

AWARD NUMBER: W81XWH-19-2-0042

TITLE: Identification of Predictors for Clinical Outcomes in
Femoroacetabular Impingement Surgery

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14. ABSTRACT: To date there are no major findings to report. Femoroacetabular Impingement (FAI) is a complex pre-arthritis hip disorder affecting an increasing number of military personnel and young active individuals in the general population. This disorder has come to the forefront as the most common cause of hip pain, pre-arthritis hip dysfunction and eventual secondary osteoarthritis (OA). FAI can restrict military personnel function during active duty, cause long-term disability, and increase the need for total hip replacement (THR) in our active duty, veteran and general populations. This disorder is characterized by structural deformities of the acetabulum and femur that produce repetitive abutment ("impingement") at the acetabular rim causing intra-articular soft tissue injury (acetabular labrum and articular cartilage), progressive joint degeneration and development of secondary OA over time. FAI is currently the focus of intense interest directed at surgical treatment to relieve pain, enhance function and potentially delay or prevent OA. Despite the surge in diagnosis and enthusiasm for surgical interventions, there is a paucity of clinical evidence to guide treatment. Our grant project specifically seeks to cover the FY2018 PRORP-CTRA surgical care focus area of osteoarthritis. The overarching goal of the proposed investigations is to provide novel clinical evidence to inform future surgical strategies for treating FAI, and improve the clinical outcomes of FAI surgery.					
15. SUBJECT TERMS Femoroacetabular Impingement (FAI); Patient-Reported Outcomes (PRO); see Table of Keywords (page 4)					
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Table 1. Abbreviations and Keywords Within the Report (Added by WUSTL For Report)

ANCHOR	Academic Network of Conservational Hip Outcomes Research
CHEO	The Children’s Hospital of Eastern Ontario
CR	Continuing Review
CT	Computerized Tomography
DCC	Data Coordinating Center/Data Management Center (located at WUSTL)
DoD	Department of Defense
FAI	Femoroacetabular impingement
FE	Fully Executed
FERPA	Family Educational Rights and Privacy Act
FU	Follow-up
HIPPA	Health Insurance Portability and Accountability Act
ICD	Informed Consent Document(s)
IRB/REB/HRPO	Institutional Review Board/Research Ethic Review Board/Human Research Protections Office
MOP	Manual of Operations
NCE	No Cost Extension
PI	Principal Investigator
PR	Progress Report
PRO/PROs/PROMs	Patient-Reported Outcomes
PROMIS	Patient-Reported Outcomes Measurement Information System
QA/QC	Quality Assurance Quality Control
REDCap	Research Electronic Data Capture
REDCap FR	Research Electronic Data Capture, French Version
SAMMC	San Antonio Military Medical Center
SIV	Site Initiation Visit
SOW	Statement of Work
T8	Minimum 8-year time point
TOH	The Ottawa Hospital
TSRH	Texas Scottish Rite Hospital
UM	University of Michigan
UW	University of Wisconsin - Madison
USAMRDC OHARO OHRO	U.S. Army Medical Research and Development Command Office of Human and Animal Research Oversight (OHARO's Office of Human Research Oversight)
WUSTL	Washington University Washington University School of Medicine

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose & scope of the research.*

FAI is a condition of the hip characterized by abnormalities of the acetabular rim (hip socket) and the femoral head/neck (hip ball) region. With hip motion the femoral head and neck “bump” the acetabular rim and over time, this repetitive contact injures the hip joint, causes pain and leads to secondary osteoarthritis (OA). This disorder commonly affects military personnel and young active individuals in the general population, but also affects middle-aged and elderly patients as the disease progresses and OA develops. In fact, FAI is thought to be the most common cause of hip OA. FAI can restrict military personnel function during active duty, cause long-term disability, and increase the risk for hip OA and total hip replacement in our active duty, veteran and general populations. This condition is currently the focus of intense interest directed at surgical treatment to relieve pain, enhance function and delay or prevent OA. Despite the increase in diagnosis and enthusiasm for surgery, there is a major need to improve FAI treatments. To develop improved FAI treatments, this study will identify predictors of FAI surgery outcomes. Young patients with symptomatic, pre-arthritis FAI are being studied. This patient population is most commonly between 14 and 40 years of age, is highly active and has hip pain and limitations due to FAI. Recent research has shown that 87 percent of active military personnel with hip symptoms have FAI. Our study is being performed by the *Academic Network of Conservational Hip Outcomes Research (ANCHOR)* study group, to include two patient cohorts; FAI-1: This first cohort had surgical treatment of FAI between 2008 and 2012 and has been followed at a minimum 8 years. The analysis of this established ANCHOR cohort will have rapid impact on FAI treatment; FAI-2: This second (new) cohort is characterized by novel imaging techniques, standardized arthroscopic procedures and contemporary outcome measures. It is providing novel clinical evidence to optimize future surgical treatments. The findings from this second cohort will be introduced to the scientific and orthopaedic communities two to four years after study initiation. Given the major disease burden of FAI spanning pre-arthritis disease in young active duty members to endstage disease in veterans and the general population, there is an urgent need to focus on improved FAI treatments. This study will provide novel findings to improve the clinical outcomes of FAI surgery, optimize soldier return to duty, and minimize lifelong FAI disease progression in our career military, veterans and the general population.

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

Answer for YR 4 Annual: Please Refer to *Abbreviations: Table of Key Words within the Report* on page 4.

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project? *List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

What was accomplished under these goals? *For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

Answer for YR 4 Annual:

- **Specific Aim 1:** Determine the predictors of mid-term PROs and treatment failures in an established prospective longitudinal cohort of FAI surgeries (ANCHOR FAI-1 cohort).
- **Specific Aim 2:** Determine the impact of three-dimensional femoral and acetabular morphology on PROs at short-term FU in a novel prospective longitudinal cohort of arthroscopic FAI surgery (ANCHOR FAI-2 cohort).
- **Specific Aim 3:** Determine if the new Patient-Reported Outcome Measurement Information System (PROMIS) correlates with legacy PROs in patients undergoing FAI surgery.

Specific Aim 1, 2, and 3 Accomplishments: Please refer to SOW Table below for specific details.

Revised SOW Referenced in Formal Award/Contract: Section 10.ii <u>Project Performance Information</u>				
Major Task 1: FAI-1 cohort FU	Timeline (in Months)	Year 4 PR Completion Status		
Subtask 1: Prepare Regulatory Documents, Research Protocol & Negotiate Contracts/Subawards with DoD & All Participating Centers				
Negotiate DoD Contract & Site Sub-Award Agreements	1-3	Milestone Achieved with all performance centers; NEW: NCE (YR5) subaward modifications distributed to all performance centers.		
<i>Milestone Achieved: Contracts & All Sub-Award Agreements FE</i>	3	Milestone Achieved: FE subawards completed at all sites; NEW: NCE (YR5) subaward modifications distributed to all performance centers.		
Finalize study protocol/assent & consent docs	1-3	Completed at all performance sites		
Coordinate with ALL Performance Sites for: A. Submission of protocol & ICDs; B. IRB Review & approval	1-3	Complete. Local, IRB approval granted to each performance sites Please see Table 2 below for specifics.		
Coordinate with Sites for Military IRB review (USAMRDC OHARO OHRO)	1-3	Complete: Initial USAMRDC OHARO OHRO approval granted to all performance sites. Please see Table 2 below for specifics.		
<i>Milestone Achieved: IRB Approval granted at each participating site (ANCHOR FAI-1 & ANCHOR FAI-2)</i>	3	Table 2. Initial, local IRB & DoD OHARO OHRO Approval		
		Performance Site	Local IRB	USAMRDC OHARO OHRO
		1. WUSTL	Approved	Approved
		2. Beaumont	Site Closed on 12/9/2022	
		3. BocaCare	Site Closed on 05/18/2023	
		4. BCH	Approved	Approved
		5. CHEO & 6. TOH (combined REB)	Approved	Approved
		7. CHU de Quebec	Approved	Approved
		8. Mayo Clinic	Approved	Approved
		9. SAMMC	Approved	Approved
		10. TSRH	Approved	Approved
		11. TCO	Approved	Approved
		12. U of Colorado	Approved	Approved
		13. U of Iowa	Approved	Approved
		14. U of Michigan	Site Closed on 01/20/2023	
15. U of Wisconsin	Approved	Approved		
Submit amendments, adverse events and protocol deviations as needed	As Needed	Since submission of YR1 PR, no serious adverse events <i>directly related to study procedures</i> , have been reported. Protocol deviations, in the form of PROM non-completion/non-compliance, is tracked by REDCap's robust, built-in audit trail functionality which logs all user activity/inactivity for viewing and/or exporting.		
Coordinate with Sites for annual IRB report for CR review (from all sites)	Annually	For sites not operating under the <i>2018 Common Rule</i> , annual CR approval (local and USAMRDC OHARO OHRO) is ongoing.		
<i>Milestone Ongoing: CR IRB approval granted at <u>each</u> participating site</i>	Annually	Milestone Ongoing: For sites not operating under the 2018 Common Rule, annual CR approval (local and USAMRDC OHARO OHRO) is ongoing.		
Subtask 2: ANCHOR FAI-1 cohort clinical FU (minimum 8-yr FU PRO data)				
Determination of patients with active 7-10 yr. clinical f/u	1-3	Milestone Achieved: In YR1, minimum T8 FU eligibility was determined by WUSTL and Site PI/Coordinators were each provided their site's eligibility list.		
Identification of patients reaching endpoints	1-3	Milestone Achieved: ANCHOR FAI-1 collection of T8 FU PROM data is complete. Please see Table 3 below for site specific information and details.		

Revised Statement of Work Referenced in Award/Contract: Section 10.ii Project Performance Information (cont.)

Major Task 1: FAI-1 cohort FU (cont.)	Timeline (in Months)	Year 4 PR Completion Status			
<p><i>Milestone Achieved: List of eligible ANCHOR FAI-1 patients developed and disseminated to each site</i></p>	3	Table 3. ANCHOR FAI-1 Cohort Milestone Achievement T8 Follow Up At Closure of Enrollment on 3/7/2022			
		Performance Site	Total Hips	# of Hips Reaching an End Point	% Reaching End Point
		1. WUSTL*	357	293	82.07%
		2. Beaumont	155	47	30.32%
		3. BCH*	35	29	82.86%
		4. Colorado*	32	17	53.13%
		5. Mayo Clinic*	41	34	82.93%
		6. TSRH	33	9	27.27%
		7. TCO	57	20	35.09%
		8. Ottawa*	50	40	80%
		All Site Total	760	489	64.34%
*Total for Top 5 Sites being Used In Analysis	515	413	80.12%		
Subtask 3: Central site FU (if treating site unable to track patient)					
Phone contact	4-24	Enrollment in DoD, through consent “sharing” of T8 FU PRO data, completed on 3/7/2022. Please see Table 3 above for site specific information and details.			
Mail and email contact	4-24				
Advanced patient search strategies	4-24				
<i>Milestone Achieved: Eligible, locatable, & willing ANCHOR FAI-1 patients complete T8 FU</i>	24	Milestone Achieved: <u>Impact of COVID-19 on ANCHOR FAI-1 “data sharing” enrollment</u> : Widespread challenges greatly impacted our ability to complete this milestone by 24M. Final site enrollment numbers achieved on 3/7/20233 (Table 3).			
Major Task 2: FAI-1 Data Analysis					
Data cleaning and quality checks	4-36	NEW: Majority of cleaning of baseline and FU data (<i>collected to date</i>) is complete. As more FU data is collected and/or outliers appear when data is being readied for analysis, additional quality checks and cleaning will be performed.			
Univariate data analysis	36-42	The Executive and Data Management Committees continue to develop and refine their statistical plans to optimize the analytical models and subgroup analysis for use in determining the predictors of mid-term PROMs and treatment failures in the established ANCHOR FAI-1 cohort.			
Multivariate data analysis	36-42				
<i>Milestone Achieved: Report Results of Data Analysis</i>	42-48	NEW: Please see “Other, Ongoing Achievements...” section of this report for a listing of written abstracts presented and/or submitted to impactful orthopaedic conferences.			
Major Task 3: FAI-2 Study Planning & Coordination	Timeline (in Months)	Year 4 PR Completion Status			
Subtask 1: FAI-2 Study Plan Refinement and Completion					
Central Site imaging review protocols	1-3	Completed by WUSTL in YR1			
Surgeon & research coordinator standardization, education, & in-person pre-study meeting	1-3	Completed YR 1 (Nov. 2019) during study-wide standardization and education in-person meeting in Chicago (attended by Site PIs and Coordinators).			
Imaging Repository Testing at each site	1-3	Completed: Low dose CT testing/Dyonics compatibility at all sites.			
<i>Milestone Achieved: FAI-2 study plan & implementation process finalized</i>	3	Milestone Achieved			

Revised Statement of Work Referenced in Award/Contract: Section 10.ii Project Performance Information (cont.)

Major Task 4: FAI-2 Study Enrollment	Timeline (in Months)	Year 4 PR Completion Status
<p>Active patient enrollment and FU</p> <p>(Initial FAI-2 enrollment completed in December 2022. Active FU continues for enrolled participants through their 2YR follow-up time point)</p>	<p>4-42</p>	<p>Prospective ANCHOR FAI-2 enrollment initiated at 13/15 sites with formal, prospective enrollment completed on December 31, 2022.</p> <ol style="list-style-type: none"> 1. WUSTL – Launched Feb 2020 2. Beaumont (FU of T8 FAI-1 cohort only) Formal local & ORP OHARO OHRO closure on 12/9/2022 3. BCH – Launched September 2020 4. Boca Care Orthopedics: Site never launched; Formal local & ORP OHARO OHRO closure on 5/18/2023 5. SAMMC – Launched September 2020 6. TSRH - Launched Sept. 2020 / Full launch Feb 2021 7. U of Colorado – September 2020 8. U of Iowa – Launched August 2020 9. Mayo Clinic – Launched October 2020 10. Colorado – Launched February 2021 11. CHU de Quebec – Launched February 2021 12. TCO – Full Launch March 2021 13. CHEO TOH – Launched August 2021 14. U of Wisconsin – Launched September 2021 15. U of Michigan: Launched November 2021; Formal closure with OHARO OHRO on 1/20/2023
<p>Data quality checks (ongoing)</p>	<p>4-42</p>	<p>In April 2021, Dr. Amber Salter accepted a faculty position at UT Southwestern Medical Center. To retain her scientific and statistical expertise, WUSTL fully executed a subaward after prior approval was granted by both our Grants Officer, Teresa Parker-Reeser, and our Grants Specialist, Jennifer Shankle.</p> <p>NEW: Dr. Amber Salter’s subaward concluded on Sept. 29, 2023.</p> <p>Dr. Susan Thapa has assumed all work activities, deliverables, and timetables for the project as previously defined in Dr. Salter’s SOW. She will continue to help guide the scientific direction for the project’s robust statistical planning and data analysis. Additionally, she will:</p> <ol style="list-style-type: none"> 1. Provide oversight of the study’s established electronic database, REDCap, and implement programming activities necessary to maximize the accuracy and completeness of entered data. 2. Provide expert oversight to REDCap Data Manager, Tanner Thornton, regarding: <ul style="list-style-type: none"> • QA/QC activities through report generation and refinement 3. Assist leadership with data correlation, power, and subgroup stratification analysis; Statistical and strategic input in the writing and planning of abstracts and manuscripts derived from this research project; Perform and/or supervise complex statistical analyses and create or provide input to statistical reports; Provide internal statistical review and technical guidance as requested; Perform analyses to support programmatic activities; Provide expertise in managing and/or analyzing large complex datasets. 4. Participate & provide expertise and guidance on the monthly Executive and Data Management Committee ZOOM calls. <p>Specific YR4 data cleaning tasks are either listed below or included in Table 8:</p> <p>1. Ongoing QC of real-time data being entered at each performance site through:</p> <p>1A. Ongoing analysis of data accuracy and completeness: REDCap’s built-in quality control features help ensure accurate and complete data. The system keeps a log of who enters and/or changes data, a feature that permits DCC to discuss -with the data enterer- any concerns regarding a particular data item.</p>

Other QC measures for ongoing collected of FU data:

1. Range checks to flag values outside a pre-defined acceptable range. Quality checks for outliers/improper values tied to “logical consistency”. These are flagged for review and potential modification.
2. Accepting only a predefined set of values for categorical measures.
3. Form tracking that facilitates easy identification of site/staff member who entered specific data if a data correction is discovered.
4. Visual checks of completed forms for site staff to use to confirm completeness and reasonableness after each form is filled out.

1B. Ongoing Data audits: Specific forms/fields are identified by leadership and fully queried for completion results.

1C. Ongoing Training and Certification of New Personnel:

1. DCC continues to ensure all new, performance site staff are collecting data in accordance with REDCap system requirements. With the ongoing level of Coordinator turnover, standardized training remains a key focus for DCC to help ensure that new staff gain appropriate familiarity with REDCap to permit competency with data entry procedures.

To further accomplish these goals, DCC:

2. Participates in all SIVs to discuss date-entry details & standardization of data collection procedures. During each performance site ZOOM SIV call, DCC provides visual aids (power point slides) that cover data collection procedures.
3. Certifies new site staff on: Familiarity with REDCap; Required data-entry competencies and knowledge within our “practice” database environment before access to the “live” project is granted.
2. Ensures that unique, user IDs are included on each electronic data form to facilitate data entry corrections detected by the DCC query system. REDCap data modifications are tagged with timestamp & User ID for ease of identification.
3. Maintains a site-specific list of certified personnel with current, active, access to REDCap through each site’s data access group (DAG).

1D. YR4: Continuation of all SAS-Generated Data Summary Reports: DCC has developed a series of weekly reports that is shared with each Site PI and Coordinator every Monday to better focus their follow-up data collection efforts.

1. **Window Report | Data Progress Collection Report:** Used to focus FU efforts in contacting participants who are about to “exit” each study window (see left for report example). After the full report is emailed to each site, WUSTL staff sends a separate email alerting the Site PI and Coordinator of all participants who will “exit” a window within the next several weeks. This additional scrutiny is intended to help increase FU rates to 80% or higher at each performance site.

<i>Nearing End of 1 Year Window</i>		
Surgeon name	ANCHOR ID	End of Window
John Clohisy, MD	WU1R-5362	10/10/2023
Jeffrey Nepple, MD	WU1L-5428	10/15/2023

2. **Site Remuneration Report:** Using specific and required data points – and their completion dates - this report determines when a site should be reimbursed for each consented participant.
3. **ANCHOR FAI-1 Site Productivity:** Last report generated in March 2022 when T8 FU PRO enrollment concluded.

Enrollment audit – Months into enrollment

8, 12, 16, 18

Please see **Table 4** below for current FAI-2 enrollment numbers.

Table 4. ANCHOR DoD FAI-2: Amended Enrollment and Data Collection Progress Report Through September 27, 2023

Site - Target Enrollment	On Study	Surgical day data	Post-Operative PROMs Eligible and Collected							
			3M Eligible	3M Data Collected	6M Eligible	6M Data Collected	1Y Eligible	1Y Data Collected	2Y Eligible	2Y Data Collected
BCH - 80	74	74	74	53 (72%)	74	49 (66%)	65	42 (65%)	37	15 (41%)
Quebec - 30	25	25	25	23 (92%)	25	25 (100%)	18	16 (89%)	1	0
Mayo - 100	116	116	116	97 (84%)	116	77 (66%)	108	75 (69%)	63	32 (51%)
Ottawa - 15	17	17	17	14 (82%)	17	15 (88%)	15	12 (80%)	0	0
CHEO - 15	20	20	20	15 (75%)	20	16 (80%)	18	13 (72%)	4	0
SAMMC -30	27	27	27	24 (89%)	27	23 (85%)	24	20 (83%)	9	3 (33%)
TSRH - 30	9	9	9	9 (100%)	9	9 (100%)	8	8 (100%)	5	4 (80%)
Twin Cities - 100	66	65	66	64 (97%)	66	57 (86%)	62	51 (82%)	13	7 (54%)
Colorado-30	27	26	27	16 (59%)	27	11 (41%)	24	11 (46%)	5	1 (20%)
Iowa -150	126	125	126	119 (94%)	126	119 (94%)	114	97 (85%)	71	49 (69%)
WUSM-125	109	109	109	92 (84%)	109	95 (87%)	105	85 (81%)	60	38 (63%)
WISC - 65	79	79	79	66 (84%)	79	69 (87%)	65	56 (86%)	0	0
Total	695	692	695	592 (85%)	695	565 (81%)	626	486 (78%)	268	149 (57%)
<p><i>Milestone Achieved: Report initial, per site FAI-2 Enrollment</i></p>			18	<p><u>Milestone Achieved:</u> Initial enrollment of our new, prospective ANCHOR FAI-2 cohort concluded on Dec. 31, 2022 (M39 of grant). <u>Ongoing:</u> 1yr - 2yr follow-up of all enrolled ANCHOR FAI-2 participants. <u>Impact of COVID-19 on achieving full enrollment by month 18:</u> The world-wide emergence of the novel coronavirus, and its infection resurgence through all variants, significantly impacted orthopedic surgery practice and in-person clinic visits at each performance site. Throughout the U.S. and Canada, the initial impact to clinical research occurred between March-June 2020 when all elective, surgical procedures and non-emergency in-person clinic visits were completely halted. The long-term economic impact from the virus - through staff layoffs, furloughs, job eliminations, and staff turnover - continued to cause reduced procedural volumes. Our rapid deployment of workflow modifications to enable verbal, virtual and/or REDCap-enabled consenting, clinic prep, and virtual (telemedicine) helped to minimize participant/staff infection risk and disruptions based on diversion of healthcare resources.</p>						
<p>Major Task 5: FAI-2 cohort baseline & follow-up data</p>			<p>Timeline (in Months)</p>	<p>Year 4 Completion Status</p>						
<p>Subtask 1: ANCHOR site clinical Follow Up</p>										
<p>Phone contact</p>			4-42	<p><u>REDCap Automated Survey Invitation Function for PROMs collection:</u> As stated earlier, when a specific study window opens, REDCap delivers an automated <i>survey invitation</i> to each participant’s master email address. REDCap then sends a follow-up <i>survey reminder</i> to the participant every 5 days/up to 5 times if s/he does not complete their PROMs after the <i>initial survey invitation</i> is received.</p>						
<p>Mail and email contact</p>			4-42	<p>Following this automated <i>survey invitation</i> process, Site Coordinators have been trained to use the weekly report (sent every Monday) to focus contact efforts with their participants. This added attention is meant to increase follow-up PROMs completion rates to 80% or higher at each performance site. NEW: Our approved, NCE extends the project through September 2024 allowing the 1-2yr follow-up PROMs collection to continue towards achievement.</p>						

Subtask 2: Central site Follow Up		
Phone contact	4-42	To date, no performance site has activated WUSTL to assist with centralized FU/advance search strategies (to re-locate their participants). WUSTL remains ready to assist each performance site, if activated.
Mail and email contact	4-42	
Advanced patient search strategies	4-42	
<i>Milestone Achieved: If activated to assist participating site with centralized FU, report clinical outcome metrics assessed at postoperative time points</i>	4-42	To date, no performance site has activated WUSTL to assist with centralized FU/advance search strategies (to re-locate their participants). WUSTL remains ready to assist each performance site, if activated.
Radiographic & CT transfer to central site (WUSTL)	4-42	<u>Ongoing:</u> In accordance with transfer guidelines and timeframes elucidated within the study's protocol, all required post-op imaging data continues to be transferred to WUSTL BOX (a cloud-based file storage & collaborative tool system providing automatic backup & encryption of data in transit/at rest. Provides both FERPA and HIPAA compliance. 256-bit Secured Socket Layer (SSL) encryption is used on the data between the end user and Box. SSAE 16 Type II security standards, ongoing audits and 24x7x365 monitoring and video surveillance. Data is stored on a secure internal storage cluster behind an enterprise-grade firewall, with redundant connections to multiple Internet backbones).
Radiographic and CT analysis for all site data	4-42	<u>Ongoing Process of Analysis:</u> In accordance with study deliverables, all newly transferred imaging are WUSTL-reviewed to ensure timely and accurate FAI hip impingement evaluation. Dyonics, a software application developed specifically for CT orthopaedic analysis of the Hip and Pelvis, is being employed for this evaluation. At the end of each month, WUSTL provides each Site PI and Coordinator their monthly <i>Imaging Report</i> defining all transferred/missing images per enrolled subject, per post-op time point.
<i>Milestone Achieved: Report Results of CT transfer and analysis (by sites)</i>	20	<u>Ongoing:</u> This milestone represents continuous and time-sensitive study procedures related to image transfers and QC analysis. Ongoing work efforts continue in accordance with site deliverables elucidated within each site's SOW. For current image transfer progress, please refer to Tables 5, 6 and 7 below. NEW: Our approved, NCE extends the project through September 2024 and will allow these 1-2yr follow-up imaging collection milestones to continue to continue towards achievement.

Table 5. Overall Imaging Report Through September 30, 2023

Site Name	Cases Enrolled	Surgery Completed (SC)	N = % of <i>Surgery Complete</i> Images Received at WUSTL			
			X-Rays Rec'd	Low Dose CT	Hip Scope	Fluoroscopy
Colorado	27	27	25	25	21	22
Boston	74	74	74	74*	74*	74
Mayo Clinic	116	116	116	116*	116	116
Iowa	126	126	126	126*	126	126
SAMMC	27	27	27	27	27*	27
TSRH	9	9	9	9	9	9
Twin Cities	66	66	66	66*	66*	66
WUSTL	109	109	109	109*	109*	109*
Quebec	25	25	25	25	25	25
CHEO	20	20	20	20	20*	20
Ottawa	17	17	17	17	17*	17
Wisconsin	79	79	79	79	79	79
Total	695	695	693 (99)	693* (99)	689* (99)	691* (99)

* Case exam centralized, or exam recorded as "not done/not accessible/not saved" post site confirmation

Table 6. Follow-Up Imaging Report Through September 30, 2023

Site	Cases Enrolled	Eligible for 3M	3M Archived	3M Protocol Compliant	Eligible for 1YR	1 YR Archived	1 YR Protocol Compliant
Colorado	27	27	23	2	25	--	--
Boston	74	74	28	2	67	14*	11
Mayo Clinic	116	116	116*	92	113	--	--
Iowa	126	126	104	104	118	66*	56
SAMMC	27	27	22	17	25	1	1
TSRH	9	9	9	3	8	6	6
Twin Cities	66	66	66*	58	65	4	4
WUSTL	109	109	109*	73	106	85*	31
Quebec	25	25	25	25	21	13	13
CHEO	20	20	20*	15	18	9	9
Ottawa	17	17	17*	12	17	9	9
Wisconsin	79	79	78*	44	71	22	21
Totals	695	695	617*	447	654	229*	161

Table 7. Overall Preoperative CT Protocol Compliance Report Through September 30, 2023

Site Name	Cases Enrolled	Surgery Completed	CT Complete (CC) n	Protocol Complaint n (% of CC)	Protocol Non-Compliant (PNC) or CT Not Done (ND) Prior to Surgery (n)	CT Not Centralized, QI/QC Checked, or Not Yet Ordered (n)
Colorado	27	27	25	22 (88)	3 - PNC	2
Boston	74	74	72	70 (97)	2 - PNC 2 - ND	0
Mayo Clinic	116	116	115	109 (95)	6 - PNC 1 - ND	0
Iowa	126	126	125	123 (98)	2 - PNC 1 - ND	0
SAMMC	27	27	27	27 (100)	0	0
TSRH	9	9	9	9 (100)	0	0
Twin Cities	66	66	65	61 (94)	4 - PNC 1 - ND	0
WUSTL	109	109	108	106 (98)	2 - PNC 1 - ND	0
Quebec	25	25	25	25 (100)	0	0
CHEO	20	20	20	20 (100)	0	0
Ottawa	17	17	17	16 (94)	1 - PNC	0
Wisconsin	79	79	79	69 (87)	10 - PNC	0
Total	695	695	687	657 (96)	30 PNC (4) 6 ND	2

Major Task 6: FAI-2 Data Analysis		Timeline (in Months)	Year 4 Completion Status	
Data cleaning and quality checks		42-48	<p><u>Completed (baseline):</u> Data cleaning continues as WUSTL DCC refines QC/QA measures. Previously, <i>Data Auditing Query Reports</i>, identified missing data forms and/or missing key item-level data points were produced monthly and provided directly to each performance site. These DCC reports are securely housed on WUSTL BOX for ease of accessibility by all Site Coordinators. As these reports were completed, data was either accounted for, or understood and confirmed to be true missing. These baseline data reports included, but were not limited to: Missing baseline PROMs <i>completion dates</i>; Missing <i>Surgeon intraoperative</i> form; Missing <i>Dates for surgery and Day of Birth</i>; Missing <i>Surgeon Follow-up Form</i>; Missing <i>Complications Form</i>.</p> <p><u>Ongoing:</u> Other QC measures that continue to clean newly added study FU data <u>include:</u> Range checks that flag values outside a pre-defined acceptable range; Accepting only a predefined set of values for categorical measures; All data forms contain the identification number of the person who completed the form, facilitating easy access to the source if there are problems with a form.</p> <p>Please see Table 8 for specific, baseline data cleaning steps completed or in-process.</p>	
Step	Table 8. SAS- Generated Progressive Baseline Data Query Cleaning (Missing Data)			
	Title of Data Query Report	Calendar Date Query Report Distributed	Calendar Date for Completion of Data Query Cleaning	
1	Basic demographic data (gender, age, BMI)	2/17/2023	2/28/2023	
2	Preoperative XR compiled/transferred	2/24/2023	3/03/2023	
3	Preoperative CT compiled/transferred	2/24/2023	3/03/2023	
4	<i>Surgeon Intraop</i> form data	3/20/2023	3/31/2023	
5	<i>Surgeon preop (baseline)</i> data	6/07/2023	6/30/2023	
6	<i>Intraop flouro images</i> compiled/transferred	7/01/2023	Proposed date: Oct 31, 2023	
7	<i>Intraop images</i> compiled/transferred	7/01/2023	Proposed date: Oct 31, 2023	
Step	Data Verification at Time of Analysis Preparation			
8	Ongoing direct contact with Site PIs and Coordinators when confounding data points are discovered in datasets being readied for analysis (e.g. additional disease process [EDS] or other <i>associated disease processes</i> coded as present).			
Univariate data analysis		42-48	Executive and Data Coordinating/Management Committees are discussing plans for FAI-2 statistical data analysis once data collection is complete.	
Multivariate data analysis		42-48	NEW: Our approved, NCE extends the project through September 2024 and will allow these milestones to continue towards achievement.	
<i>Milestone Achieved: Report Results of Data Analysis</i>		42-48	Executive and Data Coordinating/Management Committees are discussing plans for FAI-2 statistical data analysis once data collection is complete. NEW: Our approved, NCE extends the project through September 2024 and will allow these milestones to continue towards achievement.	
Major Task 7: Data Analysis of PROMIS vs. Legacy PROs		Timeline (in Months)	Year 4 Completion Status	
Data cleaning and quality checks		7-42	<p>While COVID-19, and all sub-variants, had a significant impact on orthopedic surgery practice and in-person clinic visits resulting in a slower rate of enrollment than SOW, initial ANCHOR FAI-2 is complete and 1yr-2-yr FU continues.</p> <p>As follow-up PROM data is collected from participants, QC data check reports will continue to assist performance sites with their data cleaning procedures.</p>	

Correlation analysis for PROMIS subdomains vs legacy PROs	30-48	While these major tasks/milestones were delayed due to COVID-19s negative impact on our initial ANCHOR FAI-2 enrollment, the Executive and Data Coordinating and Management Committees are beginning to analyze specific segments of the collected data while actively discussing their robust plans for more powerful and exhaustive statistical data analysis. NEW: Our approved, NCE extends the project through September 2024 and will allow these milestones to continue towards achievement.
Subgroup stratification analysis	30-48	
<i>Milestone Achieved: Report Results of Correlation & Subgroup Stratification Analysis</i>	30-48	
Data reporting; Manuscript prep	30-48	
<i>Milestone Achieved: Report Manuscript Preparation Results</i>	24-48	

Other, Ongoing Achievements since our last quarterly progress report:

- **New: MHSRS Symposium 2023:** Dr. John Clohisy attended and presented our accepted poster: *First Generation FAI Surgery: Midterm Outcomes of a Multicenter North American Cohort* during Poster Session 3 on Wednesday, August 16th as part of breakout session: Multifactorial Problems Contributing of Musculoskeletal Injuries in the Military.
- **New: 2024 Annual Conference: American Orthopaedic Society for Sports Medicine (AOSSM):** The following four (4) DoD ANCHOR FAI-2 abstracts were submitted for podium/poster consideration:
 1. Changes in the Characteristics of Patients Undergoing FAI Surgery: A Prospective Multicenter Cohort Comparison of Early and Modern FAI
 2. Activity Level Assessments at Presentation Significantly Underestimate Pre-Injury Activity Levels in FAI Patients
 3. High Prevalence of Elevated Beighton Scores in Females Undergoing FAI Surgery
 4. Does Patient Resiliency Influence Patient-reported outcomes at Presentation in Symptomatic FAI
- **New: 2024 Annual Conference: American Academy of Orthopaedic Surgeons (AAOS):** The following abstract was accepted for POSTER presentation:
 1. Patient reported outcomes and satisfaction at minimum 8 year follow-up among a prospective, multicenter cohort study of patients undergoing first generation FAI surgery
- **New: 2024 Annual Conference: Pediatric Orthopaedic Society of North America (POSNA):** The following three (3) DoD ANCHOR FAI-2 abstracts were submitted for podium/poster consideration:
 1. Does Elevated Beighton Score Correlate with Differences Hip Morphology in Adolescent Patients with Femoroacetabular Impingement
 2. Differences in Femoroacetabular Impingement Morphology on CT between Adolescent Males and Females with Symptomatic
 3. FAI Predictors of Anxiety and Depression in Adolescent Femoroacetabular Impingement Patients
- **New:** Site Initiation Visit with new Coordinator at the University of Colorado performance site (9-30-23)
- **Ongoing:** Follow-Up of all eligible participants at their 1yr – 2yr study time points
- **Ongoing:** IRB Continuing Reviews: On behalf of each performance site, WUSTL coordinates all USAMRDC OHARO OHRO CR submissions.
 - A. **Updated:** Since our last PR, the following performance sites have had their yearly CR's submitted and approved by USAMRDC OHARO OHRO:
 1. CHEO/TOH: Approved on 8/13/2023
 2. CHU de Quebec: Approved on 9/5/2023

B. Updated: Since our last quarterly PR, the following performance sites - determined to be no greater than minimal risk and no longer requiring review for continuation - have confirmed that no post-approval events (requiring prompt reporting to USAMRDC OHARO OHRO) have occurred:

1. Mayo Clinic
2. San Antonio Military Medical Center
3. Boston Children's Hospital

• Ongoing - Monthly Meetings: WUSTL continues to organize and host the following ZOOM study meetings:

1. DoD FAI-2 Executive Steering Committee: The 1st Thursday of every month
2. DoD FAI-2 Data Management: The 1st Thursday of every month
3. DoD FAI-2 Study-Wide Coordinator: The 3rd Friday of every month

Ongoing: For each of the three (3) monthly DoD meetings, WUSTL: (1) Drafts and distributes agendas prior to call, (2) Writes and distributes all meeting minutes, and (3) hosts each ZOOM audio/video recording on WUSTL BOX for viewing by all Site PIs and Coordinators.

• Statistical Plan and Data Analysis:

Update - FAI-1 Data Analysis: The Executive and Data Coordinating and Management Committee members continue to develop and refine their statistical plans to optimize the analytical models and subgroup analysis to analyze the mid-term follow-up (T8 FU) of the ANCHOR FAI-1 cohort to identify important predictors of treatment outcomes and failures in FAI surgery in order to improve clinical care and treatment decision-making by establishing refined patient selection criteria for surgery and by correlating disease and patient characteristics with clinical outcomes.

Update - FAI-2 Data Analysis: Executive and Data Coordinating/Management Committees are both developing and implementing their statistical plan and data analysis for this cohort which were elucidated in the Project Narrative of the funded study:

Specific Aim 2

For Aim 2, the effect of preoperative femoral and acetabular morphology with changes in PROs from baseline to short-term follow-up (2 years postoperatively [T2]) will be estimated in the new prospective FAI-2 cohort. The primary femoral and acetabular morphologic characteristics that will be evaluated are femoral version and regional percent femoral head coverage (anterior, lateral, and posterior), respectively. In order to estimate the effect of these characteristics on HOOS pain and HOOS function s/r, multilevel linear regression models will be developed using the approach outlined for the evaluation of modifiable factors in Aim 1. Importantly, FAI-2 will collect information on important potential confounders such as age, sex, and other characteristics identified in Specific Aim 1^[99]. Mean differences in baseline PROs and corresponding 95% confidence intervals will be calculated as estimates of the effect of morphology on short-term postoperative outcomes. Associations will be considered statistically significant with an alpha level of 0.05. We will also evaluate associations with more specific morphology characteristics, such as femoral supra-trochanteric torsion, femoral infratrochanteric torsion, cranial acetabular version (1:30), and central acetabular version (3:00).

Specific Aim 3

For Aim 3, correlations of PROMIS^[66] domains (pain interference, physical function, mobility, anxiety, and depression) with legacy PROs will be assessed in FAI-2 cohort. PROMIS and legacy PROs will be assessed for the baseline and early follow-up time points in the in the FAI-2 cohort. The distributions of PROMIS domains and each legacy PRO will be graphically described using histograms. To evaluate measures for possible floor and ceiling effects, histograms will be examined along with calculations of the percentage of scores reported at the maximum and minimum achievable values for each measure. Ceiling and floor effect will be defined if more than 15% of respondents achieved the lowest or highest possible scores, respectively^[100]. For PROMIS and normalized legacy measures, distributions will be assessed visually and skewness and kurtosis will be calculated in order to evaluate normality.

Legacy measures will be correlated with the most appropriate corresponding PROMIS domain. For each PROMIS-legacy pair, Pearson's correlation coefficient will be calculated with corresponding 95% confidence intervals, as the primary measure of correlation^[101]. A strong correlation will be defined as a correlation statistic greater than 0.7 (strongly positive) or -0.7 (strongly negative), while a moderate correlation will be defined as a correlation statistic between 0.5 and 0.7 (moderately positive), or between -0.5 and -0.7 (moderately negative)^[101]. Spearman's rank correlation coefficient will also be calculated with a divergence in the values of the Pearson's and Spearman's coefficients being indicative of a non-linear relationship between the PROMIS domain and legacy PRO^[101]. Additionally, the difference between PROMIS scores at T2 and at baseline will be calculated to evaluate responsiveness to change after surgical treatment, relative to the responsiveness of legacy PROs. Paired t-tests will be used to evaluate whether statistically significant differences are observed. Non-musculoskeletal comorbidities measured at baseline will also be evaluated as predictors of PROMIS and legacy measures at T2. As the PROMIS domains used in this study were designed to be standardized to the adult population, we will conduct sensitivity analyses in which all results are stratified between pediatric patients (14-17 years of age at surgery) and adult patients (18 years of age and older at surgery).

If strong correlations between PROMIS and legacy PRO measures are consistently observed and PROMIS scores are shown to change in response to surgical treatment, then a crosswalk between the measures will be created. Equipercentile linking methodology will be used as described in the PROsetta Stone™ project^[102] with the goal of creating a crosswalk table that will demonstrate how a summed score of domains translates to a score on key legacy PROs (HOOS-pain, HOOS-function s/r, mHHS, iHOT-12).

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Answer for YR 4 Annual PR: Training/professional development is not a part of this project.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Answer for YR 4 Annual PR: **New:** As reported above in, "Other, Ongoing Achievements since our last quarterly progress report" section:

- **New:** **MHSRS Symposium 2023:** Dr. John Clohisy attended and presented our accepted poster: *First Generation FAI Surgery: Midterm Outcomes of a Multicenter North American Cohort*, during Poster Session 3 on Wednesday, August 16th as part of breakout session: Multifactorial Problems Contributing of Musculoskeletal Injuries in the Military.
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 2. Differences in Femoroacetabular Impingement Morphology on CT between Adolescent Males and Females with Symptomatic
 3. FAI Predictors of Anxiety and Depression in Adolescent Femoroacetabular Impingement Patients

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

If this is the final report, state "Nothing to Report." Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Answer for YR 4 Annual PR: By the end of YR5 Q1 (our next reporting period), we plan to:

1. Continue to perform analysis on ANCHOR FAI-1 and ANCHOR FAI-2 and prepare abstracts and manuscripts for submission to impactful orthopaedic conferences and journals.
 2. Continue follow-up data collected (PROMs and imaging) from enrolled ANCHOR FAI-2 cohort
 3. Continue to expand data cleaning QA/QC procedures on all collected data
 4. Continue ongoing IRB Continuing Review approvals at each performance site, as needed
4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

New: Data from Specific Aims 1 and 2 have been presented and/or submitted to various national/international meetings for presentation. These data focus on improved information regarding the most important factors impacting mid to long term clinical outcomes (specific aim 1, FAI-1 cohort) and findings regarding factors that impact clinical presentation in contemporary FAI patients (specific aim 2, FAI-2 cohort). Follow-up data for the FAI-1 cohort strongly support the surgical treatment of FAI as highlighted by overall patient satisfaction of 85% at 10 year follow-up. Additionally, certain factors (BMI, age, baseline PROMs) were identified as potential predictors of FAI surgery outcomes. These findings will inform patient and physician decision-making and will further clarify specific indications for surgery. Additionally, data from the FAI-2 cohort identify patient specific-factors (Beighton score, resiliency and activity score) that may impact clinical outcomes of surgery. Understanding these baseline factors will accelerate our analysis of short term outcomes and will be further investigated as prognostic characteristics. Collectively, these data will further improve the understanding of FAI clinical presentation, selection criteria for surgery, anticipated surgical outcomes and factors impacting surgical outcomes. Improved surgical treatment of FAI patients will evolve with dissemination of these findings.

Written and Submitted Abstracts to POSNA, AOSSM, and AAOS Annual Orthopaedic Conferences:

- *First Generation FAI Surgery: Midterm Outcomes of a Multicenter North American Cohort*

- Changes in the Characteristics of Patients Undergoing FAI Surgery: A Prospective Multicenter Cohort Comparison of Early and Modern FAI
- Activity Level Assessments at Presentation Significantly Underestimate Pre-Injury Activity Levels in FAI Patients
- High Prevalence of Elevated Beighton Scores in Females Undergoing FAI Surgery
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- Differences in Femoroacetabular Impingement Morphology on CT between Adolescent Males and Females with Symptomatic
- FAI Predictors of Anxiety and Depression in Adolescent Femoroacetabular Impingement Patients

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Answer for YR 4 Annual PR: **New:** Please see list of orthopaedic abstracts above

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Answer for YR 4 Annual PR: Nothing to report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Answer for YR 4 Annual PR: Nothing to Report

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Answer for YR4 Annual PR: Nothing to Report

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:*

Answer for YR 4 Annual PR: **New:** (1) In March 2022, William Beaumont completed their DoD “data sharing” enrollment and collection of T8 FU PRO data from eligible ANCHOR FAI-1 participants. As a result, their local IRB application was closed and all documentation was submitted to USAMRDC HRPO ORP on 9/6/2022. Closure documentation, of their subaward contract, was submitted to WUSTL *Office of Sponsored Research Services* on 9/19/2022. Once completed, WUSTL will forward all documentation to William Beaumont and Jennifer Shackle (DoD Grants Specialist); (2) With the September completion of data cleaning at the *University of Michigan*, we’ve begun the same site closure process now that Site PI, Asheesh Bedi MD, has left their institution.

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Answer for YR 4 Annual PR: No changes in objectives or scope have occurred.

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Answer for YR 4 Annual PR: **New:** While the world-wide emergence of the COVID-19 coronavirus, and its infection resurgence through all variants, significantly impacted our initial enrollment timeframe for the ANCHOR FAI-2 cohort (and all subsequent follow-up time points) actions to resolve these delays have long been implemented by our rapid deployment of workflow modifications.

No new delays have been encountered since our last quarterly progress report.

Actions | Plans to Resolve the delays in recruitment/enrollment

Answer for YR 4 Annual PR:

- Continued use of technology to drive efficiency, transparency and maintain remote, intra-and-inter site communication (WUSTL BOX, ZOOM; REDCap)
 - Continued leveraging of efficient, technology-based communication systems used to stay connected with all Site PIs/Coordinators (e.g., use of Tele- or video conferences; ongoing use of secure, cloud-based WUSTL storage platform where Site PIs and Coordinators may access study protocols and other important documents 24/7).
- Ongoing surgeon use of post-op telemedicine visits when participants cannot attend in-person FU visit.
- Continued use of expanded procedures that allow consenting through multiple methods not reliant on traditional, in-person/in-clinic/face-to-face interactions with patients (e.g. REDCap, using IRB-approved *waivers of documentation of written consent* for verbal consenting).
- Ongoing and timely use of email and ListServ messages to communicate and/or disseminate updates, answer project questions, provide data reports, and share ideas between Coordinators, DCC, and leadership.
- Ongoing continuation of our monthly study-wide Coordinator ZOOM conference calls
 - WUSTL continues to maintain regular, on-going communication with all Site PIs and Study Personnel through weekly emails and monthly ZOOM conference calls, which are video-recorded and securely saved, along with all study documents, to our secure cloud-based storage that has been made available to all study personnel.

- Continued use of 100% virtual FU PROM data collection for the ANCHOR FAI-2 cohort.
 - A separate REDCap subject payment database continues to be utilized for the per-site per-participant collection of PII (including SSN) needed by WUSTL to reimburse 1-yr and 2-yr subject participation (\$25 for PRO completion and an additional \$25 for in-clinic/telemedicine visit completion)
- As needed, modification of specific REDCap data entry points to accommodate telemedicine collection and surgical data collection at follow-up study time point/clinic visits.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Answer for YR 4 Annual PR: Nothing to Report

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Answer for YR 4 Annual PR: Nothing to Report

Significant changes in use or care of vertebrate animals

Answer for YR 4 Annual PR: Not Applicable

Significant changes in use of biohazards and/or select agents

Answer for YR 4 Annual PR: Not Applicable

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”*

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

Report only the major publication(s) resulting from the work under this award.

Answer for YR 4 Annual PR (as listed above):

New: MHSRS Symposium 2023: Dr. John Clohisy attended and presented our submitted poster: *First Generation FAI Surgery: Midterm Outcomes of a Multicenter North American Cohort*, accepted for Poster Session 3 presentation on Wednesday, August 16th during the breakout session: Multifactorial Problems Contributing of Musculoskeletal Injuries in the Military.

New: 2024 Annual Conference: American Orthopaedic Society for Sports Medicine (AOSSM): The following four (4) DoD FAI-2 abstracts were submitted for podium/poster consideration for the July 2024 annual meeting:

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3. FAI Predictors of Anxiety and Depression in Adolescent Femoroacetabular Impingement Patients

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Answer for YR 4 Annual PR: Nothing to Report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Answer for YR 4 Annual PR: Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Answer for YR 4 Annual PR: **New:** Please see list of Abstracts above

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

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Answer for YR 4 Annual PR: Nothing to Report

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Answer for YR 4 Annual PR: Nothing to Report

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

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Answer for YR 4 Annual PR: Nothing to Report at this time

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Answer for YR 4 Annual PR: Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Example:

Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): *1234567*
Nearest person month worked: *5*

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support: *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Answer for YR 4 Annual: Please refer to **Table 9** that starts on next page.

**Table 9. DoD Quarterly Technical Progress Report for Period Covering:
7. Participant and Other Collaborating Organizations | What individuals have worked on the project?**

Performance Site	Name	Project Role	Research Identifier ORCID ID	Nearest person month worked (see calculator worksheet)	Contribution to the project
Washington University	John Clohisy	Project Director Principal Investigator	0000-0001-7040-616X	1.2PM	Dr. Clohisy directs the Clinical Coordinating Center, the Executive and Data Management Committee and is a significant contributor to the scientific development, execution and clinical conduct and integrity of the investigation. He is responsible for leading the project intellectually and logistically. Dr. Clohisy collaborates and work closely with the other investigators regarding the studies progress, identify problems, and seek and implement solutions.
	Jeffrey Nepple	Co-Investigator	0000-0002-7582-1415	0.6PM	Dr. Nepple serves on the Executive and Data Management Committees and is involved in all aspects of the project including patient enrollment, surgical treatment, study design, and study oversight. He collaborates and works closely with Dr. Clohisy and the other investigators regarding the studies progress, problem identification, and solutions implementation.
	Cecilia Pascual-Garrido	Collaborator	0000-0001-7487-4753	0.36PM	Dr. Pascual-Garrido will be an enrolling surgeon and will be involved in all aspects of the studies at the clinical coordinating center including patient enrollment, data analysis and data reporting.
	Liz Yanik	Research Team Member	0000-0002-5835-0201	0.36PM	Dr. Yanik serves on the Executive and Data Management Committees and participates in all activities of the executive and steering committees. She is involved in the project's statistical activities, data analysis and data reporting activities.
	Susan Thapa	Research team Member	0000-0002-4795-1116	0.12PM	Dr. Thapa serves on the Executive and Data Management Committees and participates in all activities of the executive and steering committees. She is involved in the project's statistical activities, data analysis and data reporting activities.
	Tanner Thornton	Research Team Member	0000-0001-9041-0203	6.00PM	Mr. Thornton serves as both a Data Analyst and REDCap Data Manager for the project. In this role, he closely works with Drs. Salter, Thapa, Nepple and Clohisy in the development of the data management plan (REDCap) and analysis of data.
	Caroline E. Drain	Research Team Member	NA	6.00PM	Ms. Drain serves on both the Executive and Data Management Committees. She is a Clinical Research Specialist providing management and oversight to all grant activities between WUSTL, the DoD, & each performance site. She answers site queries regarding patient enrollment, follow-up, tracking, data acquisition and interaction with the clinical coordinating center for all aspects of the studies.
	Zak Robben	Research Team Member	NA	6.00PM	Mr. Robben serves on both the Executive and Data Management Committees and assists in management and oversight of the day-to-day operations of the project for the entire study. In addition, he supports the enrollment of patients for WUSTL and assists with the patient remunerations for all sites.
	Sean Akers	Research Team Member	NA	6.00PM	Mr. Akers serves on both the Executive and Data Management Committees and manages all imaging collection efforts for the entire project. This includes, but is not limited to: creating image transfer and creation protocols that govern all performance sites; QA/QC images for archiving and analysis of all CT images, X-rays etc.

**Table 9. DoD Quarterly Technical Progress Report for Period Covering:
7. Participant and Other Collaborating Organizations | What individuals have worked on the project?**

Performance Site	Name	Project Role	Research Identifier ORCID ID	Nearest person month worked (see calculator worksheet)	Contribution to the project
UTSW	Amber Salter	Associate Professor Section Head, Statistical Planning and Analysis	0000-0002-1088-110X	3.00PM	Dr. Salter served on the Executive and Data Management Committees and provided expert, scientific guidance to data management/data coordinating center and to Principle Investigator and Site PIs with: Data, correlation, power, and subgroup stratification analysis; Provided statistical and strategic input in the writing and planning of manuscripts derived from this research project; Performed and/or supervised complex statistical analyses and create or provide input to statistical reports; Provided internal statistical review and technical guidance as requested by the Principal Investigator and Site PIs. Dr. Salter is now a faculty member at the University of Texas Southwest where a subrecipient award mechanism allowed her to continue to provide expert guidance to the project. NEW: Dr. Salter's subaward ended on Sept. 30, 2023.
Beaumont Hospital	Ira Zaltz	Site Formally closed locally and with ORP OHARO OHRO on 12/9/2022			
Boca Raton	James Ross	Site Formally closed locally and with ORP OHARO OHRO on 5/18/2023			
Boston Children's Hospital	Eduardo Novais	Collaborator	0000-0002-9187-3100	0.12PM	Dr. Novais is an enrolling surgeon who is involved in all aspects of the project at Boston Children's Hospital including patient enrollment, surgical treatment, study implementation, and study oversight.
	Young-Jo Kim	Collaborator	0000-0002-0855-0168	0.12PM	Dr. Kim is an enrolling surgeon who is involved in all aspects of the project at Boston Children's Hospital including patient enrollment, surgical treatment, study implementation, and study oversight.
	Yi-Meng Yen	Site PI/Collaborator	0000-0002-1306-4201	0.24PM	Dr. Yen is Site PI, and an enrolling surgeon who is involved in all aspects of the project at Boston Children's Hospital including patient enrollment, surgical treatment, study implementation, and study oversight.
	Michael Millis	Collaborator	0000-0002-1380-5495	0.12PM	Dr. Millis will work closely with his Boston colleagues to implement data collection. He will oversee the overall implementation of the study and focus efforts on the retrospective collection of their ANCHOR FAI-1 cohort.
	Mikayla Flowers	Research Manager	0000-0002-6566-046X	0.08PM	Ms. Flowers is involved in study administration, implementation, management, and study oversight of all newly hired staff at BCH and all performed on this project. She has been working on the project for the past 3 months
	Ani Maroyan	Clinical Research Coordinator	NA	4.5PM	Ms. Maroyan assists in management and oversight of the day-to-day operations of the project. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning, and all IRB submissions.
	Nancy Wan	Research Team Member	NA	1.5PM	Ms. Wan assists in management and oversight of the day-to-day operations of the project. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning, and all IRB submissions.
The Ottawa Hospital Research	Paul Beaulé	Site PI/Collaborator	0000-0001-7667-9994	0.24PM	Dr. Beaulé will lead the team at The Ottawa Hospital Research Institute as the nominated site PI. He is responsible for overseeing the trial at The Ottawa Hospital Research Institute and ensuring adequate resources are available to support the work.

**Table 9. DoD Quarterly Technical Progress Report for Period Covering:
7. Participant and Other Collaborating Organizations | What individuals have worked on the project?**

Performance Site	Name	Project Role	Research Identifier ORCID ID	Nearest person month worked (see calculator worksheet)	Contribution to the project
Institute Children's Hospital of Eastern Ontario (CHEO)	Ariane Parisien	Clinical Research Coordinator	NA	1.2PM	Mrs. Parisian is a Clinical Research Coordinator assisting with all management and day-to-day administrative activities including IRB submission, data collection, imaging transfer to WUSTL, and data entry /cleaning.
	Sasha Carsen	Site PI/Collaborator	0000-0002-8180-9770	0.24PM	Dr. Carsen is the key enrolling surgeon at The Ottawa Hospital/CHEO involved in all aspects of the project including patient enrollment, surgical treatment, study implementation, and study oversight.
	Holly Livock	Research Team Member	0000-0003-3171-4447	0.12PM	Ms. Livock is a Clinical Research Coordinator assisting with the ethics submission and study-start up locally at The Ottawa Hospital Research Institute/CHEO. She will support all local IRB submissions.
	Patrick Sachsalber	Clinical Research Assistant	0000-0001-6674-8909	2.4PM	Mr. Sachsalber is a Clinical Research Assistant assisting with enrollment, data collection, imaging transfer to WUSTL, and data entry /cleaning.
CHU Quebec	Etienne Belzile	Site PI/Collaborator	0000-0003-2837-981X	.24PM	Dr. Belzile will be an enrolling surgeon and will be involved in all aspects of the studies at the CHU de Quebec-University Laval site. He collaborates and work closely with Dr. Clohisy and with the other investigators regarding the studies progress, identify problems, and seek and implement solutions.
	Sylvie Turmel	Research Team Member	0000-0002-3200-356X	3.6PM	Ms. Turmel is a Clinical Research Specialist assisting with the IRB ethics approval and project preparation. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning.
Mayo Clinic	Rafael Sierra	Site PI/Collaborator	0000-0002-8513-1477	0.24PM	Dr. Sierra is the Principal Investigator for Mayo Clinic's portion of the DoD and JP2 Grants. He will be an enrolling surgeon and will be involved in all aspects of the study for Mayo patients that includes enrollment, data analysis, and data reporting.
	Aaron Krych	Collaborator	0000-0003-3248-8007	0.12PM	Dr. Krych will be an enrolling surgeon and will be involved in all aspects of the study for Mayo patients that includes enrollment, data analysis, and data reporting.
	Bruce Levy	Collaborator	0000-0002-7694-1814	0.12PM	Dr. Levy will be an enrolling surgeon and will be involved in all aspects of the study for Mayo patients that includes enrollment, data analysis, and data reporting.
	Karina Gonzalez-Carta	Research Associate and Instructor of Medicine	0000-0003-2383-3868	0.06PM	Dr. Gonzalez Carta oversees staff and assist the enrolling surgeons with project management and oversight of the day-to day activities including all IRB submission.
	Riley Voll	Research Coordinator	NA	0.96PM	Mr. Voll is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning.
SAMMC	Matthew Schmitz	Site PI/Collaborator	0000-0002-4156-5177	0.60PM	Dr. Schmitz is involved in all aspects of the project including patient enrollment, surgical treatment, study design, and study oversight. He participates on the Executive Committee for Grant management. He is the site PI at SAMMC and enrolling surgeon.

**Table 9. DoD Quarterly Technical Progress Report for Period Covering:
7. Participant and Other Collaborating Organizations | What individuals have worked on the project?**

Performance Site	Name	Project Role	Research Identifier ORCID ID	Nearest person month worked (see calculator worksheet)	Contribution to the project
	Liz Summerfield	Research Team Member	NA	.24PM	Mrs. Summerfield manages the Regulatory lifecycle of research study applications to ensure compliance with ICH, GCP and all other regulatory bodies. Coordinates and maintain the tracking and reviewing of regulatory submissions including annual reports, informed consent forms, protocol reviews & review for accuracy & completeness.
	Roseann Eberhardt	Research Team Member	NA	.24PM	Ms. Eberhardt is assisting Dr. Schmitz with patient follow-up and REDCAp data entry.
Twin Cities Orthopedics	Christopher Larson	Site PI/Collaborator	0000-0002-9910-0145	0.6 PM	Dr. Larson is the Site PI involved in all aspects of the project including patient enrollment, surgical treatment, and study oversight. He collaborates and works closely with Washington University Physician Investigators and with the other investigators regarding the studies progress.
	Kayla Seiffert	Research Team Member	0000-0002-7715-4724	3.0 PM	Ms. Seiffert assists in management and oversight of the day-to-day operations of the project. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning, and all IRB submissions.
SCH (formally TSRH)	Henry Ellis	Site PI/Collaborator	0000-0001-5444-094X	.12PM	Dr. Ellis is the Site PI involved in all aspects of the project including patient enrollment, surgical treatment, study implementation, and study oversight.
	Daniel Sucato	Collaborator	0000-0003-3352-5551	.06PM	Dr. Sucato is involved in study implementation while assisting with efforts on the retrospective arm of the study.
	David Podeszwa	Collaborator	0000-0002-2367-2657	.06 PM	Dr. Podeszwa is involved in study implementation while assisting with efforts on the retrospective arm of the study.
	Lauren Osborne	Clinical Research Coordinator	NA	2.4PM	Ms. Osborne assists in management and oversight of the day-to-day operations of the project. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning.
	Bayley Selee	Clinical Research Coordinator	NA	1.2PM	Ms. Selee assists in management and oversight of the day-to-day operations of the project. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning.
	Laura Mayfield	Clinical Research Manager	NA	1.2 PM	Ms. Mayfield assists in management and oversight of the day-to-day operations of the project. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning, and all IRB submissions.
U of Iowa	Robert Westermann	Site PI/Collaborator	0000-0002-5289-4689	0.6 PM	Dr Westermann is the Site PI and enrolling surgeon involved in all aspects of the studies including patient enrollment, data analysis and data reporting.
	John Gentile	Research Team Member	NA	1.8 PM	Mr. Gentile assists in management and oversight of the day-to-day operations of the project. He is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning, and all IRB submissions.
U of Michigan	Site Formally closed with ORP OHARO OHRO on 1/20/2023 after Dr. Asheesh Bedi transitioned to another institution.				

**Table 9. DoD Quarterly Technical Progress Report for Period Covering:
7. Participant and Other Collaborating Organizations | What individuals have worked on the project?**

Performance Site	Name	Project Role	Research Identifier ORCID ID	Nearest person month worked (see calculator worksheet)	Contribution to the project
U of Colorado / Children's Hospital of Colorado	Stephanie Mayer	Site PI/Collaborator	0000-0002-9432-8191	.40PM	Dr. Mayer is involved with all aspects of the research study at the University of Colorado and Children's Hospital Colorado from study implementation, oversight, enrollment, surgical treatment, and study follow-ups.
	Lauren Heylmun	Clinical Research Manager	NA	0.60PM	Ms. Heylmun has taken over full-time duties of Ms. Orahovats. Laura assists in study management and oversight of day-to-day operations of the project. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning, and all IRB submissions.
	Alexandra Orahovats	Research Project Manager	0000-0002-9433-5420	0.12PM	(Part-time) Ms. Orahovats assists in study management and oversight of day-to-day operations of the project including: Screening, consenting, enrollment, data collection, and patient follow up.
U of Wisconsin	Andrea Spiker	Site PI/Collaborator	0000-0003-1243-9726	0.60PM	Dr. Spiker is involved in all aspects of the project including patient enrollment, surgical treatment, and study oversight. He collaborates and works closely with Washington University Physician Investigators and with the other investigators regarding the studies progress.
	Amie Armstrong	Regulatory Manager	NA	0.60PM	Ms. Armstrong is the clinical research manager and assists in management and oversight of day-to-day operations of the project. She is involved in all aspects of the study including, data collection, data imaging transfer to WUSTL, and data entry/cleaning, and all IRB submissions.

Has there been a change in the active, other support of the PD/PI(s) or Senior/Key Personnel since the Last Reporting Period?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Answer for YR 4 Annual: Nothing to Report

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Answer for YR 4 Annual: Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

Answer for YR 4 Annual: We have uploaded our updated QUAD chart to our eBRAPS submission page.

9. **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Answer for YR 4 Annual: All nine (9) referenced abstracts (plus a copy of the 2023 MHSRS accepted poster) are attached to this report.

First Generation FAI Surgery: Midterm Outcomes of a Multicenter North American Cohort

Authors: Nepple J, Hood H, Thapa S, Kim JY, Sierra R, Beaulé P, Sink E, Millis M, ANCHOR Study Group, and Clohisy J.

Corresponding Author: John Clohisy, MD/Washington University

ABSTRACT

Background: Femoroacetabular impingement (FAI) is a common source of hip dysfunction in young athletes and military personnel, and is the most common disorder associated with premature, secondary osteoarthritis. To date, there is a paucity of literature describing the mid to long-term treatment outcomes of FAI surgery. The purpose of this study was to analyze a prospective, multicenter FAI surgery cohort to investigate (1) patient-reported outcome measures (PROMs) (2) predictors of clinical outcome, and (3) rates of treatment failure at a minimum 8 year follow-up.

Methods: A prospective, multicenter cohort study was performed on patients treated for FAI with hip arthroscopy or surgical dislocation by seven surgeons at five institutions. Patients were assessed at minimum 8 years postoperatively with PROMs (mHHS, UCLA activity, HOOS domains, and SF-12 physical/mental). Achieving a minimally clinically important difference (MCID) threshold and the need for reoperation were assessed. Multivariate logistic and linear regression was performed to identify independent predictors of outcome.

Results: Three-hundred sixty-nine hips were evaluated at a mean of 9.6 ± 2.7 years follow-up after surgery for symptomatic FAI. The mHHS increased from 61.6 ± 15.1 to 83.3 ± 19.3 ($p \leq 0.001$) with 70.0% of patients achieving MCID at final follow-up. All HOOS domain scores (pain, sport and recreation, symptoms, QOL, ADL) improved from preoperative to follow-up ($p \leq 0.001$) and the percent of patients meeting MCID ranged from 65 to 74%. SF-12 physical improved from 38 ± 10.8 to 48 ± 11.1 ($p \leq 0.001$) with 58% meeting the MCID threshold. BMI ≥ 30 was associated with lower postoperative improvements in mHHS and all HOOS domains. Age ≥ 30 was associated with lower improvements in mHHS and HOOS QOL. Revision hip preservation surgery was performed in 4.9% of patients and 9.2% (34 hips) progressed to total hip arthroplasty (THA). Age at surgery \geq

30 [HR 12.97 (1.67, 100.8); p = 0.03] and BMI \geq 30 [HR 3.07 (1.09, 8.63); p = 0.01] were both significant predictors of conversion to THA.

Conclusion: This study indicates that FAI surgery is an effective treatment option with maintained improvements in PROMs, for the majority of patients at an average 9.6 year follow-up. Patients with an age \geq 30 and BMI \geq 30 were at increased risk for suboptimal clinical outcomes and conversion to THA. Patients with these characteristics should be carefully indicated for surgery and counseled regarding surgical expectations.

Objectives

Report FAI surgery clinical outcomes at an average 10 years in a prospective, multicenter study.

Describe the rates of reoperation and conversion to total hip arthroplasty at a mean 10 years after early FAI treatment.

Discuss risk factors for suboptimal clinical outcomes and conversion to total hip arthroplasty ten years after FAI surgery.

Introduction

- Femoroacetabular impingement (FAI) is a common cause of hip dysfunction in young athletes and military personnel ¹
- Most common disorder associated with secondary osteoarthritis (OA) ²
- Identify risk factors for suboptimal outcomes after FAI surgery

Purpose

The purpose of this study was to analyze a prospective, multicenter FAI surgery cohort to investigate

- Patient reported outcome measures (PROMs)
- Predictors of clinical outcomes
- Rates of treatment failure at a minimum of 8 years follow-up

Methods

- Multicenter, prospective cohort study of patients undergoing treatment for FAI with either hip arthroscopy (HA) or surgical hip dislocation (SHD) from 2008-2012
- 7 treating surgeons at 5 institutions
- Inclusion criteria was the presence of isolated cam FAI or combined cam/pincer
- Exclusion criteria were previous ipsilateral surgery or residual pediatric hip disease (Legg-Calve-Perthes or slipped capital femoral epiphysis)
- Primary outcome measure was the modified Harris Hip score (mHHS)
- Secondary outcome measures included the Hip disability and Osteoarthritis score (HOOS), University of California Los Angeles (UCLA) activity score, and Short Form-12 (SF-12) physical and mental subscores
- The minimal clinically important difference (MCID) and patient acceptable symptom state (PASS) for the mHHS were defined as 8 and 74 respectively¹
- Suboptimal outcome was defined as reoperation, or failure to reach either MCID or PASS

Statistics

- Linear regression analysis were used to identify predictors of PROMs
- Poisson regression was used to identify predictors and estimate risk ratios for the association of outcomes with the independent variables

Results

- Among 478 eligible patients initially enrolled in the study, 369 had follow-up at minimum 8 years (mean 9.6 ± 2.7) post surgery or reached an endpoint of reoperation
- Final cohort was 53.7% female, average age was 31.8 ± 12.1 years with 53.7% being 30 years or older at time of surgery
- 53.1% had isolated cam, 46.8% had combined cam/pincer pathology
- Baseline mean lateral center edge angle (LCEA) was 29.1 ± 7.3°
- 7.9% has baseline LCEA ≥ 40°

PROMs change preoperative to final follow-up and percent meeting MCID

Variable	Pre-operative Mean ± Standard Deviation	Post-operative Mean ± Standard Deviation	(%) Meeting MCID	P value
mHHS	61.6 ± 15.1	83.3 ± 19.3	70	<0.001
HOOS domain				
Pain	56.9 ± 20.8	80.0 ± 22.5	69.9	<0.001
ADL	66.6 ± 21.7	83.9 ± 21.6	69.7	<0.001
QoL	30.9 ± 19.3	64.6 ± 29.2	74.4	<0.001
Symptom	57.0 ± 19.3	74.8 ± 21.6	74.4	<0.001
Sport & Rec	44.9 ± 24.9	73.1 ± 30.0	65.1	<0.001
UCLA 9 or 10, %	38.8	52.7	28.4	0.002
SF-12 Physical	38.4 ± 10.8	48.32 ± 11.0	57.9	<0.001
SF-12 Mental	52.2 ± 10.6	52.4 ± 10.0	28.9	0.85

Predictors and risk ratios of MCID, PASS and THA Conversion

Outcome RR Confidence Interval P Value	Age ≥ 30	BMI ≥ 30	Baseline mHHS Score	Sex (Female vs Male)
mHHS MCID				1.66 (1.07, 2.60) 0.03
mHHS PASS		0.44 (0.23, 0.83) 0.01	1.05 (1.03, 1.07) <.0001	
Conversion to THA	12.97 (1.67, 100.8) 0.03	3.07 (1.09, 8.63) 0.01		0.32 (0.12, 0.87) 0.02

Results

- 68.3% of patients were found to have a labral detachment
- 59.9% of patients underwent a labral repair while 29.5% had labral debridement
- Labral repair versus debridement was not associated with outcomes
- 75.8% of patients has hip arthroscopy with osteochondroplasty and 24.1% had SHD
- BMI ≥ 30 was a significant predictor for final mHHS, mHHS PASS, HOOS Pain, HOOS Sport & Rec, HOOS QoL, HOOS ADL, HOOS Symptoms, conversion to THA
- 34 hips (9.2%) underwent THA at a mean of 5.2 ± 3.1 years
- An additional 18 patients (4.9%) underwent revision preservation surgery at a mean of 2.0 ± 1.5 years
- 15-27% of patients remained symptomatic (failed to reach MCID for mHHS or HOOS Pain) but did not undergo additional ipsilateral surgery
- Among patients completing satisfaction surveys, 90.7% reported that they were "satisfied" with the outcome
- 8.8% of patients reported being "unsatisfied" with surgery
- 86.5% of patients said they would have the surgery again

Conclusions

- This study represents the largest cohort of patient outcomes at mid-term follow-up
- This study demonstrated high rates of satisfaction
- 86% of hips were preserved
- 5% of hips underwent revision surgery
- 9% of hips converted to THA
- Patients with age ≥30 or BMI ≥30 were at increased risk for suboptimal clinical outcomes and conversion to THA
- Patients with these characteristics should be counseled regarding surgical expectations

References

1. Clohisy JC, (2010) Surgical treatment for Femoroacetabular impingement: a systematic review of the literature. Clin Orthop Relat Res, 468, 555-564
2. Ganz R. (2008). The Etiology of Osteoarthritis of the Hip. Clin Orthop Relat Res, 466,264-272.

High Prevalence of Elevated Beighton Scores in Females Undergoing FAI Surgery

Background

Femoroacetabular impingement (FAI) is classically described as restricted internal rotation in flexion resulting in labral and cartilage pathology. Despite 20 years of FAI research, there is still limited understanding of the drivers of symptomatology in the subset of patients with underlying FAI morphology. While the prevalence of FAI morphologies is substantially higher in males, numerous studies have shown more females being treated for FAI than males. Soft-tissue laxity and hip instability are increasingly recognized as a potential contributor to symptoms in addition to FAI. The Beighton score is a well-accepted means to quantify soft-tissue laxity and has been validated for self-scoring. The purpose of the current study was (1) to investigate the prevalence of soft tissue laxity in male and female patients presenting with symptomatic FAI in a multicenter prospective cohort study, as well as correlate soft tissue laxity with patient primary complaints of either mobility, stability, or pain.

Methods

A prospective multicenter cohort study of 696 FAI patients undergoing primary hip arthroscopy surgery was performed and utilized for the current study. Inclusion criteria are patients aged 14-45 years with idiopathic FAI not caused by childhood disease. Exclusion criteria are previous ipsilateral hip procedures or disease processes such as neuromuscular disease or Tonnis 2 or greater osteoarthritis. The Beighton score was assessed by electronic patient self-scoring. Beighton scores of four or greater were considered a marker of soft tissue laxity. The MSP index was utilized to have patients rank from most to least the biggest problems with their hip: Mobility (M), Stability (S), or Pain (P). The Chi-squared or Fisher's Exact Test were utilized to compare groups.

Results

The prevalence of Beighton scores of 4 or greater was 57.2% in females, compared to 29.3% in males ($p < 0.001$). In females, 44.4%, 22.6%, and 7.7% had Beighton scores of 5+, 7+, and 9 respectively, compared to 16.7%, 5.8%, and 1.8% in males (all $p < 0.005$). In the overall FAI cohort, pain was the primary complaint in 72.1% of patients, compared to 24.2% complaining primarily of mobility and 3.7% complaining primarily of stability. Among female patients, the presence of soft tissue laxity (relative to thresholds of Beighton 4, 5, 7, and 9) did not significantly influence the patient primary complaints (with pain being the predominant complaint). Overall, 85 females had a Beighton score of 7 or greater and only 2.4% reported stability of the hip as a primary complaint, compared to 2.4% of females with a Beighton of less than 7. Stability was more commonly indicated as a second most important factor in the setting of soft tissue laxity, compared to mobility. Among females with a Beighton of 7 or greater, 29.5% reported stability as a primary or secondary complaint, compared to 15.2% of female patients with a Beighton score less than 7.

Conclusions

Over half of female patients undergoing FAI surgery have underlying soft tissue laxity as measured by the Beighton score. In the setting of soft tissue laxity, patient primary symptomatic complaint remains pain, but a secondary complaint is significant more likely to be stability rather than mobility (compared to FAI patients without soft tissue laxity complain of mobility secondarily over stability). Further research is needed to better understand the role of soft tissue laxity in the pathophysiology of FAI and the outcomes of surgical treatment.

Patient reported outcomes and satisfaction at minimum 8 year follow-up among a prospective, multicenter cohort study of patients undergoing first generation FAI surgery.

Background: Femoroacetabular impingement (FAI) is a common source of hip dysfunction and secondary osteoarthritis, yet reports of the mid to long-term outcomes of first-generation FAI surgery are limited. The purpose of this study was to characterize patient reported outcome measures (PROMs) at a minimum of eight years postoperatively after FAI surgery, as well as to identify predictors of clinical outcome.

Methods: A prospective, multicenter cohort study was performed on patients treated for FAI with hip arthroscopy or surgical dislocation by seven surgeons at five institutions from 2008 to 2012. Inclusion criteria included diagnosis of isolated cam or combined cam/pincer type FAI after failure of at least 3 months of conservative treatment. Patients with prior ipsilateral hip surgery, diagnoses of slipped capital femoral epiphysis, or Legg-Calve-Perthes were excluded. Patients were assessed with modified Harris Hip Scores (mHHS) and Hip Disability and Osteoarthritis Outcome Scores (HOOS) for pain, sport and recreation, symptoms, quality of life (QOL), minimal clinically important difference (MCID) thresholds, and satisfaction surveys at a minimum of eight years postoperatively. Four hundred seventy-eight hips were enrolled and 367 hips completed follow-up data at a mean of 9.6 ± 2.7 years postoperatively. Multivariate logistic and linear regression was performed to identify independent predictors of outcome.

Results: At a minimum eight year follow-up, the mHHS remained increased from 61.6 ± 15.1 to 83.3 ± 19.3 ($p < 0.01$) with 70.0% of patients achieving MCID at final follow-up. HOOS Pain scores improved from 56.9 ± 20.8 to 80.0 ± 22.5 ($p < 0.01$). Predictors negatively effecting post-operative mHHS were age ≥ 30 years at time of surgery [beta estimate (BE) -0.08; $p = 0.001$] and BMI ≥ 30 [BE -0.11; $p = 0.02$]. BMI ≥ 30 was also inversely associated with improvements in HOOS Pain [BE -0.09; $p = 0.02$], HOOS Sport and Recreation [BE -0.16; $p = 0.02$], HOOS ADL [BE -0.15; $p = 0.03$], HOOS QOL [BE -0.26; $p = 0.03$], HOOS Symptoms [-0.14; $p = 0.04$]. Surgical technique (hip arthroscopy vs surgical dislocation), lateral center edge angle, alpha angle, and labral repair were not predictive of outcome measures. Among the patients with completed satisfaction surveys, 90.7% ($n = 292$) reported that they were satisfied with their surgical outcome.

Conclusion: This study indicates that FAI surgery is an effective treatment option with maintained improvements in PROMs for the majority of patients at an average 9.6 years follow-up.

Patient reported outcomes at baseline and minimum 8-year follow up.

PROMs	N	Baseline	Minimum 8-year follow-up	N(%) of patients meeting MCID	% meeting PASS	p value [#]
mHHS	369	61.6 ± 15.1	83.3 ± 19.3	258 (70.0)	67.0	<.0001
HOOS						
Pain	339	56.9 ± 20.8	80.0 ± 22.5	237 (69.9)	-	<.0001
Sport and recreation	338	44.9 ± 24.9	73.1 ± 30.0	220 (65.1)	-	<.0001
Symptoms	206	57.0 ± 20.7	74.8 ± 21.6	138 (67.0)	-	<.0001
QOL	207	30.9 ± 19.3	64.6 ± 29.2	154 (74.4)	-	<.0001
UCLA activity score 9 or 10, %	356	38.8	52.7	101 (28.4)	-	0.002
SF-12 physical	311	38.4 ± 10.8	48.3 ± 11.0	180 (57.9)	-	<.0001
SF-12 mental	311	52.2 ± 10.6	52.4 ± 10.0	90 (28.9)	-	0.85

p value compares baseline and final follow-up data using McNemar test for categorical and paired t-test for continuous variables, MCID:minimum clinically important difference, PASS:patient acceptable symptom state

Does Elevated Beighton Score Correlate with Differences Hip Morphology in Adolescent Patients with Femoroacetabular Impingement

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LOE: Lesser quality RCT, prospective comparative study or retrospective study-Level II

FDA: FDA Clearance is NOT APPLICABLE.

Introduction: Since femoroacetabular impingement (FAI) was first acknowledged twenty years ago, our understanding of this disease has improved and the role of soft tissue laxity in hip pathology has only recently become well recognized. The purpose of the current study was to compare the CT hip morphology of adolescent FAI patients with and without underlying soft tissue laxity (Beighton score ≥ 5).

Methods: A multi-center, prospective study of FAI patients was enrolled. Sub-analysis of patients aged 14-18.9 was performed. Inclusion criteria were patients with idiopathic FAI. Beighton score and low-dose CT characterization of hip morphology were assessed analyzed. Regression was used to determine whether associations existed between Beighton score ≥ 5 (versus Beighton < 5) and CT morphologic findings, including multivariable regression to control for sex.

Results: 696 hips were enrolled including 27.9% (n=194) adolescents. Overall, 42.9% of females and 15.7% of males had Beighton ≥ 5 (p<0.001). The maximum alpha angle was lower in Beighton ≥ 5 at $66.3^\circ \pm 11.6^\circ$ compared to $70.0^\circ \pm 12.0^\circ$ (p=0.041) and had a more anterior location at $1:28 \pm 0:51$ compared to $1:10 \pm 0:33$, respectively (p=0.003). For Beighton ≥ 5 , alpha angles were lower at positions 1:00, 58.0 ± 13.2 compared to 65.0 ± 13.6 (p=0.001), and 1:30, 60.5 ± 11.3 compared to 65.6 ± 11.4 (p=0.003). Acetabular radial coverage at 9:00, 10:00, and 10:30 was higher for Beighton ≥ 5 group at $52.0\% \pm 3.5\%$ (compared to $51.0\% \pm 3.3\%$, p=0.037), 58.5 ± 3.6 (compared to $57.2\% \pm 3.1\%$, p=0.015), and $60.8\% \pm 3.6\%$ (compared to $59.8\% \pm 3.1\%$, p=0.046), respectively. Femoral version was similar across groups (18.6 ± 8.6 vs 17.2 ± 8.9 , p>0.268). For femoral head coverage, only posterior was different between groups with Beighton ≥ 5 having more coverage with $57.4\% \pm 3.5\%$ compared to $56.3\% \pm 2.9\%$ (p=0.025). Regression, controlling for sex, demonstrated Beighton ≥ 5 was more likely to have a more anterior max alpha location (OR: 1.17, CI: 1.002-1.36, p=0.047).

Conclusion: Adolescent FAI patients with generalized soft tissue laxity (Beighton ≥ 5) have distinct CT morphologic findings when compared to patients without hyperlaxity. For patients with increased laxity, on average, there was 1.1% more posterior coverage along the clock-face, maximum alpha angles were 3.7° lower, and maximum alpha angles were located 0:18 more anterior.

Significance: Femoroacetabular impingement causes distinct CT findings that could be affected by soft tissue laxity. This study investigated the effect of soft tissue laxity using Beighton scores ≥ 5 and < 5 on CT morphologic findings.

CT Reader	Beighton ≥ 5 (n=63)	Beighton < 5 (N=127)	P-value
Age	16.5 \pm 1.2	16.5 \pm 1.3	0.779
Gender	51 (82.3)	68 (53.5)	<0.001
Acetabular Radial Coverage			
9:00	52.0 \pm 3.5	51.0 \pm 3.3	0.037
10:00	58.5 \pm 3.6	57.2 \pm 3.1	0.015
10:30	60.8 \pm 3.6	59.8 \pm 3.1	0.046
11:00	63.2 \pm 3.8	62.6 \pm 3.1	0.148
12:00	66.7 \pm 2.7	66.8 \pm 2.8	0.929
1:00	63.0 \pm 2.6	62.9 \pm 3.3	0.806
1:30	58.0 \pm 3.2	57.8 \pm 3.5	0.922
2:00	51.0 \pm 3.9	51.0 \pm 3.8	0.978
3:00	37.2 \pm 4.1	37.2 \pm 3.5	0.716
Acetabular version			
1:30	5.0 \pm 6.8	3.6 \pm 7.2	0.176
3:00	17.8 \pm 4.9	16.4 \pm 5.2	0.098
Global	16.8 \pm 5.2	15.4 \pm 5.3	0.118
Femoral head diameter	43.6 \pm 3.4	45.5 \pm 3.8	0.001
Femoral version	18.6 \pm 8.6	17.2 \pm 8.9	0.268
Femoral neck-shaft angle	133.8 \pm 4.0	133.2 \pm 4.6	0.298
Femoral Head Coverage			
Anterior	49.1 \pm 3.6	49.1 \pm 3.5	0.846
Lateral	65.2 \pm 2.4	65.0 \pm 2.6	0.592
Posterior	57.4 \pm 3.5	56.3 \pm 2.9	0.025
Global Inclination	37.3 \pm 3.2	37.2 \pm 3.5	0.982
Alpha Angle			
12:00	45.9 \pm 12.9	48.1 \pm 15.3	0.179
1:00	58.0 \pm 13.2	65.0 \pm 13.6	0.001
1:30	60.5 \pm 11.3	65.6 \pm 11.4	0.003
2:00	57.7 \pm 11.1	60.3 \pm 11.1	0.141
3:00	43.6 \pm 9.4	47.2 \pm 10.8	0.026
Maximum	66.3 \pm 11.6	70.0 \pm 12.0	0.041
Location	1:28 \pm 0:51	1:10 \pm 0:33	0.003

Differences in Femoroacetabular Impingement Morphology on CT between Adolescent Males and Females with Symptomatic FAI

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LOE: Lesser quality RCT, prospective comparative study or retrospective study-Level II

FDA: FDA Clearance is NOT APPLICABLE.

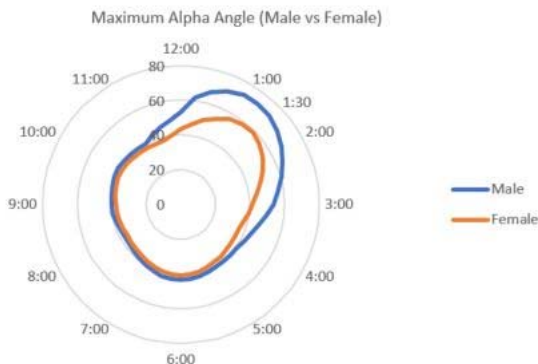
Introduction: Understanding of femoroacetabular impingement (FAI) continues to improve. Low-dose computed tomography (CT) is increasingly utilized due to its improved ability to characterize the complex and variable hip morphologies of different FAI patients, compared to plain radiographs. This study defined FAI morphology in adolescents and compared males and females utilizing low-dose CT.

Methods: A multi-center, prospective cohort of FAI patients undergoing arthroscopy was performed. Patients 14-18.9 years of age were the focus of the current study. All patients underwent low-dose CT for preoperative planning with radiation exposure, similar to 3-4 AP pelvis radiographs. Localization with a clock-face was utilized (3:00 was anterior and 9:00 posterior). Univariate analysis and multivariable regression were used to determine differences between male and female groups.

Results: 696 hips were registered with 27.9% (n=194) being adolescent. Utilizing low-dose CT, males had higher alpha angles at $76.7^{\circ} \pm 10.3^{\circ}$ compared to females $63.9^{\circ} \pm 10.1^{\circ}$ ($p < 0.001$). The largest difference was noted at 1:00 and was $72.9^{\circ} \pm 10.7^{\circ}$ for males compared to $56.6^{\circ} \pm 11.5^{\circ}$ for females ($p < 0.001$). Furthermore, when classified into alpha angles of $< 55^{\circ}$, $55-62.9^{\circ}$, and $\geq 63^{\circ}$, female distribution was 17.3%, 32.7%, 50%, and male distribution was 1.5%, 4.4%, and 94.1%, respectively ($p < 0.0001$). The location of maximal alpha angle was more anterior in females at $1:21 \pm 0:37$ and $1:07 \pm 0:42$, respectively ($p = 0.002$). Females had higher femoral version at $19.1^{\circ} \pm 8.7^{\circ}$ compared to $15.4^{\circ} \pm 8.4^{\circ}$ ($p = 0.005$). Femoral neck-shaft angle was higher in females at $134.4^{\circ} \pm 4.2^{\circ}$ compared to $131.7^{\circ} \pm 4.4^{\circ}$. Acetabular coverage at 10:30 was higher for females with $61.2\% \pm 3.2\%$ compared to males with $58.5\% \pm 2.9\%$ ($p < 0.001$). Acetabular coverage at 1:30 was lower for females with $57.1\% \pm 3.3\%$ compared to males with $59.2\% \pm 3.1\%$ ($p < 0.001$). Cranial (1:30) and central (3:00) acetabular version was about 3 degrees higher for females compared to males (p -values < 0.05). Regression analysis demonstrated that females had increased acetabular coverage at 10:30 (OR: 1.30, CI: 1.06-1.61, $p = 0.014$) and males had increased femoral head diameter (OR: 1.94, CI: 1.49-2.53), $p < 0.001$) and increased alpha angles at 1:30 (OR: 1.08, CI: 1.02-1.14, $p = 0.011$).

Conclusion: Adolescent males and females with symptomatic FAI have significant differences in FAI morphology that are important to recognize. Females have 2.1% less anterior coverage, 2.7% more posterior coverage, about 3° higher cranial and central version, 3.7° higher femoral version, 12.8° lower maximum alpha angle, a more anterior cam location, and 2.7° higher femoral neck-shaft angle.

Significance: CT has recently been recognized as a supplement to plain radiographs for assessing morphology of FAI. Differences between CT morphologic findings for males and females were presented.



Predictors of Anxiety and Depression in Adolescent Femoroacetabular Impingement Patients

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LOE: Lesser quality RCT, prospective comparative study or retrospective study-Level II

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Introduction: Symptomatology of femoroacetabular impingement (FAI) can be exacerbated by underlying mental health disorders such as anxiety and depression. Recent literature has correlated patient-reported outcomes measurement information system (PROMIS) anxiety scores ≥ 62 with DSM-5 diagnosis of generalized anxiety disorder and PROMIS depression scores ≥ 60 with DSM-5 diagnosis of major depressive disorder. The purposes of the current study were (1) to characterize the rates of anxiety and depression in adolescent FAI patients, and (2) to identify clinical predictors of anxiety and depression in this population.

Methods: A multicenter, prospective cohort study of adolescent undergoing FAI treatment was performed. Inclusion criteria included a diagnosis of idiopathic FAI in patients with age 14 to 18.9 years at time of arthroscopic treatment. Data recorded included demographics, pain chronicity, and patient-reported scores. PROMIS anxiety ≥ 62 was defined as “high anxiety” and PROMIS depression ≥ 60 was defined as “high depression.” Multivariate logistic regression was utilized to determine whether associations existed with high anxiety or high depression.

Results: A total of 194 adolescent hips undergoing FAI surgery were included. The rate of high anxiety in the cohort was 18.8%, including 25.2% (95% CI: 19.1%-31.4%) in females compared to 8.3% (95% CI: 4.4%-12.3%) in males ($p=0.004$). The rate of high depression in the entire cohort was 13.6%, including 17.6% (95% CI: 12.2%-23.0%) in females compared to 6.9% (95% CI: 3.3%-10.5%) in males ($p=0.049$). Overall, the rate of either high anxiety or high depression in females was 28.8% (95% CI: 22.4%-35.2%) compared to 11.1% (95% CI: 6.7%-15.6%) in males ($p=0.006$). Among patients with high anxiety, 54.1% of patients had high depression compared to 3.9% of those without high anxiety ($p<0.001$). Additionally, patients with high depression were more likely to have high anxiety at a frequency of 76.9% compared to 10.2% ($p<0.001$). Multivariate logistic regression demonstrated that patients having high depression had a 12 times increased chance of having high anxiety ($p<0.001$). Having high anxiety had a 17 times increased chance of having high depression ($p<0.001$).

Conclusion: Over 20% of adolescent patients with femoroacetabular impingement have associated mental health conditions, such as anxiety or depression. When present, many patients have both high anxiety and high depression.

Significance: Adolescents can be concurrently affected by FAI and mental health disease such as anxiety or depression. The present article discusses these associations to help clinicians identify concurrent depression or anxiety so that patients may be treated appropriately.

Does Patient Resiliency Influence Patient-reported Outcomes at Presentation in Symptomatic Femoroacetabular Impingement

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Abstract

Background

The role of psychological factors in the clinical presentation and outcomes of treated is increasingly recognized in orthopaedic surgery. Particularly, in pre-arthritis hip disorders, young adult hip patients often have significant psychological undertones. Patient resiliency, as quantified by the brief resiliency scale (BRS), is a static patient characteristic and has been increasingly recognized for its potential role in pain and symptomatology. The purpose of the current study was to investigate the correlation between BRS and traditional hip patient-reported outcome metrics (PROMs).

Methods

A prospective multicenter cohort study of 696 FAI patients undergoing primary hip arthroscopy surgery was performed and utilized for the current study. Inclusion criteria are patients aged 14-45 years with idiopathic FAI not caused by childhood disease. Exclusion criteria are previous ipsilateral hip procedures or disease processes such as neuromuscular disease or high-grade osteoarthritis. PROMs included the patient reported outcomes measurement information system (PROMIS) domains of pain interference, physical function, mobility, anxiety and depression, as well as hip disability and osteoarthritis and outcome score (HOOS), modified Harris hip score (mHHS), international hip outcome tool (iHOT-12), and short form-12 (SF-12). Resiliency was divided into low resiliency (score < 3), normal resiliency (score 3 - 4.3), and high resiliency (score > 4.3) as described by Smith et al.¹ to use as categorical variables to compare to the other patient-reported scores. The Pearson correlation coefficient (r) was calculated and the Kruskal Willis test was used to measure association between BRS and the other PROMs for continuous and categorical values, respectively. R-values ≥ 0.7 , ≥ 0.4 ,

and ≥ 0.1 signify a strong, moderate, and weak correlation, respectively. For categorical analysis, p-values < 0.05 were considered significant.

Results

The cohort of 696 patients had mean age was 24.9 ± 7.9 years and a female predominance at 56%. Average BRS scores were 3.7 ± 0.7 . Overall, 13.7% of patients had low resiliency, while 65.8% had normal resiliency and 20.5% had high resiliency. Linear correlation, using Pearson coefficients, found associations between BRS and all other scores. There were only weak associations between BRS scores and PROs (all $r < 0.25$) except a moderate correlation with PROMIS depression ($r = -0.476$, $p < 0.001$) and PROMIS anxiety ($r = -0.481$, $p < 0.001$). Patients in higher resiliency groups reported less severe symptoms in HOOS QoL ($p < 0.001$), HOOS sports and recreation ($p = 0.004$), HOOS ADL ($p = 0.004$), HOOS pain ($p = 0.026$), iHOT-12 ($p = 0.01$), mHHS ($p = 0.004$), SF-12 mental ($p < 0.001$), PROMIS physical function ($p = 0.003$), PROMIS pain ($p < 0.001$), PROMIS mobility ($p < 0.001$), PROMIS depression ($p < 0.001$), and PROMIS anxiety ($p < 0.001$). Patients with higher activity levels (UCLA ≥ 9) demonstrated higher resiliency ($p = 0.04$).

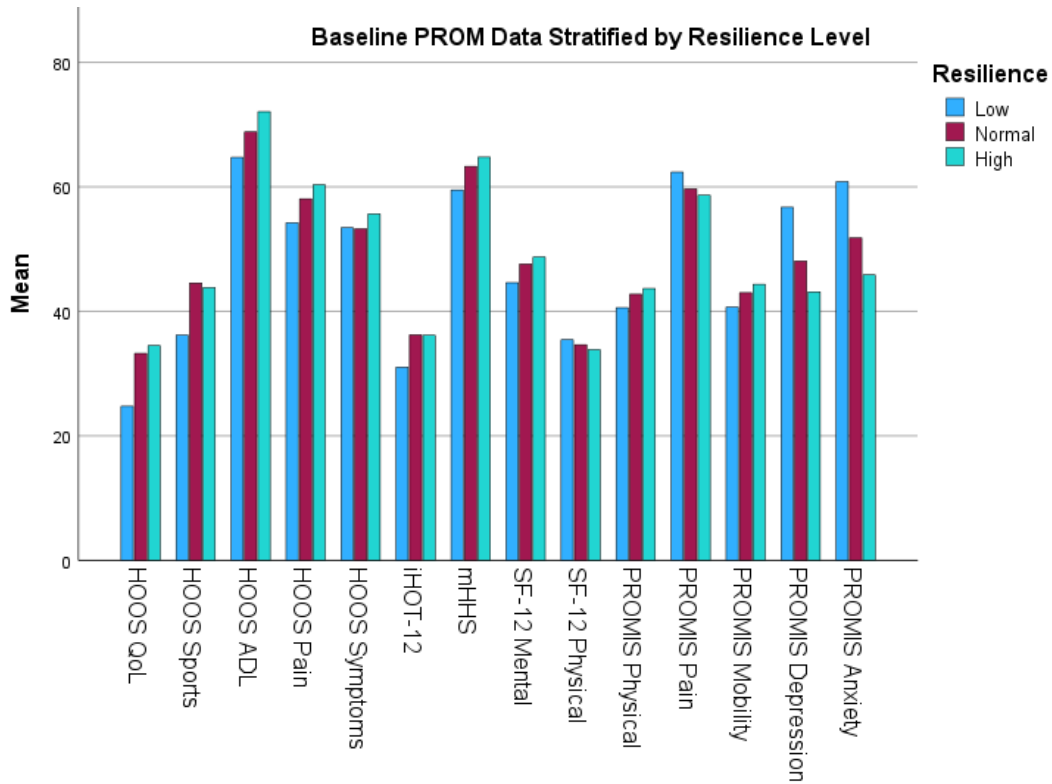
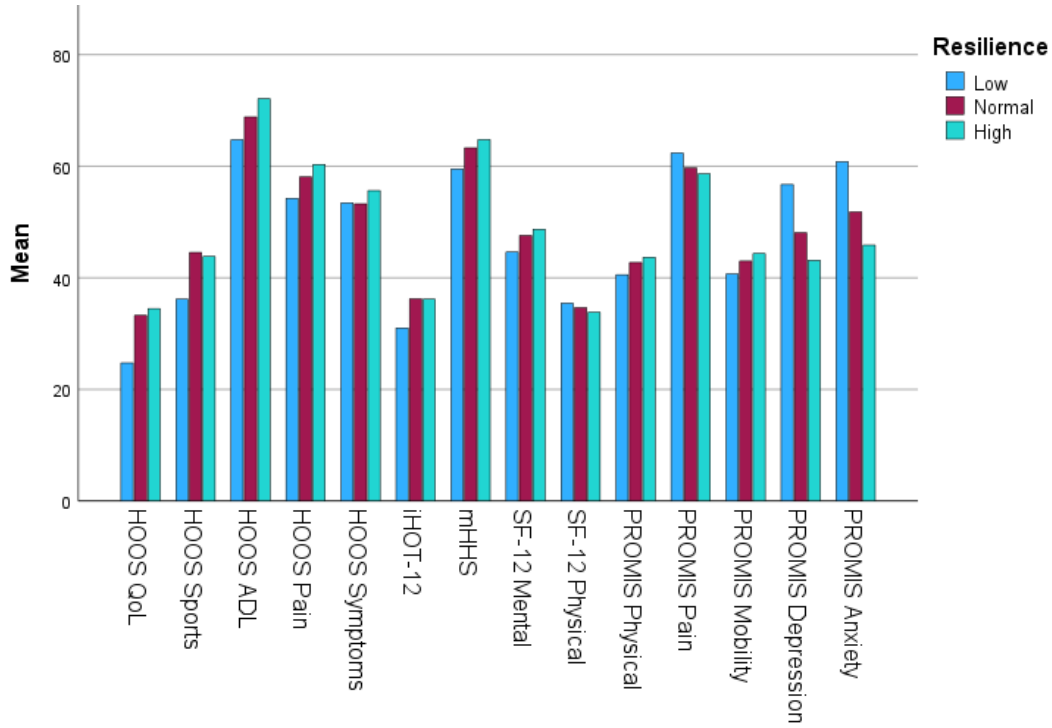
Conclusion

In FAI patients, patient resiliency appears to influence baseline PROs. Overall, 14% of patients had low resiliency while 21% had high resiliency. Further studies are needed to investigate this relationship and whether concurrent psychological treatment will help improve patient outcomes after hip arthroscopy for FAI.

Reference

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Figure 1: Baseline PROM Data Stratified by Resilience Level



Changes in Characteristics of Patients Undergoing FAI Surgery: A Prospective Multicenter Cohort Comparison of Early and Modern FAI

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Abstract

Background

Our understanding of femoroacetabular impingement (FAI) has evolved significantly since its original description by Ganz and colleagues 20 years ago. This includes a variety of aspects of diagnosis, physical examination, and treatment decision-making. The purpose of the current study was to compare the patient characteristics of first-generation FAI surgery (years 2008 to 2011) to modern FAI surgery (years 2020 to 2022) utilizing two prospective multicenter cohort studies.

Methods

Two prospective multicenter prospective cohort studies of the treatment of FAI were utilized for the current study. For the contemporary cohort, inclusion criteria are patients aged 14-45 years with idiopathic FAI not caused by childhood disease. Exclusion criteria are previous ipsilateral hip procedures or disease processes such as neuromuscular disease or high-grade osteoarthritis. Patient reported outcomes measurement information system (PROMIS) and legacy patient reported outcome measures (PROM) were recorded pre-operatively along with all demographic data. The first-generation FAI-1 cohort was treated from 2008 to 2011 across 12 surgeons at 8 institutions. The modern FAI-2 cohort was treated from 2020 to 2022 across 16 surgeons and 12 institutions.

Results

After enrollment, 696 hips were included in the FAI-2 cohort, compared to 1,129 hips in the FAI-1 cohort. The average age was 24.9 ± 7.9 years compared to 26.9 ± 10.5 years ($p < 0.001$). There was a similar female predominance in both cohorts (FAI-2 56%, FAI-1 55%, $p = 0.2$). Surgeon diagnosis of FAI subtype appears to have changed over time with more isolated cam-type FAI (73% FAI-2, 47% FAI-1) and less combined cam/pincer FAI (24% FAI-2, 45% FAI-1). For pain chronicity at time of surgery, 40% of patients now present before a year with symptoms compare to 31% in FAI-1 ($p < 0.001$). No significant differences in any baseline PROMs were present between FAI-1 and FAI-2. The alpha angle was significantly greater in the FAI-2 group (FAI-2 $66.9^\circ \pm 12.0^\circ$, FAI-1 $63.0^\circ \pm 13.6^\circ$, $p < 0.001$), as well as a higher LCEA in FAI-2 (FAI-2 $30.0^\circ \pm 6.2^\circ$, FAI-1 $28.7^\circ \pm 8.3^\circ$, $p = 0.002$).

Conclusion

Our understanding of FAI continues to evolve. The current study demonstrates changes in the population of patients undergoing FAI surgery compared to a decade prior. Patients are now presenting at a younger age with a higher isolated CAM type FAI, lower mixed type FAI, greater alpha angles, and greater LCEA.

Activity Level Assessments at Presentation Significantly Underestimate Pre-Injury Activity Levels in FAI Patients

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Abstract

Background

Activity level plays an important role in the pathophysiology of femoroacetabular impingement (FAI) and often pain limiting participation in an activity plays a critical role in patient's decision-making for surgery. The ability to return to pre-injury activity level often is a critical component of patient satisfaction after FAI surgery. The UCLA activity scale is most commonly utilized assessment of activity, but generally asks patients activity currently (UCLA-current) or in the last six months (UCLA-6month). However, given the chronicity of symptoms, many patients may have changes in their activity level for extended periods before surgery from their original preinjury activity level (UCLA-preinjury). The purpose of the current study was to investigate the pre-operative activity levels of patients undergoing FAI surgery using the UCLA activity scale preinjury compared to in the 6-month time period before treatment and at the time of surgery.

Methods

A prospective multicenter cohort study of 696 FAI patients undergoing primary hip arthroscopy surgery was performed and utilized for the current study. Inclusion criteria are patients aged 14-45 years with idiopathic FAI not caused by childhood disease. Exclusion criteria are previous ipsilateral hip procedures or disease processes such as neuromuscular disease or high-grade osteoarthritis. The UCLA activity scale was determined based on a self-administered patient questionnaire that has a scale of 1-10 with 1 being completely inactive and 10 being active participation in impact sports such as tennis or skiing. UCLA activity was assessed preinjury (UCLA-preinjury), as well as prior six months (UCLA-

6months) and current (UCLA-current). The McNemar and Wilcoxon Signed-Rank tests were used to determine whether differences existed at different time points with regards to the UCLA scores for categorical and ordinal data, respectively.

Results

The cohort of 696 patients had mean age was 24.9 ± 7.9 years and a female predominance at 56%. 60% of patients participated in sports and 38% of these patients participated in competitive sports. The mean UCLA-preinjury score was 9.1 ± 1.9 ($p < 0.001$), compared to UCLA-6months 6.8 ± 2.8 and UCLA-current 6.4 ± 2.9 . For females, mean UCLA-preinjury score was 8.9 ± 2.1 , compared to a mean UCLA-6months of 6.32 ± 2.9 UCLA-current of 5.92 ± 2.8 . For males, mean UCLA-preinjury score was 9.3 ± 1.7 , compared to a mean UCLA-6months of 7.5 ± 2.7 and mean UCLA-current of 7.0 ± 2.9 . The percentage of patient with scores of 9 or 10 were 81% for UCLA-preinjury, compared to 42% for UCLA-6months, and 37% for UCLA-current, respectively. The UCLA-preinjury was greater than the UCLA-6months in 58% of patients with 12% reporting a difference of 6 points.

Conclusion

In FAI patients, there is a decline in activity level as disease progresses and symptoms increase. Research studies assessing activity level in FAI patients should assess pre-injury activity level, rather than activity level at the time of presentation or prior six months. Assessment of surgical outcomes relative to the preinjury activity level will provide the best assessment of truly returning FAI patients back to normal.