 				

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

Ancillary study of the parent OASIS trial received notice of award. 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?

Kelechi Adejumo, PT, ScD is 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 will be responsible for overseeing and conducting quality control of the rehabilitation aspect of the trial and research follow-up visits. Additionally, it is expected that she will propose secondary and ancillary investigations related to or in-conjunction with the OASIS trial.

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. Finalize latest version of Manual of Operations and detailed study protocol with all modifications and suggested edits from DSMB
2. Initiate the execution of subaward and data use agreements with sites that have achieved IRB reliance
3. Pilot test and launch the Electronic Data Capture System
4. Create recruitment video for approval and use
5. Perform site-initiation visit for all sites set to begin recruitment
6. Distribute completed and approved Rehabilitation Guidelines and training materials associated with the research testing procedures

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

1. Collect additional sites’ reliance documents, submit modification(s) to include site(s) to sIRB until all sites have been completed.
2. Initiate the HRPO review and approval process for all sites that have completed the reliance process with the University of Pittsburgh IRB
3. Execute subcontracts and Data Use Agreements at all collaborating clinical sites
4. Continue with quarterly Investigator Meetings
5. Conduct series of webinars for Research Coordinator Training prior to site-initiation visits

C. Initiate Major Task 2: Subject Recruitment

1. Distribute recruitment video after filming and processing
2. Create study cards/reminders to be utilized by clinical staff during recruitment and enrollment
3. Complete site initiation visits and start recruitment at all approved sites
4. Begin subject recruitment and enrollment at all approved (local IRB, sIRB, HRPO) sites.
5. Begin monthly monitoring of recruitment

D. Initiate Major Task 3: Clinical Monitoring & Quality Control Procedures

1. Conduct monthly review of quality control reports
2. Present study to DSMB for approval prior to recruitment
3. Finalize AE and SAE adjudication committee
4. Monitor for protocol deviations and fidelity to randomization

E. Initiate Major Task 4: Subject Follow-up

1. Collect clinical follow-up, physical therapy self-report forms, and PROs of any enrolled participants

F. Major Task 5: Study Governance

1. Continue with monthly Executive Steering Committee meetings
2. Hold Investigators' call on quarterly basis
3. Conduct Research Coordinator webinars and conference calls in preparation for site-initiation visits.

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:

All of the protocol changes were deemed not to have been significant changes and were therefore not submitted to the Department of Defense for prior approval.

Changes in approach and reasons for change:

Changes in the protocol that have been made since the beginning of the project along with the rationale for the change are summarized in the table below. These changes have been submitted for review and approval to the University of Pittsburgh IRB on 8/27/2021 (reviewed at meeting 10/5/2021).

Section	Original Proposal	Proposed Modification	Rationale for Modification
Inclusion/Exclusion	Neuromuscular conditions including seizure disorders	Adding neurologic disorders	Neurologic disorders can also include seizures which frequently lead to shoulder instability events.
Inclusion/Exclusion	Vascular injuries	Clarify vascular injuries by adding “vascular injuries that compromise adequate/normal healing or will interfere with usual course of care.”	The possibility of minor vascular injuries that would not disrupt or change the course of surgical or rehabilitative care is present. Further specificity is provided in the exclusion criteria to explicitly state that the vascular injuries need to be deemed significant enough, by the treating clinician, to have a detrimental effect or interfere with the usual course of surgical or rehabilitative care.
Inclusion/Exclusion	Previous Stabilization Surgery	History of shoulder surgery in involved shoulder – Prior instability surgery that involved: 1) arthroscopic Bankart with remplissage of Hill-Sachs lesion; OR 2) open Bankart; OR 3) Latarjet	Given the high recurrence rate associated with isolated arthroscopic Bankart repairs in the study population, it is anticipated that a high percentage of individuals presenting with subcritical bone loss after an instability event will have had a previous stabilization surgery. However, given that all three procedures that a participant could be randomized to in this trial are substantially different than an isolated arthroscopic Bankart repair, and are used to address more complex instability presentations, a potential participant with a previous isolated Bankart repair would still be eligible. If the previous stabilization surgery for an

			<p>individual is one that is utilized in the study [(1) arthroscopic Bankart repair with remplissage of Hill-Sachs lesion; (2) open Bankart; or (3) Latarjet] they will be deemed ineligible as the trial would not be able to guarantee the participant would be randomized to a procedure that was different than what had failed previously.</p>
<p>Inclusion/Exclusion</p>	<p>Individuals will be excluded if their shoulder instability is considered non-traumatic, multidirectional instability, if they have concomitant shoulder injuries (rotator cuff tears, motor nerve pathologies, osteoarthritis of a Samilson-Prieto grade > 2), if they have neuromuscular conditions including seizures, if they have vascular injuries, or a history of shoulder surgery (prior instability surgery, rotator cuff repair, intra-articular soft tissue surgery), humeral sided bone lesion (Hill-Sachs lesion) that is sufficiently large enough to render the lesion “off-track” even if a bony augmentation procedure would be performed. Additionally, cognitively-impaired adults will not be recruited and enrolled in this study</p>	<p>Individuals will be excluded if:</p> <ol style="list-style-type: none"> 1) their shoulder instability is considered non-traumatic, multidirectional instability 2) they have concomitant shoulder injuries in the involved shoulder (rotator cuff tears requiring intervention [repair], motor nerve pathologies, osteoarthritis of a Samilson-Prieto grade > 2) 3) they have neuromuscular or neurologic conditions including seizures 4) they have vascular injuries that compromise adequate/normal healing or interferes with usual course of care 5) they have a history of shoulder surgery in the involved shoulder (prior instability surgery that involved any of the three interventions to which a participant could be randomized to 'arthroscopic Bankart repair with remplissage of a Hill-Sachs lesion; open Bankart; Latarjet), rotator cuff repair, intra-articular soft tissue surgery) 6) humeral sided bone lesion (Hill-Sachs lesion) that is sufficiently large enough to render the lesion “off-track” even if a bony augmentation procedure 	<p>This is more detailed and encompassing exclusion criteria generated after multiple executive steering committee meetings with study investigators.</p>

		<p>would be performed.</p> <p>7) Any cartilage lesion finding in the involved shoulder that would interfere with usual course of care</p> <p>8) any relevant medical condition that would preclude participation in the research procedures</p> <p>9) known pregnancy at the time of imaging and/or surgery based upon standard of care testing procedures</p> <p>10) any issue with the contralateral shoulder that would preclude participation in research procedures</p> <p>11) any condition in the opinion of the investigator/clinician, that would preclude or limit full participation in the study activities</p> <p>12) absence of a fixed address or no means of contact</p> <p>13) a known inability to be available at all follow-up time points</p> <p>all of the above will not be recruited and enrolled in this study.</p>	
Data Management	REDCap	Removing REDCap and replacing with Electronic Data Capture system	OASIS Trial is not using REDCap, but using an Electronic Data Capture system developed and built at the University of Pittsburgh School of Health and Rehabilitation Sciences (SHRS) Data Center.
Recruitment	5 military sites	6 military sites	An additional military site has been added to change the number of military sites from 5 to 6. We are in the process of attempting to bring this total to 7, but will update as the material are collected to officially on-board the site.
Study Schedule	Activity survey done in conjunction with 3 & 4	Add 5 month to research activity for Return to	It was decided to start the monthly return to activity at 3

	month physical therapy session.	Duty/Activity Assessment, add 5 month hours of .25, add 5 month payment of \$10, change total payment to subject from \$430 to \$440	months and the return to activity survey can be done in conjunction with 3 & 4 month physical therapy testing session. The 5 month survey will be sent electronically in order for subjects to complete since they do not have a 5 month physical therapy visit. Therefore, the additional \$10 payment is required.
Safety of Subjects	5 DSMB individuals	4 DSMB individuals	Justification: DSMB requires at least three members. The committee will include two orthopaedic surgeons (there will be a separate medical monitor not part of the DSMB), one physical therapist and one biostatistician. All members have been identified and the initial DSMB meeting is set for mid October 2021.
Study Procedures/Evaluations	Push-up test performed twice	Push-up test performed once.	Push-up test performed once as standard testing in a military setting.
Consent	Any minor individual that turns 18 during participation in this study will be asked to complete a "Continuation of Consent" form.	Consent process for any minor individual that turns 18 during participation, consent for continued participation will be obtained using the adult consent.	In order to ensure continued consent of participation, once a minor ages to a legal adult (18 years) we will re-consent the participant with the adult consent. We believe re-consent with this process will be more efficient and will allow utilization of previously approved consent documents, both locally and at external sites.
Randomization	Randomization will occur prior to surgical intervention.	Randomization can occur 1-3 days prior to surgery.	This will allow the site time to set the Operating Room schedule. The participant will be informed of what procedure they are receiving prior to or on the day of the surgery, after having given surgical consent to all of the possible surgical stabilization procedures.
Study Procedures/Evaluations	WOSI patient reported outcome was not clear when to be given.	Added WOSI patient reported outcome to Research procedures under PROs.	This is the primary outcome of the study and was listed below in the research activities, but will be given at the time of the PROs.
Study	Strength testing	Crane-scale and the resultant	It was determined the use of a

Procedures/Evaluations	descriptions from involving a Hand-Held Dynamometer	change in positions/procedures associated with the change in equipment	crane-scale and handle would provide 1) a more reliable method of assessing isometric strength, 2) a method that reduces the variability of the assessor, and 3) is 1/10 the cost of the electronic HHD originally planned for use. The change in positions of assessment is due to how the participant can best be tested with the crane scale.
Study Procedures/Evaluations	Not included	Added the Standing Power Throw	The addition of the SPT is to better replicate common testing performed on military personnel as this test is a part of a battery of tests performed in the military.
Study Procedures/Evaluations	PT-case report form (CRF)	Removed the PT-case report form (CRF)	We will not be reaching out to PTs to get them to fill out questionnaires as they are not a part of the study team and establishing agreements with all possible clinics would be impossible. Therefore, we are eliminating this data form. In place of this, we will have the participant complete a self-reported form related to physical therapy.

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

We are behind our initial timeline for the commencement of recruitment and enrollment because we have experienced greater than anticipated delays to the onboard all remote sites, including achieving IRB reliance, DoD HRPO approval, and meeting all regulatory requirements at all institutions. While working on addressing the above issues, we have been slowed in our efforts to finalize all recruitment materials, training materials, and the electronic data capture system. we anticipate that as we have just received approval of the modifications submitted to the IRB that were related to minor edits to the protocol, we will be able to process onboarding modifications that will allow us to start the HRPO approval process for external sites. Further, as we near presentation to and approval from the DSMB of the study protocol, we will be able to initiate local recruitment and enrollment at the University of Pittsburgh (an any other recently approved sites).

Because of the delays in on-boarding sites and obtaining all approvals, we have not met our CY2020 (Quarter 3 & 4 projections) to recruit 132 participants. Therefore, in our quad chart, we have updated the goals for CY 2021 and 2022 to reflect that we will recruit an additional 40 participants during CY 2022 and 2023, and to finish recruitment in Q4 of CY2023. This will push final follow-up back to Q4 of 2024 and into a no cost-extension period of 2025.

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.

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.

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 described in table above & first Continuing Review
10/13/2021	On-boarding Modification (Wake Forest and Naval Medical Center San Diego) submitted to IRB

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**

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)**

Nothing to report.

- **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 the start-up phase of this multicenter clinical trial, including the efforts to obtain IRB and HRPO approval, conducted the conference calls with the Executive Steering Committee, Investigators 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 has been the responsibility of Dr. Popchak

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.

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: 2 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. 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.

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.

Name: Kelechi Adejumo, BPT, ScD

Project Role: Postdoctoral Associate, Research Coordinator responsible for rehabilitation related items
Researcher Identifier (e.g., ORCID ID):

Nearest person month worked: 6 calendar months

Contribution to Project: Dr. Adejumo has worked closely with Drs. Popchak and Irrgang during discussions and production of items related to the rehabilitation arm of the trial. She has assisted with the development of the rehabilitation protocol for distribution, the development of the training materials for the research testing procedures, written sections of the manual of operations, and the rehabilitation protocol.

Name: Kelly Dunn, BA

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

Nearest person month worked: 12 calendar months

Contribution to Project: Ms. Dunn has closely with Drs. Popchak, Dickens, Irrgang, Patterson Gil, and Adejumo 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. Additionally, she took the lead role in developing "site tracker" documents, creating and editing IRB related modifications, set meetings for committees and sub-committees, and assisted with finalizing the study protocol. She has assisted with the development of the Clinical Monitoring, Adverse Events reporting, Data Safety and Monitoring, and set the DSMB meeting. She is also involved in planning, organizing, and attending the coordinator webinars and training sessions.

Name: Robert Winners

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

Nearest person month worked: 3 calendar months

Contribution to Project: Mr. Winners is building the electronic data collection system. In doing so, he has built (or is building) 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.

Name: Benjamin Gibbons

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

Nearest person month worked: 3 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.

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	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
University Orthopaedics / Rhode Island Hospital	Brett Owens	Site PI	Contributions to ESC and Investigator Meetings; Forms review	1 month	Institutional
	Cynthia Chrostek	RC	Preparation of local IRB submission; establishment of non-human subjects subcontract	1 month	Grant (subcontract to University Orthopaedics)
Steadman-Philippon Clinic (Vail)	Matt Provencher	Site PI	Contributions to the Investigator Meetings	1 month	Institutional
	Suzanne Page	RC	Preparation of local IRB submission; establishment of non-human subjects subcontract	1 month	Grant (subcontract to Steadman-Philippon Clinic (Vail))
Brooke Army Medical Center (San Antonio)	Andy Sheean	Site PI	Contributions to ESC and Investigator Meetings;	1 month	Institutional

	Patrick Wood	RC	Preparation of local IRB submission	1 month	Institutional
University of Virginia	None until subcontract established				
Evans Army Community Hospital	Rosieann Cain	RC	Preparation of local IRB submission	1 month	Grant (Geneva Foundation)
Naval Health Clinic Annapolis	Jacob Dowe	RC	Preparation of local IRB submission	1 month	Grant (Geneva Foundation)
Naval Medical Center San Diego	Lucas McDonald	Site PI	Contributions to ESC and Investigator Meetings;	1 month	Grant (Geneva Foundation)
	Ashley Hughey	RC	Preparation of local IRB submission	1 month	Grant (Geneva Foundation)
Wake Forest University	Brian Waterman	Site PI	Contributions to ESC and Investigator Meetings; Forms review	1 month	Institutional
	Nina Cruz	RC	Preparation of local IRB submission	1 month	Grant (subcontract to Wake Forest)

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

Nothing to report.

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 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: 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 <i>(onboard pending)</i> 100 Brewster Blvd Camp Lejeune, NC 28547	*Site 12: Keller Community Army Hospital <i>(onboard pending)</i> 900 Washington Road West Point, NY 10996
*Site 13: Duke University <i>(onboard pending)</i> 2301 Erwin Rd Durham, NC 27710		

*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

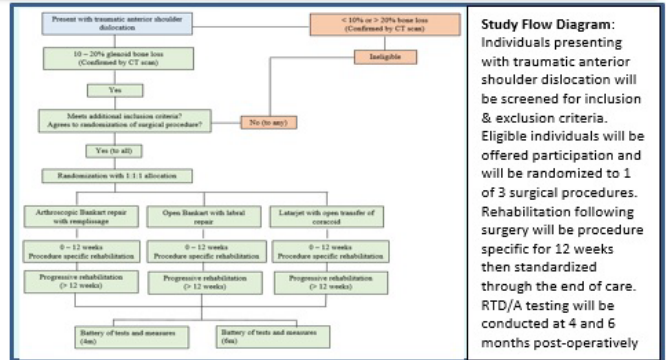
Study/Product Aim(s)

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 45, 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 specific 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: Proceeding through site reliance and HRPO approval. Have received approval of the IRB continuing review. Submitted modification for IRB approval of reliance for 2-sites. DSMB meeting set for November 18, 2021.

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	\$0.19	\$1.2	\$1.02	\$0.55

Updated: 21 October 2021

Goals/Milestones:

- CY20 Goals - Study start-up**
- Obtain IRB approval for coordinating center
 - Obtain IRB approval for local sites (2/11 achieved)
 - Obtain HRPO approval for coordinating center
 - Obtain HRPO approval for local sites
- CY21 Goals – Begin Recruitment & Follow-up**
- Begin recruitment at approved site(s)
 - 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 09/30/2020 - 09/29/2021)
 Projected Expenditure: \$859,286 (total costs)
 Actual Expenditure: \$170,400.37

**Appendix B:
Study Status Update**

#	Site	PI	Coordinator(s)	Sub-contract	Data Use Agreement / CRADA	Pitt IRB			DoD HRPO		Database Certified	Site Initiation Visits				Site Recruitment Began
						Reliance Agreement Sent	Submitted	Approved	Submitted	Approved		Remote SIV		On-site complete	Action items complete	
												Research complete	Rehab complete			
01	Walter Reed National Military Medical Center	Jonathan Dickens	Jonathan Henry			✓	✓									
02	University of Pittsburgh	Adam Popchak	Kelly Dunn Kelechi Adejumo	✓	NA	✓	✓	✓	✓	✓						
03	Rhode Island Hospital-University Orthopaedics	Brett Owens	Cyndi Chrostek	✓		✓										
04	Steadman-Vail	Matt Provencher	Suzanne Liv Page Emily Benstead	✓		✓	✓	✓								
05	Brooke Army Medical Center San Antonio	Andy Sheean	Patrick Wood			✓	✓	✓								
06	University of Virginia	Stephen Brockmeier	Kaitlyn Shank Elizabeth Leitch			✓										
07	Evans Army Community Hospital	David Tennent	Rosieann Cain Whitley Lucio	✓												
08	U.S. Naval Health Clinic Annapolis	Lance LeClere	Jacob Dowe Whitley Lucio	✓		✓										
09	Naval Medical Center San Diego	Lucas McDonald	Ashley Hughey Rebecca Schmidgal Whitley Lucio	✓		✓	✓	✓								

10	Wake Forest University	Brian Waterman	Nina Cruz-Diaz Erica Lynn Hartzell	✓		✓	✓	✓								
11	Naval Medical Center, Camp Lejeune	Kyle Nappo				✓										
12	Duke University	Brian Lau	Emily Reinke Shekeya Council													
13	Keller Army Community Hospital	Matt Posner	Kenneth Cameron Kathy Robinson													