Improving Rehabilitation Outcomes After Total Hip Arthroplasty

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I. HYPOTHESES AND SPECIFIC AIMS

Over the next 20 years, the number of total hip arthroplasties (THAs) performed to alleviate pain and disability associated with osteoarthritis (OA) is expected to double to more than 500,000/year.[1] Most patients report improved health-related quality of life following surgery;[2-4] however, deficits in physical function and quality of life persist. Specifically, Veterans with THA have a higher prevalence of severe ADL limitations[5] and report severe physical health-related quality of life deficits.[6] The increased THA utilization, combined with long-term functional deficits which increase heath care utilization,[5] suggests a need for targeted rehabilitation strategies to improve physical function for Veterans after THA.

Movement compensations are a biomarker of functional decline in a variety of older adult populations.[7,8] For patients with THA, persistent movement compensations are seen in activities of daily living, such as level walking, sit-to-stand transitions, and stair climbing.[9-11] These movement compensations likely stem from a combination of poor muscle strength and a failure to integrate available muscle strength into functional movement. *Functional strength integration* (FSI) during daily tasks refers to the ability of the body to produce stable, coordinated movements.[12] At the hip joint, optimal FSI is largely dependent on the ability of hip abductor muscles to produce sufficient hip abduction moments to stabilize the pelvis during unilateral stance tasks.[13,14] Thus, inability to integrate hip abductor muscle strength during functional tasks results in poor pelvic stability and movement compensations. Lack of FSI possibly explains the deficits in functional recovery after THA.[15] However, current rehabilitation practices do not target the integration of strength and functional movement to resolve movement compensations.

Rehabilitation emphasizing *functional strength integration* after THA has the potential to substantially improve postoperative physical function by remediating movement compensations with greater hip abductor strength and recruitment during function, providing greater pelvic control and better movement quality. **Therefore**, **we propose a randomized controlled trial of 100 participants to determine if an 8-week functional strength integration (FSI) program improves physical function and muscle performance more than control intervention (CON) after unilateral THA.** The secondary goal is to determine if FSI improves movement compensations during functional activity (walking and stair climbing). Outcomes will be assessed pre-operatively (PRE); intervention mid-point, 4 weeks (POST1); intervention end-point, 8 weeks (POST2) (primary endpoint); and late recovery, 26 weeks (POST3).

Aim 1: To determine if FSI results in better *physical function* and *muscle performance* after unilateral THA compared to usual care rehabilitation. Physical function will be measured with standardized performance-based tests [6-Minute Walk (primary outcome), Four-Meter Walk, 30 second sit-to-stand, and Functional Gait Assessment] and self-report measures [Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Veterans RAND 12-Item Health Survey (VR-12)]. Muscle performance will be assessed with measures of muscle strength (hip abduction force) and muscle endurance (modified Trendelenburg test). Hypothesis 1: The FSI group will have greater physical function and muscle performance improvements than the CON group from baseline to POST2 (primary endpoint), and group differences will persist at POST3.

Aim 2: To determine if FSI intervention more effectively reduces movement compensations than CON intervention after unilateral THA, as measured by *peak internal hip abduction moments* during gait. Hypothesis 2: The FSI group will have greater increases in surgical-limb peak internal hip abduction moments during gait compared to the CON group from baseline to POST2, and group differences will persist at POST3.

Impact: Chronic movement compensation, a key biomarker of functional decline, is overlooked in current rehabilitation strategies following THA. The application of functional strength integration (FSI) is effective in remediating movement compensation for athletic populations recovering from orthopedic surgeries (e.g. anterior cruciate ligament reconstruction). This study will be the first to apply advanced FSI techniques in the

rehabilitation of older Veterans with THA in order to shift the current rehabilitation paradigm and target persistent movement compensation and poor physical function outcomes.

II. BACKGROUND AND SIGNIFICANCE

Significance of the proposed study is based on: 1) the anticipated increase in utilization of total hip arthroplasty (THA), 2) the unknown efficacy of physical rehabilitation after THA, 3) the long-term strength and functional deficits after THA, 4) direct associations between movement compensations and physical function following THA, and 5) a novel rehabilitative approach to remediate movement compensations and improve functional performance.

A1. Anticipated Increase in Utilization of Total Hip Arthroplasty Surgery

Total hip arthroplasty (THA) is considered a common orthopedic procedure.[16] Currently, there are over 230,000 THAs performed each year in the United States to alleviate pain and disability associated with osteoarthritis (OA).[17] As a result of the country's aging population and the increasing prevalence of obesity, the need for THA to treat the pain and disability from hip OA is expected to increase.[18] Specifically, it is projected that more than 500,000 THA procedures will be performed per year to relieve pain with hip OA by 2030.[1]

A2. Efficacy of Physical Rehabilitation after THA is Unknown

Despite evidence that strength training improves hip muscle strength and physical function, there is **no consensus on the course of postoperative care following THA**.[19,20] In fact, surgeons commonly state they do not refer patients for rehabilitation after THA in large part because of the variability in rehabilitation approaches and concerns over dislocation risk. Furthermore, current rehabilitation practices have not addressed the common movement compensations observed before and after THA, nor evaluated their effect on physical function.

Persistent muscle weakness, movement compensations, and physical function deficits after THA suggest inadequate postoperative management. It is likely that *isolated* strength training may not address movement compensations seen during activities such as walking and stair climbing after THA. The combination of evidence that 1) strength training improves outcomes after THA and 2) functional strength integration techniques improve outcomes in other patient populations[12,21-27], suggests that the addition of *functional strength integration* may further improve rehabilitation outcomes following THA. Rehabilitation after THA needs a paradigm shift to more effectively improve movement quality and function.

A3. THA Results in Long-term Strength and Function Deficits

After THA, individuals demonstrate deficits in muscle strength, postural stability, and physical function compared to age-matched cohorts.[28-30] Specifically, **hip muscle strength** is negatively impacted for several years after THA.[30,31] Patients after THA lack 20% of the hip muscle strength of healthy adults[31] and demonstrate 20% less strength in the surgical hip muscles compared with their non-surgical hip one year postoperatively. The resultant hip strength deficits are a combination of muscle weakness carryover from before THA[32] and further declines in hip strength immediately following surgery.[33] Despite experiencing improvements in pain following THA, full remediation of strength deficits remains an important issue in postoperative management. Muscle weakness is associated with poor self-reported function[28], decreased single limb balance[28], and increased fall risk.[34] In fact, the odds ratio associated with weakened hip musculature ranges from 1.9 for recurrent falls (i.e. ≥2 falls) to 10.3 for falls in general (i.e. at least one fall).[32] Additionally, individuals experience **difficulty with postural stability (i.e. balance)** following THA. Specifically, Trudelle-Jackson *et al*.[28] reported significant differences in postural stability in patients' surgical hips one year after surgery and found correlation between self-reports of decreased function and decreased hip abductor strength. Further, Nallegowda *et al.*[35] reported impairments in dynamic balance and compensatory balance strategies in individuals following THA compared to healthy adults. The failure to regain adequate postural stability during functional tasks could be related to difficulties regaining strength after THA, as well as an inability to integrate muscle strength into functional tasks to stabilize the pelvis and provide a stable base for functional movement.

Full **recovery of physical function is challenging** after THA, as patients recover physical function to only 80% of healthy adults.[36] The difficulty with physical function in the several years following THA

may explain why patients have lower scores on the SF-36[3] and are less physically active one year after THA.[37] Additionally, significant drops in SF-36 scores have been observed 5 and 7 years after surgery.[3,4] Difficulty with gait activities such as level walking[10,38] and stair climbing[9] is an important and persistent problem after THA. For example, gait speed is nearly 20% slower than healthy older adults[11] even 10 years after surgery[39], and 46% of patients followed for 7 years after THA required an assistive device during walking, compared with only 8% of healthy older adults followed over the same time period[3], suggesting that, after THA, patients have long-term difficulty with ambulatory activities of daily living. Indeed, 6-minute walk (6MW) outcomes are one of the key long-term functional limitations identified for people living with THA.[40] The recovery of physical function may be even more challenging for Veterans undergoing THA. Veterans with THA have a higher prevalence of severe ADL limitations[5] and report severe physical health-related quality of life deficits[6] compared with Veterans not receiving joint arthroplasty and compared to the US population not receiving joint arthroplasty.[5] Mobility disability (e.g. the inability to independently walk and climb stairs)[41] places a significant financial burden on our healthcare system[42] and is a risk factor for decreased life expectancy in older adults.[41] Furthermore, mobility disability can lead to loss of independence[43] and increases in fall risk[34], which may increase hospitalization and health care utilization.[43] In fact, Veterans with THA higher comorbidities and heath care utilization.[5] The combination of the long-standing deficits present after THA, particularly in the Veteran population, suggests that more effective rehabilitation interventions to improve physical function and quality of life for Veterans after joint arthroplasty are warranted.

A4. Physical Function and Movement Compensations

Functional task performance after THA is characterized by the presence of movement compensations. Recently, movement compensations have been found to serve as important biomarkers of functional decline in a variety of older adult populations[7,8] and are linked to increased fall risk[7,8] and poor functional outcomes.[44] Persistent movement compensations are common after THA during activities of daily living, such as level walking and stair climbing. Therefore, it is not surprising that deficits in physical function after THA specifically relate to abnormal movement compensations. In particular, slow walking speeds observed after THA are related to **low internal hip abduction moments,** reflecting abnormal movement control at the hip and pelvis during gait.[10,24,45,46]

Low internal hip abduction moments are seen prior to surgery during functional tasks and persist after THA.[10,24] Intentional integration of muscle strength training into functional movement patterns is likely needed for patients to break habitual movement compensation patterns and incorporate post-surgical strength gains into daily functional activity. For daily movement tasks, coordinated hip and pelvic muscle activity[23] provides pelvic stability relative to the lower extremities to minimize movement compensations. Around the hip and pelvis, stability is largely dependent on the ability of hip abductor muscles to **produce internal hip abduction moments to control pelvis motion during unilateral stance.**[13,14] In fact, the role of the hip abductor musculature is to adapt to perturbations experienced during function to maintain a stable pelvic base.[23] For patients with THA, the hip abductor musculature does not adequately stabilize the pelvis, resulting in reduced internal hip abduction moments of the surgical hip.[10,24,45] The resulting movement compensations can then stress other joints and create difficulty performing activities of daily living.[15] Full **integration of muscle strength** requires the hip and lumbopelvic muscles to work in concert during functional task performance, thus providing stability around the hip and pelvis, which is not achieved solely through strength training alone. Further, this muscle strength integration will improve the hip abductor musculature's ability to generate internal hip abduction moments to improve stability, and therefore improve recovery of physical function after THA. **However, current rehabilitation practices have not targeted functional strength integration to address the resolution of movement compensations.**

A5. Integration of Strength and Function Improves Outcomes

Resolving movement compensation requires exercise beyond strength training alone. Specifically, concentrated training to improve muscle recruitment improves movement quality and may minimize injury risk in numerous other patient populations.[21,47] Targeted **functional strength integration**: 1) utilizes weight-bearing exercises to improve muscle coordination and joint stabilization[12], 2) aims to improve sensorimotor control and stability by emphasizing muscle co-activation, and 3) focuses on remediating movement

compensations by emphasizing muscle recruitment and movement quality which requires functional muscle strength, coordination, and stability.[48]
Combining strength and functional training has been used successfully in rehabilitation for other chronic injury populations—specifically, after anterior cruciate ligament (ACL) reconstruction and for patients following ankle sprain.[21,27,49,50] Emphasizing proper muscle recruitment, stability, and strengthening for improved stability during functional tasks effectively improves gait mechanics[27], increases hip abductor strength[21], increases joint stability[50], and prevents further injury.[49] Additionally, this type of integrated training has been utilized successfully in older adults with hip and knee OA, but not after THA.[12] The addition of this type of training to a postoperative THA rehabilitation protocol has the potential to not only resolve persistent movement compensations following THA, but also to change the rehabilitation approach for patients after THA.

In summary, full recovery of physical function after THA entails both strength training and remediation of movement compensations through improved integration of strength and function, thus improving recovery and physical functioning after surgery. Because no evidence-based recommendations exist to guide exercise prescription after THA, this study will add significant knowledge for postoperative rehabilitation guidelines and thereby has high potential to change clinical practice for Veterans undergoing THA.

The proposed study is innovative in that it will: 1) uniquely target movement compensations to promote pelvic stability for improved physical function, 2) shift clinical practice evidence regarding postoperative rehabilitation, and 3) challenge current convention that rehabilitation is not necessary after THA.

B1. Unique Approach to Target Movement Compensations
The proposed RCT uses a unique rehabilitation paradigm following THA to target movement compensation. Our pilot feasibility study used instrumented motion analysis to quantify movement compensations after THA by focusing on the internal hip abduction moments that control the pelvis during functional tasks. In the pilot study, we demonstrated that targeted functional strength integration substantially attenuated movement compensations through improved surgical limb internal hip abduction moments during walking and stair stepping tasks. The proposed RCT will build upon the results of our pilot feasibility study and **be the first trial to specifically target remediation of physical function and muscle performance to alleviate movement compensations and improve hip abduction moments during gait**. The intervention strategy for the pilot feasibility study included a targeted functional strength integration (FSI) program, designed to address movement compensations and impaired surgical limb internal hip abduction moments present during single-limb support tasks such as walking. Zeni and colleagues[51] have recently shown that patients with unilateral hip OA have lower internal hip abduction moments during gait on the affected limb compared to the unaffected limb before surgery. Consistent with existing literature[46,51], our pilot data confirm the presence of impaired internal hip abduction moments on the surgical limb before surgery and also demonstrate that without targeted intervention, surgical-limb hip abduction moments worsen after surgery (see section D1.4). Other studies have also shown that peak internal hip abduction moments are impaired after THA during walking and stair climbing.[45,52] Identification of the peak internal hip abduction moment as a specific metric to quantify movement compensations is critical for assessing targeted rehabilitation strategies. This proposed study is the first to provide a specific intervention to target resolution of movement compensations and provide peak internal hip abduction moment as a specific metric for quantifying improved movement patterns.

B2. Shift in Clinical Practice Patterns
Shifts in rehabilitation strategy have occurred in other patient populations, but not for THA. For example, following a lateral ankle sprain injury, once considered a relatively minor injury, individuals often suffer from chronic joint instability.[27] After identifying that individuals suffered from chronic functional mobility limitations, pain, and instability, rehabilitation professionals began incorporating balance, neuromuscular re-education, and sensorimotor training techniques to improve outcomes for individuals after ankle sprain, similar to the proposed FSI protocol. Recent publications indicate that these training techniques have improved ankle strength and postural stability[25,27], improved ankle movement during gait[26], and reduced the risk of reinjury.[24] Rehabilitation following injury in the knee has had a similar evolution. In addition to more aggressive mobilization and strength training following ACL surgery, functional neuromuscular re-education techniques, similar to the proposed FSI protocol, have been used successfully to improve strength[21,48], to improve movement strategies, and to reduce risk of ACL injury in at-risk populations.[49] The application of similar rehabilitation strategies to a

post-THA rehabilitation protocol should have a similar positive impact on future rehabilitation standards of practice.

B3. Challenge Current Postoperative Convention

Current practice patterns following THA do not routinely include rehabilitation. After an inpatient hospital stay, including rehabilitation strategies to prepare patients to go home, home-based physical therapy is occasionally utilized, and outpatient more rarely. Recent communication with 6 local hospitals in the Denver area indicates that none routinely refer their patients to outpatient rehabilitation due to lack of evidence establishing the benefits of, and guidelines for, rehabilitation. Only 2 of the 6 hospital facilities recommend 1-2 weeks of home physical therapy (2x/wk). Although not well documented in the literature, conversations with rehabilitation specialists and orthopaedic surgeons suggest a common *misperception* that early, intensive intervention may increase musculoskeletal injury (e.g. specifically hip dislocation risk). These conversations further suggest that healthcare professionals desire evidence of safe and effective rehabilitation approaches for THA patients. Although no consensus exists for managing patients after THA, emerging literature supports the benefits of physical rehabilitation after surgery. In a systematic review of rehabilitation strategies following THA, DiMonaco and Castiglioni concluded that rehabilitation can improve muscle strength and functional performance outcomes following THA.[53] However, **variable approaches to types of exercise, timing of rehabilitation initiation, and exercise intensity** led to a lack of agreement on the optimal rehabilitation prescription following THA. A second review article by Minns-Lowe *et al*. also identified benefits of rehabilitation after THA, but emphasized that **study quality and intervention improvements are needed**.[54] Preliminary studies have provided evidence that progressive, high intensity strength training early after THA may be safe and effective for improving strength and physical function.[22,55-58] However, **studies have not emphasized functional strength integration as a central component of a rehabilitation program to address movement compensations that affect functional performance**. The successful implementation of our proposed FSI program will explore whether such an emphasis more effectively remediates functional performance deficits after THA than previous rehabilitation strategies. Furthermore, improved outcomes will challenge the perception that rehabilitation is not necessary or increases injury after THA surgery.

III. PRELIMINARY STUDIES

A1. Preliminary Studies

Dr. Jennifer Stevens-Lapsley (PI) has led the design, implementation, and publication of several clinical research studies involving patients with total joint arthroplasty[59-66], including 2 recently completed randomized controlled trials (NIH R03AR054538 and K23AG029978)[66,67] and one large-scale RCT in the final stages of completion (R01HD065900). These clinical trials involved acute (48 hrs), subacute (1-6 months), and long term (12-24 months) measures of muscle strength and function and successful implementation of postoperative, multi-site rehabilitation programs. The PI and investigative team have also recently completed two investigations to 1) characterize physical recovery after THA and 2) provide initial data on the efficacy of rehabilitation focused on functional strength integration after THA as currently proposed.

A1.1. Outcomes Following Total Hip Arthroplasty

In a previous longitudinal, observational study,[33] the investigative team concluded that patients experience early postoperative strength losses and decreased functional capacity after posterolateral THA, and these deficits persist. Specifically, one month after THA, patients had 15% less hip flexor and extensor torque, 26% less abductor torque, 14% less knee extensor and flexor torque, and worse performance on the stair climbing, timed-up-and-go (TUG), and 6-minute walk (6MW) compared to preoperative values. Twelve months after THA, patients had 17% less knee extensor torque, 23% less knee flexor torque, and performed approximately 10-15% worse on measures of physical function (e.g. stair climbing, TUG, and 6MW), than healthy peers. SF-36 Physical Component Scores, although significantly improved from preoperative levels, were significantly worse than healthy adults 1 year after THA ($p < 0.01$). **These results demonstrate that strength and physical function deficits do persist after THA, and indicate that rehabilitation might address these deficits, especially in the first month after surgery when deficits are greatest.**

A1.2. Functional Strength Integration after Total Hip Arthroplasty: A Pilot Study

A second study conducted by the investigative team was designed as the feasibility and initial efficacy study for the current proposal. In this pilot THA rehabilitation study, a multi-component intervention with specific focus on integrating strength and function as currently proposed (i.e. FSI; see D2.2) was compared to control group

outcomes. The *control group* participated in supervised home-based recovery following surgery. Study staff visited patients at home once per week in the early postoperative period and continued to follow patients by telephone and home visits in the later postoperative period. Control group participants continued prescribed exercises from their hospital stay throughout the study intervention phase, with advice to progress as tolerated. Further, study staff advised patients in assistive device use, functional mobility around the house, and encouraged participation in activities of daily living as tolerated. Results of the pilot study (n=20) suggest strong potential for functional strength integration (FSI) to improve functional outcomes. Specifically, at the end of intervention, the FSI group had significantly greater improvements in SCT (P=0.030), 4MW (P=0.001), and 6MW (P=0.002) compared to controls (Figure 1). At 10 weeks after THA, there was a trend for the FSI group to remain more stable at the pelvis during static single limb support (p=0.070) and have greater hip abductor strength improvement (P=0.090). Further, the FSI group had significantly greater improvements in self-reported function in the HOOS ADL (P=0.010), Pain (P=0.009) and QOL (P=0.040) subscales. **This investigation provides strong initial evidence that physical function can be improved through FSI intervention, but a larger scale intervention is necessary to more definitively demonstrate benefits of FSI intervention.**

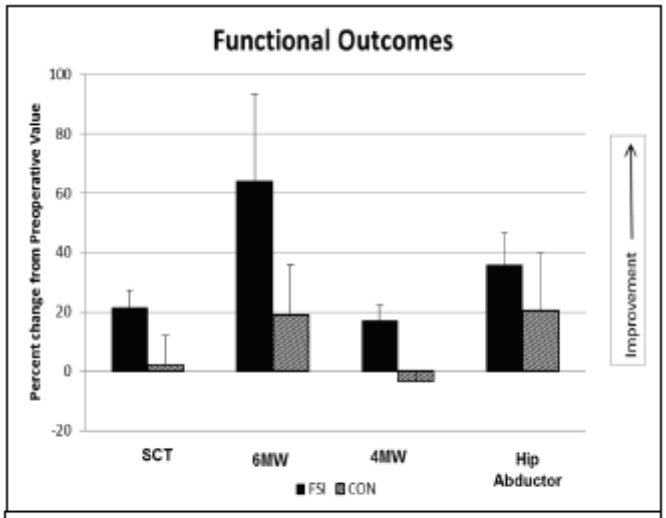

Figure 1. Percent change from preoperative testing to end of FSI intervention (8 weeks) for stair climb test (SCT), 6-minute walk (6MW), 4-meter walk (4MW), and hip abductor strength.

A1.3. Anterior Surgical Approach THA

Patients in the two aforementioned preliminary studies received a posterolateral THA. Because of increasing interest in a direct anterior surgical approach for THA[68], we investigated functional outcomes and response to FSI intervention in a cohort of individuals undergoing THA surgery using an anterior approach. The results of this sub-study indicate that **individuals undergoing a direct anterior approach THA had similar outcomes postoperatively and responded similarly to the FSI rehabilitation program as patients undergoing posterolateral approach THA**. Specifically, there were no significant differences in early postoperative outcomes (2 weeks) for 4MW speed or TUG times between the posterolateral and anterior approach groups. Additionally, the anterior cohort had similar trajectory of functional recovery as the FSI posterolateral group, with no group differences in SCT, 6MW, or 4MW at the conclusion of the intervention period. There is currently a paucity of prospective data; those that do exist are conflicting with some finding differences in functional outcomes[68-70] and others finding no differences in functional outcomes between surgical approaches.[71-75] With conflicting evidence, no definitive conclusions can be drawn as to the effect of surgical approach on functional recovery. It is clear that hip abductor performance and pelvic stability are impaired **prior** to surgery[51], and therefore, regardless of surgical approach, need to be addressed with postoperative rehabilitation. Because of increasing utilization of the direct anterior approach, randomization for the proposed investigation will include stratification by surgical approach (posterolateral or direct anterior approach THA). Including patients with both surgical approaches will increase the generalizability of study findings to more substantially impact clinical practice.

A1.4. Movement Compensations are Sensitive to Targeted Rehabilitation

We examined movement compensations in a subset of patients from the pilot study (D.1.2) using 3-D motion analysis, with specific analysis of hip joint moments (n=15). The pilot study analysis revealed that movement compensations can be identified in the functional hip joint mechanics after THA and that these measures are sensitive to change with FSI intervention. Specifically, the control group had *reduced* surgical limb internal hip abduction moments after surgery (Figure 2). However, the FSI intervention group had increased surgical-limb peak hip abduction moments after intervention, during both level ground walking and stair stepping. Specifically, in our small cohort of 15 patients (5 control and 10 intervention) we found a minimal *increase* (0.02 Nm/kg) in internal hip abduction moment during walking from before surgery to 10 weeks after surgery in the FSI intervention group and a *decrease* (-0.20 Nm/kg) in the control group. **The changes seen in the surgical**

limb peak internal hip abduction moments resulted in greater asymmetry in movement patterns at the 10-week time point for the control group than for the FSI intervention group. This can be seen when looking at the internal hip abduction moments across the gait cycle for both the surgical and non-surgical limbs (Figure 3), resulting in less gait compensation for the FSI intervention group. It is possible that the improvement in gait compensation is directly linked to the observed improvement in functional outcomes seen in the FSI intervention group (Section D.1.2). **The proposed study aims to specifically answer the question of how targeted FSI can affect both gait compensation and functional outcomes after THA.**

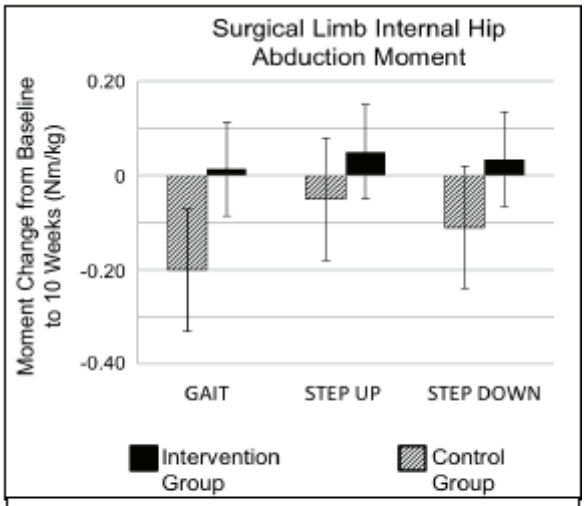

Figure 2. Peak internal hip abduction moment changes over time for the pilot-study intervention and control groups for the surgical limb during walking, step-up, and step-down tasks. (n=5 Control; n=10 Intervention)

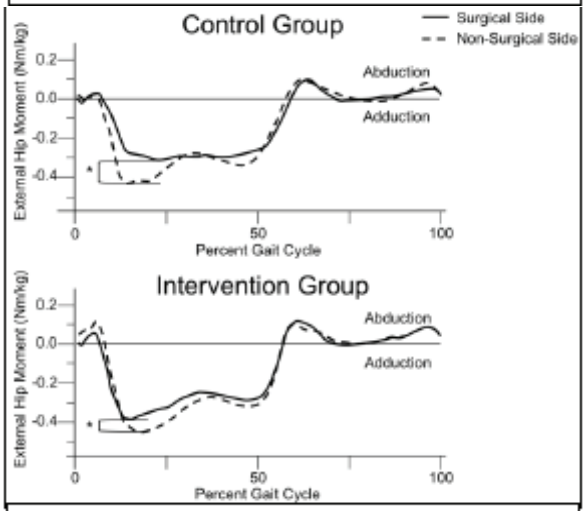

Figure 3. Internal hip abduction moments across the gait cycle in the pilot-study intervention and control groups for both hips during walking. * The bracketed lines highlight the between-limb asymmetry in peak internal hip abduction moments for each group. (n=5 Control; n=10 Intervention)

IV. RESEARCH METHODS

A1.1. Patients

One hundred-fifty patients aged 50-85 years with hip OA, scheduled for a unilateral, primary THA will be enrolled, with at least 80 patients expected to complete the study. Patients will have a THA performed by surgeons who will refer patients who meet the following criteria: 1) no severe contralateral leg OA (< 5/10 pain with stair climbing) nor other unstable orthopaedic conditions that limit function, 2) no neurological or pulmonary problems that severely limit function, 3) no uncontrolled hypertension or diabetes, and 4) body mass index ≤40 kg/m2 (for motion capture reliability). Referring surgeons will perform THA using their preferred surgical approach (anterior or posterolateral). Upon referral and prior to surgery (PRE), eligible patients will visit the **GRECC Human Movement Analysis Lab** for informed consent and baseline measurements. Two weeks after surgery, with physician approval, they will be **randomization into 1 of 2 treatment arms: FSI (experimental) group or CON (control) group.** The randomization process and maintenance of treatment code records will be managed by Jeri Forster, PhD (biostatistician), who will not be involved in patient testing/treatment. This will maintain the double-blinded condition for participants/researchers collecting data.

A1.2. Rehabilitation

Following THA surgery, standardized **inpatient** rehabilitation programs will be implemented for all patients (Figure 4). Upon returning home, patients in both groups will receive a phone call and/or home visits (if necessary) from a study physical therapist from our research team to ensure safety, provide ADL training, and monitor for complications. Randomization and initiation of study treatment will follow this 2-week recovery period to allow for early recovery before intervention. Following randomization, both groups will participate in an 8-week outpatient rehabilitation program (~40 minutes per session) at the outpatient PT Clinic, or at the

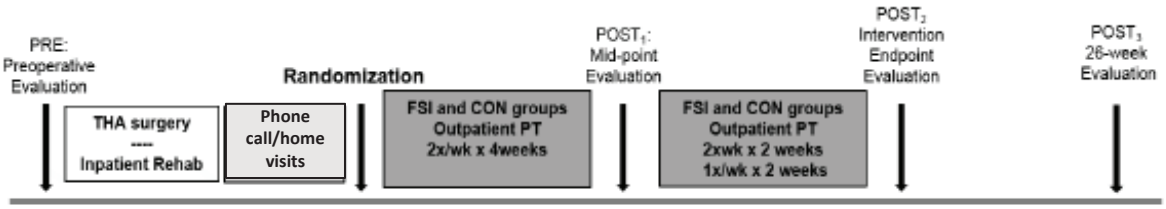

Figure 4. Proposed Study Design.

participant's home. PTs will use full PPE (gloves, mask, and face shield): 2x/week for 6 weeks and 1x/week for the last 2 weeks. Both groups will also have a home exercise program. The FSI group will receive specific exercises focusing on integration of strength and function to optimize femoropelvic alignment and pelvic stability. The CON group will mimic typical postoperative care focused on ADL training and range of motion (ROM) (see details below & appendix).

Functional Strength Integration Group Rehabilitation Program

The **FSI program** will target the integration of strength gains into lumbopelvic stability and movement quality during daily living, thus optimizing physical function for Veterans after THA. The exercise program consists of rehabilitation techniques to address the well-established, long-term impairments of muscle weakness and functional movement compensations after THA.[11,30,39] Specifically, the FSI intervention involves strengthening for the hip musculature similar to previously published protocols[22,56], combined with focused techniques emphasizing early initiation of hip muscle recruitment to stabilize the pelvis, thus integrating strength and movement pattern training to maximize functional recovery. The FSI program includes therapeutic exercise in 3 domains: **pelvic stability (PST) training, functional training (FT), and strength training (ST)** (Table 1). Activities in the **PST** domain include early surgical-limb weight bearing activities and core muscle strengthening exercises designed to progressively increase in difficulty based on patient performance benchmarks and therapist monitoring. Activities in the **FT** domain focus on gait and stair climb exercise, which progresses to higher level agility training. The **ST** domain includes progressive, resistance exercise to remediate strength in the lower extremities in the major muscle groups impacted by THA.[33] The ST exercises will include use of weighted pulleys and weight-training machines. Therapists will determine an 8-repetition maximum for each muscle group and weight will be increased by at least 10% every 2 weeks to maximize muscle hypertrophy and strength gains. The novelty of the FSI program lies in the focus on **integrating strength and function** through progressive functional exercises promoting muscle coordination around the hip, thus optimizing alignment between femur, pelvis and lumbar segments.[13]

Control Group Rehabilitation Program

There is no standard of care for rehabilitation following THA.[53] Observed practice patterns from previous investigations[33] and discussion with physical therapists indicate that patients receive rehabilitation services during the 2-3 day hospital stay after THA, but not routinely after hospital discharge. Yet, to control for attention and volume of rehabilitation for the FSI group, patients in the control group will attend outpatient physical therapy for 14 visits (40 minute sessions) over 8 weeks. This control program will mimic the typical postoperative experience for patients in our community, in which patients independently manage their activity. This program will focus on patient education, functional ADL training, and therapeutic exercise. However, the activities in the exercise domain will be limited to low load exercise such as isometric muscle exercise, ROM, and flexibility activities. These activities are specifically designed to mirror usual care activity. These activities will not include progressive strength training exercise or specific functional activity to improve pelvic stability and core muscle strength, which are exclusive to the FSI group.

A1.3. Data Collection and Outcome Measures

Baseline testing will occur 2 weeks prior to THA. To develop a more precise estimate of the trajectory of recovery after THA, we will assess outcomes at 3 times postoperatively. Postoperative testing will occur at intervention mid-point, 4 weeks (POST1); intervention end-point, 8 weeks (POST2) (primary endpoint); and late recovery, 26 weeks (POST3). The 4-week test will allow for identifying if any changes occur early in the intervention, the 8-week test will serve as the primary endpoint for assessing intervention efficacy, and the 26-week test is important to assess persistence of intervention effects. Testing will be performed using standardized procedures described below. Testing may occur remotely via Zoom or video call, at the participant's home, or on the Anschutz campus.

Phase	Functional Strength Integration Program (FSI) *	Control Group Program (CON)**
Phase 1 ***Weeks 1-2***	**PST:** Standing weight shifting and supported single leg balance; isometric abdominal training supine; **see progression criteria below*** **FT:** Gait training, review postop precautions; **see progression criteria below*** **ST:** Lower extremity progressive resistance exercise (2 sets x 8 reps at 8RM); **see progression criteria below***	**PED:** Review postsurgical precautions, ADL advice **FT:** Gait training with AD **TE:** Muscle setting exercise for hip and knee (continue from inpatient therapy), P/AAROM for all hip motions
Phase 2 ***Weeks 3-5***	**PST:** Foam surface weight shifting, unsupported single leg balance, standing pelvic lift; resisted abdominal stabilization training (supine)* **FT:** Gait training with no AD, sit-stand activity, small step-up forward and lateral; **ST:** Progress lower extremity resistive exercise by **at least** 10% (2sets x 8 reps)*	**PED:** Continue education on postsurgical precautions, AD utilization and ADL advice **FT:** Gait training with AD **TE:** AA/AROM for all hip motions, low load supine resistive exercise; flexibility activity for spine and lower extremity.
Phase 3 ***Weeks 6-8***	**PST:** Foam surface single leg balance and pelvic lift, balance board, progress to BOSU ball for all activity; supine bridging, upper abdominal curl, hundreds (Pilates), side lying series (Pilates).* **FT:** Moderate → high step ups forward, lateral, down. Agility training, wall squats.* **ST:** Progress lower extremity progressive resistive exercise by **at least** 10% (2 sets x 8 reps).*	**PED:** AD progression, ADL advice on safe activity resumption **FT:** Gait training with/without AD as indicated **TE:** AROM all hip motions, supine resistive exercise, stretching, and flexibility activity for spine and lower extremity.

Abbreviations: PST= Pelvic Stability Training; FT= Functional Training; ST= Strength Training; PED: Patient Education, TE= Therapeutic Exercise, AD= Assistive Device.

*FSI group activities in each domain will be supervised closely with verbal, visual, and tactile cues to promote optimal posture and movement quality. **Progression of activities in the PST and FT domains** will be based on therapist assessment of movement quality, specifically the absence form fatigue, and the ability to maintain a level pelvis with hip muscle activation during the task. Therapists will **progress strengthening exercises** when patients are able to demonstrate proper form during the prescribed 8 repetitions (e.g. 80% of 1 repetition maximum). Therapists will be encouraged to push patients to work at a high level of difficulty and progress toward Phase 3 as quickly as possible.

** CON group activities are progressed based on the post-operative timeline indicated above (by phase and week)

A1.3.1. Performance-based Physical Function Measures

Performance-based measures of physical function with well-established reliability and validity will include the 6-minute walk test **(6MW) (primary outcome)**, 4 meter walk test (4MW), 30 second sit-to-stand test, and the Functional Gait Assessment (FGA) (Table 2). Patients will also perform a 6MW test[76], which assesses how far a patient walks in 6 minutes. The 6MW test was chosen as the primary outcome because it captures performance over a period of time that best mimics community ambulation with activities of daily living. The 6MW test is reliable and valid in the post-THA population and can detect small changes in function after THA.[77] The 4MW test measures the time to walk 4 meters and has been used to generate gait speed values, which have been associated with morbidity and mortality in older adults.[78] Participants will perform the 4MW with instructions to walk in their "normal, everyday pace." The 30 second sit-to-stand test assesses functional lower extremity strength and endurance, and has been validated and found reliable in older adults at various physical activity levels and physical independence levels.[79-81] Participants will also perform the FGA, which is a 10-item objective outcome measure designed to measure dynamic balance while walking in the presence of external demands, and will provide information on patients' stability before and after THA.[82] The FGA has been shown to be a reliable and valid measure, effective in classifying fall risk in older adults and predicting unexplained falls.[82,83]

A1.3.2. Self-reported Outcomes

Patients will complete the Veterans RAND 12-item health survey (VR-12), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and a motivation scale at each visit. The Patient Activation Measure (PAM) survey will be administered only at the baseline visit. The VR-12 is a reliable, self-report survey for assessing health-related quality of life.[84-86] The WOMAC assesses the impact of osteoarthritis on pain, stiffness, and disability.[87] The WOMAC has been shown to be a valid, reliable, and responsive instrument often used in clinical trials.[87] The PAM survey assesses patient knowledge, skill, and confidence for self-management, as self-efficacy exhibits a positive relationship with preventive actions and health outcomes.[88,89] The motivation scales asks the participant "How motivated do you feel to participate in physical therapy?", and rating on a 0 (not at all motivated) to 10 (very motivated) scale.

A1.3.3. Muscle Performance Measures

Isometric strength of the quadriceps and hip abductor muscles will be assessed on a handheld dynamometer. All strength testing will be performed in positions that minimize the risk of hip dislocation post-operatively, while still allowing for optimal trunk and pelvic stabilization. Isometric quadriceps strength testing will be performed in sitting at 0° hip flexion and 60° knee flexion. Isometric hip abduction strength testing will be performed in side lying at 0° flexion/extension and 0° hip abduction.[33] Testing will include warm-up repetitions, followed by three separate maximal voluntary isometric contractions while receiving visual and verbal feedback. Additionally, patients will complete hip abductor endurance testing using a static single-limb balance test, based off of the Trendelenburg test proposed by Hardcastle[14] and measurement of pelvis angle by Youdas, *et al.*[90] and Asayma *et al.*[91] This modified Trendelenburg test[14] assesses neuromuscular control during timed, single limb stance and indicates the ability of the lateral hip muscles to maintain pelvic control during closed-chain, functional tasks and therefore serves as a measure of hip abductor muscle endurance.[14] This test will be performed in the GRECC Human Movement Analysis Lab using a high-speed motion-capture system to assess lateral pelvic tilt (see D2.3.1). Differences will be analyzed in pelvic tilt angles from preoperative to postoperative assessments during the single-limb task on the surgical leg.

A1.3.4. ActiGraph Physical Activity Monitoring

ActiGraph physical activity monitors (ActiGraph Inc. Pensacola FL) will be used to obtain an objective measure of physical activity (PA). ActiGraph activity monitors assess PA using accelerometry, which allows objective evaluation of the relative volume (steps/day) and intensity (activity counts) of physical activity with high validity and reliability.[92-94] Each participant will wear the ActiGraph for at least 4 days at all time points to assess average daily PA (steps/day).[95,96] The ActiGraph monitor will be used only for outcome data (not intervention) and provides no feedback to participants.

Outcome Measures	Baseline	$POST_1$	$POST_2$	$POST_3$
Physical Function: 6MW	X	X	**X***	X
Physical Function 4MW, 30 sec Sit-to-Stand, FGA	X	X	X	X
Muscle Strength: Quadriceps and Hip abductor strength, Trendelenburg	X	X	X	X
Peak internal hip abduction moment	X	X	X	X
ActiGraph Physical Activity Monitors	X	X	X	X
Self-report: VR-12, WOMAC, PAM survey (baseline only), Motivation scale ($POST_1$ and $POST_2$ only)	X	X	X	X
Safety Outcomes: Falls, injury, pain		X	X	X
*Primary end-point and outcome measure				

Table 2 Timetable of Outcome Measures

A1.3.5. Biomechanical Analysis and Measures of Pelvic Stability

Lower extremity biomechanical measures will be used to quantify movement patterns during level walking and stepping up/down from an 8" stair step in the GRECC Human Movement Analysis Lab**.** Similar protocols for the assessment of movement patterns have been performed in the pilot studies leading to the current proposal and other previous work on movement patterns for patients with hip OA and THA.[24,45,51,52] Surgical limb peak internal hip abduction moment, will be calculated with 3-D instrumented motion analysis. Briefly, lower extremity joint kinematics will be quantified from wearable sensors and retro-reflective markers tracked via an 8-camera, high speed motion capture system (Vicon Motion Systems, Oxford, UK) at 100 Hz. Lower extremity joint kinetics will be derived from ground reaction force data recorded from two force platforms (2000 Hz) embedded in the floor that are synchronized with the cameras (Bertec, Columbus, OH). Continuous internal hip abduction moments will be calculated during functional task performance using a standard inverse dynamics approach integrating kinematic and kinetic data using Visual 3D software (C-Motion, Germantown, MD). From the continuous hip moments, peak surgical limb internal hip abduction moments during the Loading Response phase of the stance period of the walking trials will be collected. All joint moments will be normalized to participant body mass. Dr. Cory Christiansen (co-investigator) will oversee all aspects of the biomechanical analysis.

A1.3.6. Safety Outcomes

Patients will report falls, musculoskeletal injury history, and pain levels at rest and with activity (numerical pain rating scale [NPRS; 0= no pain, 10= worst possible pain]) on a weekly basis during the intervention and biweekly via phone calls through 26 weeks. Additionally, treating physical therapists will monitor incidence of musculoskeletal injury (specifically, hip dislocation) by completing a brief examination at each treatment session. Finally, surgical success will be evaluated by incidence of neurologic palsy, infection, deep vein thrombosis/pulmonary embolism, skin necrosis, delayed wound healing, vascular injury, and surgical revision.

A1.4. Procedural Reliability

Procedural reliability is critical to the success of the proposed intervention. We have established mechanisms to assure consistency of treatments across sites consistent with previous reports of procedural oversight and treatment fidelity.[97] Participating Veterans will attend outpatient PT visits at one of the following locations- Denver VAMC (9^{th} Ave. clinic), AMC PT program clinic, PFC Floyd K. Lindstrom Outpatient Clinic at Colorado Springs, or Golden Outpatient Clinic with structured oversight seen to by the investigative team. Dana Judd, PT, PhD (co-investigator) will oversee the standardization and implementation of the rehabilitation programs at the clinical site. The PI will oversee the methodological issues related to fidelity of treatment across treating therapists and address any clinical trials issues specific to rehabilitation. She will meet regularly with Dr. Judd to troubleshoot any difficulties that arise and provide additional oversight to ensure the fidelity of the investigation.

There will be 2 therapists to treat study patients (1 FSI and 1 CON) at each PT clinic. This will minimize the potential for contamination, as each therapist will be unfamiliar with the specifics in the other program. Furthermore, patients by group will be scheduled for morning vs. afternoon treatments to minimize patient contamination. Dr. Judd and the PI will provide 3 initial training sessions to review treatment protocols and documentation. FSI-trained therapists will receive instruction on providing visual, verbal, and tactile feedback during FSI activities, as well as instructions on monitoring pelvic position to maximize muscle recruitment and movement quality and how to determine form fatigue. This specific training will ensure successful implementation of the FSI program and ensure therapists are providing the same feedback to patients during exercise and using the same criteria to dose exercise. CON-trained therapists will receive instruction on topics to be included for patient education, specific activities to include in the clinic and home exercise programs, and proper dosages for each activity. A manual will be provided to the clinic with protocol details for each group (FSI and CON), clinic and home exercises, and documentation forms. Separate manuals for each program will be produced, and therapists will be instructed not to share intervention details with other therapists. In addition, every month for the first year, and every 3 months thereafter, treating therapists from the clinical site will meet with Dr. Judd to discuss treatment guidelines and any issues that have surfaced. Dr. Judd will monitor patient treatments weekly for the first 2 patients in each treatment group. Should new therapists be added to the treatment team during the course of the proposed investigation, the same procedures for initial training/monitoring will be implemented. For each clinical site, a procedural reliability checklist (Appendix) for adherence to the rehabilitation protocol across therapists will be completed weekly for each of the first 2 patients in each treatment group. For the remaining patients, procedural reliability will be evaluated at the midpoint and end of treatment. If the procedural reliability is below 90%, additional training sessions will be scheduled with individual therapists. Procedural reliability using this approach for our existing studies with patients following knee and hip arthroplasty (n=192 patients) at similar clinical sites has been 96.6%. Therefore, based on our extensive experience with this approach with procedural reliability in similar trials (NIH R01-HD065900, R03-AR054538, K23-AG029978), we expect the procedural reliability to be greater than 90% for all observations.

A1.5. Data Management

Study data will be collected and managed using the REDCap (Research Electronic Data Capture) platform. REDCap is a secure, web-based application designed to support electronic data capture for research studies, providing user-friendly case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails, transaction logs, and a de-identified data export mechanism to common statistical packages. Data will be placed on the REDCap Instance at the Colorado Clinical and Translational Sciences Institute (CCTSI). This data will be used solely for the purposes defined for this specific study. Data placed on the CCTSI REDCap Instance will not be accessed or used for any other study or purpose, and will only be accessed by VA-credentialed personnel. The CCTSI REDCap Instance is a highly secure, nationally-utilized data management system, and it is housed within the highly-secure environment at the University of Colorado.

A1.6. Data Analysis

The primary outcome for this study is change in 6MW distance from baseline to POST2 (end of study intervention). Secondary physical function and muscle performance outcome measures include change in 4MW, 30 sec sit-to-stand, isometric hip abductor strength, and hip abductor muscle endurance. Secondary self-report outcome measures include the WOMAC and VR-12. Measures of movement compensation after unilateral THA include *peak internal hip abduction moments* during **walking from baseline to POST2.** Preliminary descriptive and graphical analyses (e.g. boxplots, scatterplots, and profile plots over time) will be used for data checking and visualization. All analyses will assume a two-sided test of hypothesis, with a significance level of 0.05, and be performed in SAS v9.4 or higher and R v3.2.2 or higher.

Primary Analysis: The primary analysis will be an intent-to-treat comparison between groups of the change in 6MW distance from baseline to POST2 (end of intervention). Statistical inference regarding the difference between treatment groups will be based on the estimated coefficient for a group indicator variable in an analysis of covariance (ANCOVA) model with the change from baseline at POST2 for the 6MW distance being the response variable. Additional covariates will include the stratification variables (surgical approach and Veteran/non Veteran) and the baseline value of the 6MW distance to improve the precision of the estimate.

The conclusion about differences between treatment groups will be determined by this single statistical test to protect against an elevated risk of false positive conclusions. A similar analysis will be performed on the change from baseline to POST3 to determine persistence of group differences to 26 weeks. Additionally, a sensitivity analysis will be performed utilizing a mixed-effects model and all available data, with estimation of the change from baseline to POST2 and POST3. If the sensitivity analysis is not consistent with the primary analysis, the results will be considered inconclusive.

Secondary Analyses: Differences between groups in the secondary outcomes for physical function, muscle strength and endurance, and peak internal hip abduction moment, from baseline to POST2 will also be analyzed as described above. All outcomes will be analyzed at POST3 to evaluate the long-term impact and sustainability of the FSI training. We anticipate that secondary outcomes will be correlated with the primary outcome, so that similar effects on secondary outcomes will reinforce significant differences in the primary outcome. Failure to observe consistency between primary and secondary outcomes will be taken as evidence that the effects of FSI intervention are not clear, and that further study is necessary to resolve inconsistencies. This approach reduces the risk of false-positive conclusions resulting from multiple statistical tests.

A1.7. Sample Size Estimates

Statistical power was estimated using variability estimates from Heiberg *et al.* (2015), where the change in 6MW distance was assessed for 60 participants following THA.[98] Because Heiberg's target population was comparable to that currently proposed, and their sample size was 3 times that of our pilot study, our estimates using these data[98] are expected to serve as the best estimate of samples size. As such, the observed SD at 3 months post-surgery for the sample was 81.3. Based on this SD, a 2-sample, 2-sided t-test at the 5% level with 80 patients (40 per group) would have 90% power to detect a clinically meaningful difference of at least 59.7 meters.[99] The primary analysis using linear regression will be conditioned on the baseline value of each outcome measure, in addition to the sex and surgical approach stratification variables, thus improving the precision of (and giving greater power to) the estimates. We will recruit 150 participants (75/group) to allow for loss to follow-up.

A1.8. Alternative Approaches and Limitations

Missing Data. All participants with outcome measurements will be included in the intent-to-treat analysis. Although we will encourage participants to be fully compliant to their assigned treatment regimen and testing sessions, they will not be dropped from follow-up measurements for lack of compliance. The importance of complete follow-up will be stressed during enrollment and consent, and repeated during study participation. Participants will be contacted repeatedly if they miss follow-up visits, and all efforts will be made to get participants to return for scheduled follow-up visits. Although statistical methods can be used to "adjust" for missing data, these methods rely on the untestable assumption that data are "missing at random" so that the effect of the missingness can be removed through statistical modeling. We will instead focus on preventing missed follow-up visits.

Differences in surgical approach. There remains a paucity of prospective data comparing physical function outcomes with posterolateral versus direct anterior THA surgical approaches. Therefore, including both surgical approaches (and stratifying by approach) will increase the generalizability of the study. Furthermore, this strategy may also provide additional insights regarding any potential differences in surgical approaches. Finally, we have intentionally chosen not to include less common, alternative THA surgical approaches (e.g. direct lateral) to focus stratification on the most commonly used THA surgical approaches.

A1.9. Timeline

Anticipated project timeline and cumulative enrollment. Local IRB approvals will be finalized prior to initiating the investigation. Study enrollment will start in months 3-4 and continue through the first part of year 4, with a targeted accrual rate of 2-3 patients/month. Abstract and manuscript preparation will begin in years 2-3, but will increase in year 4.

A1.10. Future Investigation

1) Evaluate strategies for dissemination and implementation of study findings in clinical practice. While the proposed FSI intervention is novel, it has been designed for practical implementation in clinical settings to facilitate more rapid dissemination of study findings into routine clinical practice. We will explore strategies to optimize such dissemination and implementation.

2) Determine the optimal length of FSI intervention.
If FSI results in faster and more extensive recovery after THA, future investigations could explore whether shorter FSI intervention would achieve the same results to minimize atypical movement patterns and decrease rehabilitation costs.

3) Examine the long-term effects of FSI intervention.
If FSI results in improved recovery and movement quality, the long-term effects of these improvements should be investigated. We plan to seek additional opportunities to follow this cohort to collect data on musculoskeletal health indicated by prevalence of: additional orthopedic pain or injury, health care utilization related to musculoskeletal health, and subsequent osteoarthritis diagnoses and joint replacement surgeries in each group.

Task	**Year 1**				*Total*	**Year 2**				*Total*	**Year 3**				*Total*	**Year 4**				*Total*
Training of personnel																				
Screening & enrollment					*25*					*50*					*75*					*100*
Data collection																				
Data entry & analysis																				
Abstract/manuscript prep																				

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